UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission file number: 001-39621

OPTHEA LIMITED

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

AUSTRALIA

(Jurisdiction of incorporation or organization)

Level 4
650 Chapel Street
South Yarra, Victoria 3141
Australia
+ 61 3 9826 0399

(Address of principal executive offices)

Frederic Guerard
Chief Executive Officer
+61 3 9826 0399
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Level 4
650 Chapel Street
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Australia

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing eight ordinary shares	OPT	The Nasdaq Global Select Market
Ordinary shares, no par value*	*	The Nasdaq Global Select Market*

** Not for trading, but only in connection with the registration of the American Depositary Shares.*

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 1,091,466,771 **Ordinary Shares (including shares underlying American Depositary Shares). 11,558,534 American Depositary Shares.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b) ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Our reporting and functional currency is the U.S. dollar, and our financial statements included elsewhere in this Annual Report on Form 20-F, or annual report, are presented in U.S. dollars. The consolidated financial statements and related notes included elsewhere in this annual report have been prepared under the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which differs in certain significant respects from U.S. Generally Accepted Accounting Principles, or GAAP.

Except where the context requires otherwise and for purposes of this annual report only:

- "ADSs" refers to our American depositary shares, each of which represents eight of our ordinary shares, no par value, and "ADRs" refers to the American depositary receipts that evidence our ADSs.
- "Opthea," "we," "us" "Group" or "our" refer to Opthea Limited and its subsidiaries.
- "A$" or "Australian dollar" refers to the legal currency of Australia.
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- "AIFRS" refers to the Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board, or AASB.
- "U.S. GAAP" refers to the Generally Accepted Accounting Principles in the United States.
- "EMA" refers to the European Medicines Agaency
- "FDA" refers to the United States Food and Drug Administration.
- "US$" or "U.S. dollars" refers to the legal currency of the United States.
- "U.S." or "United States" refers to the United States of America.

Except with respect to U.S. dollar amounts presented as contractual terms, amounts denominated in U.S. dollars when received or paid and unless otherwise indicated, certain Australian dollar amounts contained in this annual report have been translated into U.S. dollars at the rate published by the Reserve Bank of Australia as of June 30, 2024. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars or Australian dollars at that or any other exchange rate as of that or any other rate. We have made rounding adjustments to some of the figures included in this annual report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them.

This annual report includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this annual report appear without the ® and ™ symbols, but the absence of those references is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks and tradenames to the fullest extent under applicable law. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

In July 2023, Opthea announced "sozinibercept" as the non-proprietary drug name for OPT-302. The American Medical Association's United States Adopted Names (USAN) Council, in consultation with the World Health Organization's International Non-proprietary Names (INN) Expert Committee, approved and adopted the non-proprietary drug name. Opthea will use the name sozinibercept in upcoming publications, public statements, and in corporate materials moving forward.

This annual report contains estimates and information concerning our industry and our business, including estimated market size and projected growth rates of the markets for our product candidates. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This information involves a number of assumptions and limitations. Although we are responsible for all of the disclosure contained in this annual report and we believe the third-party market position, market opportunity and market size data included in this annual report are reliable, we have not independently verified the accuracy or completeness of this third-party data. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and in "Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Australian Disclosure Requirements

Our ordinary shares are primarily quoted on the Australian Securities Exchange ("ASX") in addition to our listing of our ADSs on the Nasdaq Global Select Market, or Nasdaq. As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the Australian *Corporations Act 2001* and the *ASX Listing Rules*. Information furnished under the sub-heading "Australian Disclosure Requirements" is intended to comply with ASX listing and *Corporations Act 2001* disclosure requirements and is not intended to fulfill information required by this annual report.

ENFORCEMENT OF CIVIL LIABILITIES

We are a public limited company incorporated under the laws of Australia. Certain of our directors are non-residents of the United States and substantially all of their assets are located outside the United States. As a result, it may not be possible or practicable for you to:

- effect service of process within the United States upon our non-U.S. resident directors or on us;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in the United States courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- bring an original action in an Australian court to enforce liabilities against our non-U.S. resident directors or us based solely upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments that are obtained in U.S. courts against any of our non-U.S. resident directors or us, including actions under the civil liability provisions of the U.S. securities laws.

With that noted, there are no treaties between Australia and the United States that would affect the recognition or enforcement of foreign judgments in Australia. We also note that investors may be able to bring an original action in an Australian court against us to enforce liabilities based in part upon U.S. federal securities laws. The disclosure in this section is not based on the opinion of counsel.

We have appointed Corporation Service Company, located at 1180 Avenue of the Americas, Suite 210 New York,NY 10036 as our agent to receive service of process with respect to any action brought against us under the federal securities laws of the United States.

FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this annual report, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties, other factors and assumptions, including the risks described in “Risk Factors” and elsewhere in this annual report, regarding, among other things:

- the success, cost and timing of our product development activities and clinical trials, including our estimates for the release of the top-line data from our Phase 3 clinical trials in a timely fashion;
- the accuracy of our estimates regarding our expected cash runway, expenses, future revenue, capital requirements and needs for additional financing;
- our expectations about top-line data based on masked pooled data;
- our expectations about the timing or likelihood of achieving regulatory approval and the cost of our development programs, including our clinical trials;
- our reliance on the success of sozinibercept (formerly known as "OPT-302") as our only product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- our plans to research, develop and commercialize our product candidates;
- the commercialization of our product candidates, if approved and future agreements with third parties in connection with the commercialization of our product candidates;
- our ability to maintain, expand, protect and enforce our intellectual property portfolio;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- business disruptions or delays affecting the patient enrollment, development and operation of our clinical trials, including as a result of a public health emergency, macroeconomic conditions, such as inflationary pressure and supply chain disruptions or acts of war, including geopolitical conflicts;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States, Australia, Europe and other jurisdictions;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately on a timely and cost effective basis;

- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific, clinical development or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- the future trading price of the ADSs and impact of securities analysts' reports on these prices;
- compliance with the terms and conditions under the Development Funding Agreement or "Funding Agreement" or "DFA" with Ocelot SPV LP ("Ocelot") and the other investors (collectively, the "Investors"), entered into with Ocelot in August 2022 and amended and restated in December 2023 with a new co-Investor, specifically as it relates to the timelines for development, and provisions relating to the minimum cash and cash equivalents balances; and
- other risks and uncertainties, including those listed under "Risk Factors."

These risks are not exhaustive. Other sections of this annual report may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this annual report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We undertake no obligation to update any forward-looking statements made in this annual report to reflect events or circumstances after the date of this annual report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this annual report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to this annual report with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3A. Reserved

3B. Capitalization and Indebtedness

Not applicable.

3C. Reasons for the offer and use of proceeds

Not applicable.

3D. Risk Factors

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this annual report, including our consolidated financial statements and related notes included elsewhere in this annual report, before making an investment decision. If any of the following risks actually occur, it could harm our business, prospects, results of operations and financial condition. In such event, the trading price of the ADSs could decline and you might lose all or part of your investment. You should not interpret our disclosure of any of the following risks to imply that such risks have not already materialized.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length below in this summary. These risks include, among others, the following:

Risks Related to our Financial Position, Need for Capital and the Funding Agreement

- We have not received approval for any product candidate for commercial sale and, as a result, we have never generated any revenue from products, have incurred significant financial losses and expect to continue to incur significant financial losses in the future, which makes it difficult to assess our future viability.

- We will require additional capital in the future, including funding to complete the efficacy and safety stages of the trials, which may not be available to us on commercially favorable terms, or at all. Our ability to continue our development activities as a going concern may be dependent on raising such additional capital. Raising additional capital may cause dilution to holders of our ordinary shares and ADSs.

- The Funding Agreement contains terms that require us to maintain a minimum cash and cash equivalents balance of US$60 million, or the "Minimum Amount," and to provide a notice to the Investors if our cash and cash equivalents balance drops below US$50 million. Following such notice, we need to use our reasonable best efforts to consummate a public offering of private placement of equity securities to make up the shortfall of the Minimum Amount within one month thereafter. If we are unable to consummate such financing within such period, or separately if we will be unable to fund our payment obligations in the upcoming six months or reasonably expect to include a "Going Concern" opinion in our financial statements, each Investor has the right, but not the obligation, to increase funding under the

Funding Agreement to make up for such shortfall which would increase our payment obligations under the funding agreement.

- The termination provisions in the Funding Agreement ~~:~~on the part of the Investors are extensive and give the Investors a wide range of conditions to terminate the agreement. In the event of termination, unless mutual or for breach by the Investors, amounts owed by us will be multiples of the invested capital to date. Each termination trigger has a corresponding percentage to be paid, with possible outcomes requiring us to repay an amount equal to 0%, 135%, 150%, 275% or 400% of the initial amounts paid to us under the DFA. This is equivalent to potential repayments of $nil, $229.5 million, $255.0 million, $467.5 million or $680.0 million if a termination event is to occur. As of June 30, 2024, the Investors have invested US$170 million.

Risks Related to Development and Commercialization of Our Product Candidate

- Clinical trials being conducted to test our product candidate, sozinibercept, have been delayed and are more costly than anticipated. Future delays and increasing costs may occur. The trials may not obtain the desired safety and efficacy results.

- Sozinibercept may be shown to cause undesirable side effects or other adverse events that could delay or prevent its regulatory approval, limit its commercial profile or result in significant negative consequences following regulatory approval, if such approval is granted. Data from completed clinical trials indicates the safety and tolerability profile of sozinibercept is consistent with approved standard of care anti VEGF-A treatments for wet AMD based on trial results to date. There is no assurance that the safety and tolerability profile of sozinibercept will remain as observed to date.

- The Funding Agreement contains several terms that restrict our flexibility in conducting the study including governance by a Joint Steering Committee ("JSC") for changes in the original protocols, study design or timelines. Modifications require JSC approval and it will be difficult for us to make modifications on our own.

- The marketing approval process is expensive, time-consuming and uncertain, and even if sozinibercept receives marketing approval, we may not be successful in our commercialization efforts and sozinibercept may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

- Marketing approval requires completion of Process Performance Qualification ("PPQ") which typically involves the production of a minimum number of drug substance and drug product batches. PPQ batches will require extensive lead time, the purchase of raw materials and the reservation of production slots at our Contract Development Manufacturing Organization ("CDMO"). We are working with our CDMOs to produce these PPQ batches. Delays in the successful production itself may cause a delay in the filing for marketing and the receipt of marketing approval.

- We have encountered difficulties in enrolling patients in our clinical trials and may experience difficulties in the future. Patient enrollment for the COAST trial was completed in February 2024 and enrollment for the ShORe trial was completed in May 2024.

- We may face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.

- Our business could be negatively affected by the effects of health epidemics, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Risks Related to Legal and Regulatory Compliance Matters

- Disruptions at the FDA could delay or prevent new products from being developed, approved or commercialized.

- Changes in U.S. healthcare law may impact our business in ways that we cannot currently predict.

- We are subject to economic, political, regulatory and other risks associated with international operations.

Risks Related to Our Reliance on Third Parties

- We rely on third-party manufacturers to produce sozinibercept or any future product candidates. If such manufacturers do not produce acceptable product candidates, this could have a material adverse effect on our business. The manufacturers we use for production are sole source and currently no backup manufacturers exist in the event of failure at the current manufacturers.

- We are currently dependent on third parties to conduct clinical trials and some aspects of our research and development activities. Such third parties may not perform satisfactorily, including failing to meet deadlines for completion of such trial, research or testing transition of certain of these third parties could cause delay or disruption in the clinical trials and result in higher than expected costs.

Risks Related to Employee Matters and Managing Our Growth

- We may not be able to attract, integrate, manage and retain qualified personnel or key employees.

- We are increasing and expect to continue increasing the size of our organization. If we are unable to effectively manage the anticipated growth, our business, results of operations, cash flows, financial condition and/or prospects will be negatively affected.

Risks Related to Intellectual Property

- If we are unable to obtain and maintain intellectual property protection for our products and technologies, or if we are unable to protect our intellectual property rights, we may not be able to compete effectively in our markets.

- We may become involved in lawsuits to protect or enforce our intellectual property, or third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights.

- Our current intellectual property portfolio may not prove to be sufficient to protect our competitive advantage. Additional competitors could enter the market, including with biosimilar products, and sales of affected products may decline materially.

Risks Related to Ownership of the ADSs

- The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

- As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we will rely on certain home country corporate governance practices rather than the corporate governance requirements of Nasdaq. We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

- Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules for U.S. public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Even if we no longer qualify as an emerging growth company, so long as we remain a foreign private issuer, we will continue to be exempt from such compensation disclosures.

Risks Related to Our Financial Position and Need for Capital

We are a clinical-stage biopharmaceutical company with no products approved for commercial sale. We have incurred net losses since our inception, we expect to incur significant losses and increasing operating losses for the foreseeable future, and we may never be profitable.

We are a clinical-stage biopharmaceutical company with no products approved for commercial sale. To date, our operations have been limited to organizing and staffing our company, business planning, raising capital,

developing our lead product candidate, sozinibercept, and licensing certain related technology, conducting research and development activities, including preclinical studies and clinical trials, and providing general and administrative support for these operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We are not profitable and have incurred net losses since our inception. Our total comprehensive losses were US$142.4 million and US$220.2 million for the years ended June 30, 2023 and 2024. As of June 30, 2024, we had an accumulated loss of US$579.7 million. We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, sozinibercept and other future product candidates. The pivotal phase 3 trials for sozinibercept, COAST and ShORe have been delayed and the cost to complete the trials is higher than anticipated. In August 2023, Opthea announced a non-underwritten institutional placement ("2023 Placement") and fully underwritten accelerated non-renounceable entitlement offering ("2023 ANREO") of A$90.0 million (approximately US$58.2 million). We received net proceeds of approximately A$82.6 million (approximately US$54.4 million) from the 2023 Placement and 2023 ANREO (together, the "2023 Equity Offering"). In December 2023, we received US$35.0 million from Ocelot for the third tranche of funding under the Funding Agreement. In addition, we received additional funding of US$50.0 million from a new co-Investor, bringing the total funding received under the Funding Agreement to US$170.0 million, the maximum amount allowed under the terms of the Funding Agreement. As such, we no longer have any committed external source of funds. In June 2024, Opthea announced a non-underwritten institutional placement ("2024 Placement") and partially underwritten accelerated non-renounceable entitlement offering ("2024 ANREO") of A$227.3 million (approximately US$151.9 million). The 2024 Placement and the partially underwritten 2024 ANREO, which closed in June 2024, together raised approximately A$171.4 million (approximately US$114.3million) and the fully underwritten retail component of the 2024 ANREO (the "2024 Equity Retail Offering"), which closed in July 2024, raised approximately A$55.9 million (approximately US$37.6 million). We have received net proceeds of approximately A$209.5 million (approximately US$138.3 million) from the 2024 Placement, the partially underwritten 2024 ANREO and the 2024 Equity Retail Offering (together, the "2024 Equity Offering") as of July 17, 2024. See Note 39, Events After the Balance Sheet Date for more information.

We expect that with our cash on hand at June 30, 2024 of $172.5 million, together with the net proceeds of approximately $34.8 million from the 2024 Equity Retail Offering, we will be able to fund our operations into the third calendar quarter of 2025 and through the anticipated topline data readout for our Phase 3 clinical trials. This cash runway forecast is subject to a number of assumptions, including assumptions and forecasts regarding Clinical Research Organization ("CRO"), CDMO and labor costs, costs to retain and attract any required personnel and costs to engage additional consultants and advisors. We have in the past incurred significantly increased costs in connection with the activities conducted by third party CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials, and may continue to incur higher than expected costs for such activities in the future, including due to factors outside our control. If any additional factors cause the Phase 3 clinical trials to be further delayed or more costly, including higher than expected CRO, CDMO or labor costs, then we will need to obtain additional financing earlier than our forecast to report top-line data. Further, while we expect to have sufficient funds into the third calendar quarter of 2025 and through the anticipated topline data readout dates for our Phase 3 clinical trials, we will not have sufficient funds to fully fund all anticipated costs of the Phase 3 clinical trials and Opthea will require additional funding to reach commercialization of sozinibercept in any indication, including wet AMD. We will need to raise significant additional funds to complete both trials' two-year efficacy and safety phase, file a biologics license application with the FDA and EMA, potentially launch sozinibercept, if approved, and meet the obligations under the Funding Agreement including the minimum cash condition and payment of development and commercialization costs in excess of funding received under the Funding Agreement. As a result of among other things, certain obligations under the Funding Agreement and applicable law regarding liquidity, we expect to raise or obtain additional capital from external sources, in one or more transactions, earlier than the third calendar quarter of 2025 or anticipated topline data readout dates of our Phase 3 clinical trials

If sufficient capital is not available, we may seek to modify the original trial design and protocol. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing and clinical trial activities increase. Additionally, if sozinibercept is approved for commercial sale, our commercialization expenses will increase significantly as we seek a commercialization partner or establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure. As a result, our accumulated losses will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may negatively affect our business. The size of our future

net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and may continue to have a negative impact on our shareholders' equity and working capital. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If sozinibercept is approved in a major market (as defined in the Funding Agreement), we must make a fixed payment to the Investors within 90 days of approval, followed by six annual payments. The Investors will also receive a variable payment of 7% of net sales. To date, the Investors have invested $170 million. If sozinibercept is approved, the Investors will receive four times invested capital, or $680 million over approximately six years. We anticipate that profits generated by the sales of sozinibercept should be able to fund this repayment, however there can be no assurances that we will have sufficient cash resources to repay this amount when it is due.

We currently have no source of product revenue and may never become profitable.

Sozinibercept has not been approved for commercial sale, and we expect it to be several years before sozinibercept is approved, if ever, and we are able to commence sales of sozinibercept. To date, we have not generated any revenue from the licensing or commercialization of sozinibercept and do not expect to receive revenue from it for a number of years, if ever. We will not be able to generate product revenue unless and until sozinibercept or any future product candidate, alone or with future partners, successfully completes clinical trials, receives regulatory approval and is successfully commercialized. Although we may seek to obtain revenue from collaboration or licensing agreements with third parties, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements. Our ability to generate future product revenue from sozinibercept or any future product candidates also depends on a number of additional factors, including our or our future partners' ability to:

- successfully complete research and clinical development of sozinibercept or any future product candidates and obtain regulatory approvals for commercialization;
- maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply, including any scale up of manufacturing processes for sozinibercept to support our ongoing Phase 3 clinical program of sozinibercept in combination with anti-vascular endothelial growth factor-A, or anti-VEGF-A, therapy for the treatment of wet age-related macular degeneration, or AMD;
- launch and commercialize sozinibercept or any future product candidates for which we obtain marketing approval, if any, and, if launched independently, successfully establish a sales force, marketing and distribution infrastructure;
- payback amounts owed under the Funding Agreement for successful completion of the clinical trials, regulatory approval and commercial launch. Amounts owed under the Funding Agreement will be four times invested capital (currently US$170 million) to be paid in a series of seven payments over six years as well as 7% of our net sales related to sozinibercept. We or our potential partner must generate sufficient revenues to fund the repayment amounts:
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for sozinibercept or our future partners' products, if any;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biologic product development, including that sozinibercept may not advance through development, achieve the endpoints of applicable clinical

trials or receive approval for use in combination with one or more approved therapies, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the U.S. Food and Drug Administration, or the FDA, or comparable non-U.S. regulatory authorities, including the European Medicines Agency, or the EMA, to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing these products.

Even if we generate revenue from the sale of sozinibercept or any of our future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

We will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of sozinibercept or develop new product candidates.

As a clinical-stage biopharmaceutical company, our operations have consumed significant amounts of cash since our inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we continue our Phase 3 clinical trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD, continue clinical development of sozinibercept for the treatment of persistent diabetic macular edema, or DME, and other retinal diseases, and continue commercialization plans. Even if we are able to obtain regulatory approval for sozinibercept or any future product candidates that we may develop, we will require substantial additional capital to commercialize such product candidates.

Our forecasts of the period of time through which our financial resources will adequately support our operations included elsewhere in this report are forward-looking statements and involve risks and uncertainties, and actual results have in the past varied and could continue to vary as a result of a number of factors, including delays in and higher than expected costs of our Phase 3 clinical trials, the impacts of macroeconomic challenges, the timing of regulatory submissions, the performance and cost efficiency of third parties that assist us with clinical development such as CROs and CDMOs and other factors discussed elsewhere in this "Risk Factors" section. We have based these estimates on assumptions and forecasts regarding CRO, CDMO and labor costs, costs to retain and attract any required personnel and costs to engage additional consultants and advisors, that may prove to be wrong, and we have utilized, and in the future could utilize, our available capital resources sooner than we currently expect. We have in the past experienced delays in our Phase 3 clinical trials, including the establishment of trial sites and patient recruitment delays, and incurred significantly increased costs in connection with the activities conducted by third party CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials. We may experience further delays and increased costs in the future, which we may not be able to accurately predict. Our future funding requirements, both short-and long-term, will depend on many factors, including:

- the progress, costs and results of clinical trials for sozinibercept or any future product candidates we may develop, including whether the FDA or comparable non-U.S. regulatory authorities require additional clinical trials beyond our Phase 3 clinical trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD to support an approved label of sozinibercept in combination with multiple existing anti-VEGF-A therapies;

- the initiation, progress, timing, costs and results of additional clinical trials and studies to evaluate the potential for co-formulation of sozinibercept with approved and/or biosimilar forms of VEGF-A inhibitors to provide flexibility of treatment options for physicians and to reduce the frequency and number of injections for patients;

- the increasing costs incurred or might be incurred for CROs and CDMOs in connection with our ongoing Phase 3 clinical trials of sozinibercept;

- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable non-U.S. regulatory authorities;

- if approved, the costs of commercialization activities for sozinibercept, or any future product candidate that receives regulatory approval;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- market acceptance of sozinibercept or any approved product candidates, including product pricing and adequate reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost of establishing sales, marketing and distribution capabilities for sozinibercept and any future product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our future partners;
- compliance with our contractual obligations, including under the Funding Agreement, including the Minimum Amount;
- the costs of operating as a public company with securities listed in both Australia and the United States; and
- the uncertainty in the global economy including any lingering effects of the COVID-19 or any other pandemic, emerging supply chain disruptions, rising inflation and interest rates, bank failures, labor shortages, unemployment levels, as well as events such as natural disasters and acts of war (including the ongoing Russia-Ukraine and Middle East conflicts).

We will require additional capital to develop, obtain regulatory approval for and commercialize sozinibercept or any future product candidates, including to complete our ongoing Phase 3 clinical trials for sozinibercept for the treatment of wet AMD. In particular, we will require additional capital to progress our ongoing and future planned clinical trials without delays, including payments to the Investors in connection with the achievement of certain regulatory milestones. We may also require additional external funding to meet the Minimum Amount cash balance condition under the Funding Agreement or to pay for development and commercialization costs in excess of funding received under the Funding Agreement, including prior to the readout of top-line results for our Phase 3 clinical trials for sozinibercept for the treatment of wet AMD. As a result of among other things, certain obligations under the Funding Agreement and applicable law regarding liquidity, we expect to raise or obtain additional capital from external sources, in one or more transactions earlier than the third calendar quarter of 2025 or anticipated topline data readout dates of our Phase 3 clinical trials. We expect to finance future cash needs through public or private issuances of equity, such as the 2024 Equity Offering, or collaborations. However, the Funding Agreement limits the types of financing we may pursue in the future. We also intend to continue to apply for tax incentives under the Research and Development Tax Incentive scheme provided by the Australian government. See "—Risks Related to Development and Commercialization of Our Product Candidates—We have received tax credits under the Research and Development Tax Incentive scheme in Australia that may become repayable if we did not or do not comply with the rules of the scheme, or we may become ineligible for tax credits in our current or future tax years, which could harm our business, financial condition and results of operations." Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. If we are not able to raise additional capital, we may not be able to complete the clinical trials or complete them as originally planned, manufacture materials in preparation for filing and if approved commercialization continue operations or otherwise capitalize on our business opportunities, and our business and financial condition will be negatively impacted.

Failure to remain in compliance with our obligations under the Development Funding Agreement with the Investors could lead to reduced funding under the agreement and/or the acceleration of potentially significant payments to the Investors.

On August 12, 2022, we entered into a Development Funding Agreement (as amended and restated, the “Funding Agreement”) with Ocelot SPV LP ("Ocelot"), an affiliate of Carlyle and Abingworth, in collaboration with Carlyle and Abingworth’s recently formed development company Launch Therapeutics (“Launch Tx”), pursuant to which Ocelot agreed to provide funding to support our development of sozinibercept for the treatment of wet AMD. On December 22, 2023, we entered into an Amended and Restated Development Funding Agreement with Ocelot as collateral agent, pursuant to which a new co-Investor (collectively, "Investors") provided an additional US$50 million in funding, bringing the total funding received under the Funding Agreement to US$170 million, the maximum amount under the terms of the Funding Agreement. Under the Funding Agreement, Opthea will pay to the Investors (1) upon the first to occur of regulatory approval of sozinibercept for the treatment of wet AMD in the United States, United Kingdom or European Union (“Regulatory Approval”), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of sozinibercept for the treatment of wet AMD for each calendar quarter. At the time that Investor receives an aggregate of four times the funding provided (US$680 million as Investors have funded the full US$170 million under the Funding Agreement), through the combination of fixed payments and royalties Opthea’s payment obligations under the Funding Agreement will be fully satisfied.

The Funding Agreement terminates upon the payment of all payments owing to Investor, unless earlier terminated. The Funding Agreement may be earlier terminated by Investor if:

- Opthea fails to comply with certain covenants and agreements set forth in the Funding Agreement, including failure to make required payments or develop sozinibercept as set forth in the Funding Agreement;
- Opthea suffers a material adverse event;
- there is a material adverse patent impact on Opthea's intellectual property covering sozinibercept ;
- there are certain irresolvable disagreements within the joint steering committee overseeing Opthea's development of sozinibercept ;
- Opthea becomes insolvent or seek protection from creditors:
- the security interests of Opthea are invalidated or terminated other than as set forth in the Funding Agreement; or
- any Phase 3 clinical trial of sozinibercept is completed or terminated and (1) the primary endpoint is not met or (2) the required Investors reasonably determine that the results of any such trial do not support regulatory approval.

The Funding Agreement may be terminated by either party (i) if the other party materially breaches the Agreement, (ii) if sozinibercept fails to receive regulatory approval in the United States or European Union, (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in a sozinibercept clinical trial or (v) upon a change of control of Opthea.

In certain instances which may result upon the termination of the Funding Agreement, we will be obligated to pay Investors several multiples, which may vary based on the termination event of the amounts paid to us under the Funding Agreement.

The payments required under the Funding Agreement are significant. Failure to generate sufficient revenue to make such payments if and as they become due, or failure to otherwise finance such payments would have a material adverse effect on our business. In addition, if we are unable to comply with our obligations under the Funding Agreement and/or one of the termination events described above occurs, our payment obligations thereunder may be accelerated. The acceleration of payments under the Funding Agreement would have a material impact on our business and we may not be able to make such payments at such time. We may also require additional external funding to meet the minimum cash condition under the Funding Agreement or to pay for development and commercialization costs in excess of funding under the Funding Agreement, including prior to the readout of top-line results for our Phase 3 clinical trials for sozinibercept for the treatment of wet AMD. If we

are unable to obtain such additional external funding and as such are unable to meet the minimum cash condition, we are required to provide notice to the Investors. Under the Funding Agreement, upon receipt of such notice, the Investors have the option, but not the obligation, to contribute additional funds under the terms of the Funding Agreement if we are unable to raise sufficient capital in a timely manner. If the Investors choose not to contribute additional funds and we are unable to raise additional capital, we may become insolvent or may otherwise be in material breach under the Funding Agreement for failing to fund development and commercialization costs in excess of the funding received, which will result in significant payments becoming due under the Funding Agreement. Based on our current cash flow estimates, and in the absence of any additional external funding, we expect to be unable to meet the minimum cash condition prior to the third calendar quarter of 2025 and may have to provide notice to the Investors at such time.

Furthermore, the obligations under the Funding Agreement are secured by a lien on all of our assets (other than intellectual property not related to sozinibercept). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Funding Agreement. A default under the Funding Agreement, including in the event of our insolvency or our inability to pay development and commercialization costs in excess of funding received under the Funding Agreement, may result in a foreclosure on our intellectual property and seizure of all of our assets and could result in us having to pay the Investors multiples of the amounts paid to us. In addition, we may need to implement further internal controls and processes to ensure compliance with all obligations under the Funding Agreement, otherwise we could inadvertently default under it. For additional details regarding the Funding Agreement, see Note 27 Financial Liabilities to the Consolidated Financial Statements in this annual report.

Raising additional capital may cause dilution to holders of our ordinary shares and ADSs, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Holders of our ordinary shares and ADSs could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt. In February 2022, we established an "at the market" program (the "ATM Program") with Jefferies LLC ("Jefferies"). Pursuant to the ATM Program, we may offer and sell up to US$75 million of our ordinary shares in the form of ADSs, with each ADS representing eight ordinary shares, through Jefferies. Issuances of our ordinary shares sold pursuant to the sales agreement will have a dilutive effect on our existing stockholders. Further, these securities may have rights senior to those of our ordinary shares and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. If we need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day-to-day activities, which may negatively affect our ability to develop and commercialize sozinibercept and any future product candidates.

To the extent we obtain additional funding through product collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements, on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or product candidates.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, rising inflation and interest rates, bank failures, supply chain disruptions, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be harmed. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

Risks Related to Development and Commercialization of Our Product Candidates

Our business substantially depends on the success of sozinibercept, our only product candidate under clinical development, which has not completed a pivotal Phase 3 clinical trial. If we are unable to obtain regulatory approval for and successfully commercialize sozinibercept or any future product candidates, or we experience significant delays in doing so, our business will be harmed.

To date, the primary focus of our product development has been sozinibercept in combination with anti-VEGF-A therapy for the treatment of patients with wet AMD and DME. Currently, sozinibercept is our only product candidate under clinical development. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. Successful continued development and ultimate regulatory approval of sozinibercept combination therapy for the treatment of wet AMD, DME or other indications is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of sozinibercept . If we cannot successfully develop, obtain regulatory approval for and commercialize sozinibercept, we may not be able to continue our operations. The future regulatory and commercial success of sozinibercept is subject to a number of risks, including the following:

- we currently do not and in the future we may not have sufficient financial and other resources to complete the necessary clinical trials for sozinibercept , including, but not limited to, the ongoing Phase 3 pivotal clinical trials and manufacturing needed to obtain drug approval;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for sozinibercept combination therapy for the treatment of wet AMD, DME or other indications;
- in our clinical trials for sozinibercept , we may need to adjust our clinical trial procedures and may need additional clinical trial sites, which could delay our clinical trial progress as under the Funding Agreement, the JSC must approve changes in the original protocol;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable non-U.S. regulatory authorities for marketing approval;
- the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what regulatory agencies may require in pivotal clinical trials for the approval of sozinibercept ;
- the results of later stage clinical trials may not be as favorable as the results we have observed to date in our preclinical studies and phase 1 and phase 2 clinical trials;
- we cannot be certain of the number and type of clinical trials and non-clinical studies that the FDA or comparable non-U.S. regulatory agencies will require in order to approve sozinibercept combination therapy for the treatment of wet AMD, DME or any other indication, including an approved label for use of sozinibercept in combination with multiple anti-VEGF-A therapies for the treatment of wet AMD;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of our products following approval, including when used in combination with existing therapies;
- effectively competing with other therapies; and
- enforcing and defending intellectual property rights and claims.

Masked data from patients that have completed the week 52 visit in the ongoing Phase 3 clinical trials show greater mean best corrected visual acuity ("BCVA") increases from baseline than results with standard of care anti-VEGF-A monotherapy from our Phase 2b study. Masked data represent pooled data from both sozinibercept combination and standard of care monotherapy treatment arms. However, the Phase 3 clinical trial masked data are incomplete and subject to additional analysis once unmasked, and the majority of patients enrolled in the Phase 3 clinical trials had not completed the week 52 visit at the time of the analysis. There is no assurance that standard of care monotherapy in our Phase 3 clinical trials will yield similar results to our prior clinical trials or previously published clinical trials with anti-VEGF-A monotherapies. As a result, there can be no assurance that top-line results for sozinibercept from the Phase 3 clinical trials, if completed, will be consistent with results from masked data available to date

Many of these risks as described above are beyond our control, including the risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a New Drug Application or a Biologics License Application, or BLA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market sozinibercept , any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize sozinibercept . If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize sozinibercept, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. Our clinical trials may fail to adequately demonstrate the safety and efficacy of sozinibercept or any future product candidates.

Sozinibercept and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable non-U.S. regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Top-line data is expected to be reported after all patients complete the 52-week treatment period for the primary analysis, which we anticipate for COAST and ShORe in early in the second calendar quarter of 2025 and mid-calendar 2025, respectively. Investigational new drugs, such as sozinibercept , may not prove to be safe and effective in clinical trials. We may be unable in the future to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. In particular, we have incurred and experienced, and may continue to incur and experience in the future, significantly increased costs and delays in connection with the activities conducted by third-party CROs, CDMOs and other third parties to progress our Phase 3 clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced.

We have in the past experienced, and if we continue to experience delays in clinical testing, our commercial prospects will be harmed, our costs may increase and our business may be harmed.

Conducting clinical trials for any product candidates in the United States requires filing an investigational new drug application, or IND, and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such trials from the institutional review board at each such site, manufacturing clinical quantities of product candidates and supplying drug product to clinical sites. Currently, we have an active IND with the FDA in the United States for sozinibercept. If any such future IND is not cleared by the FDA, our clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated.

We cannot guarantee that we will be able to successfully accomplish required regulatory activities or all of the other activities necessary to initiate and complete clinical trials. As a result, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. We do not know whether any other clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. In particular, we have incurred and experienced, and may continue to incur and experience in the future, significantly increased costs and delays in connection with the activities conducted by third-party CROs, CDMOs and other third parties to progress our Phase 3 clinical trials. Our product

development costs will increase if we continue to experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize sozinibercept and any future product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize sozinibercept or any future product candidates and may harm our business, results of operations and prospects. Events that have in the past and may in the future result in a delay or unsuccessful completion of clinical development include:

- the unavailability of financial resources to commence and complete planned trials;
- delays in reaching agreement on acceptable terms with CROs, and clinical trial sites;
- revisions to labeling, including adding limitations on approved uses or the additions of additional warnings, contraindications or other safety information including boxed warnings;
- ongoing discussions with the FDA or comparable non-U.S. regulatory authorities regarding the scope or design of our clinical trials;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing or changes in required endpoints by the FDA or comparable non-U.S. authorities;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- the placement of a clinical hold on a clinical trial by the FDA or comparable non-U.S. authorities;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- failure of third parties, such as CROs or CDMOs, to satisfy their contractual duties to us or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials, including of drugs to be used in the proposed combination therapy with our product candidates;
- delays in enrolling participants into our clinical trials;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or otherwise;
- serious and unexpected drug-related adverse effects experienced by participants in our clinical trials;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable non-U.S. authorities with respect to approval pathways for any product candidates we are pursuing; and
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Our or our future collaborators' inability to timely complete clinical trials could result in additional costs to us as well as impair our ability to, continue development, commercialize sozinibercept or any future product candidates and generate product revenue or receive royalties on product sales. In addition, if we make changes to a product candidate, we may need to conduct additional nonclinical studies or clinical trials to bridge or

demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates.

We have in the past encountered difficulties in enrolling patients in our clinical trials and if we encounter such difficulties in the future, our clinical development activities could be delayed or otherwise negatively affected.

The timely completion of clinical trials largely depends on patient enrollment. Enrollment in our Phase 3 clinical trials has in the past been challenged in part by the COVID-19 pandemic, supply chain issues, global and regional inflation, national and local recessions, challenges in hiring, qualified staff (at sites, our CRO and distribution locations), local regulatory approvals importation and custom requirements and administrative delays. We have encountered delays in the past and may in the future encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Many factors have affected enrollment for our Phase 3 clinical trials, as described above, and additional factors may continue to affect patient enrollment for any of our future clinical trials, including:

- the size and nature of the patient population, which may be limited due to eligibility requirements;
- the number and location of clinical sites;
- competition with other companies for clinical sites or patients;
- the availability and amount of any patient stipend;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- inability to obtain and maintain patient consents;
- significant adverse events or other side effects observed, if any;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

In addition, other companies are conducting clinical trials for the same indications and seek to enroll patients in their trials that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites.

Sozinibercept or any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by sozinibercept combination therapy or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable non-U.S. regulatory authorities. Additional clinical trials may be required to evaluate the safety profile of sozinibercept combination therapy or any future product candidates. We have no clinical safety data on patient exposure to sozinibercept administered in combination with an anti-VEGF-A therapy for longer than 24 weeks.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, including, for example, immunogenicity. In such an event, we could suspend or terminate our trials, or the FDA or comparable non-U.S. regulatory authorities could order us to cease clinical

trials or deny approval of sozinibercept in combination with anti-VEGF-A therapy or any future product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could materially and negatively affect our business, financial condition, results of operations and prospects. While sozinibercept has been well tolerated in our completed clinical trials, dosed patients have experienced certain adverse events, including potentially treatment-related serious adverse events, or SAEs, of myocardial infarction, endophthalmitis and vitritis in our Phase 2b clinical trial of sozinibercept combination therapy for the treatment of wet AMD, and a potentially treatment-related SAE of stroke for one patient in our Phase 1b/2a clinical trial of sozinibercept combination therapy for the treatment of DME.

It may be difficult to discern whether certain events or symptoms observed during our clinical trials or by patients using our approved products are related to sozinibercept or any future product candidates or approved products, including anti-VEGF-A therapies used in combination with sozinibercept, or some other factor. As a result, we and our development programs may be negatively affected even if such events or symptoms are ultimately determined to be unlikely related to sozinibercept or any future product candidates or approved products. We are developing sozinibercept to complement existing VEGF-A inhibitors, including ranibizumab and aflibercept. There are some potential side effects associated with intravitreal anti-VEGF-A therapies such as intraocular hemorrhage, intraocular pressure elevation, retinal detachment, inflammation, vasculitis, artery occlusion or infection inside the eye and over-inhibition of VEGF, as well as the potential for potential systemic side effects such as heart attack, stroke, wound-healing problems and high blood pressure. Further, sozinibercept in combination with anti-VEGF-A therapies for the treatment of wet AMD is administered as sequential intravitreal injections over several weeks. There are risks inherent in the intravitreal injection procedure of drugs such as existing anti-VEGF-A therapies in combination with sozinibercept which can cause injury to the eye and other complications including conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, which results in a discharge, intraocular inflammation and inflammation of the interior of the eye. For example, in our completed clinical trials, patients dosed with sozinibercept have experienced potentially treatment-related ocular adverse events such as eye pain, vitreous floaters, eye irritation and raised intraocular pressure.

We cannot assure you that additional or more severe adverse side effects than those observed to date related to sozinibercept combination therapy or any future product candidates will not be observed in our clinical trials or in the commercial setting. If observed, such adverse side effects could delay or preclude regulatory approval of sozinibercept combination therapy or any future product candidates, limit commercial use or result in the withdrawal of previously granted marketing approvals. If we or others identify undesirable or unacceptable side effects caused by sozinibercept combination therapy or any future product candidates or products:

- we may be required to modify, suspend or terminate our clinical trials;
- we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies;
- we, or any future collaborators, may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we may be required to conduct costly additional clinical trials;
- we may be subject to limitations on how we may promote our approved products;
- sales of our approved products may decrease significantly;
- regulatory authorities may require us to take our approved products off the market;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive or our reputation may suffer.

Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Even if we complete the necessary Phase 3 pivotal clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of sozinibercept for the treatment of wet AMD or any other indication as well as for any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, and sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable non-U.S. regulatory authorities. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. While we expect to expand our internal regulatory function to support the marketing approval process for sozinibercept, we have no prior experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely in part on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and in other jurisdictions, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates, including for sozinibercept in other indications, may be harmed, and our ability to generate revenues will be materially impaired.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties with product candidates for wet AMD or DME, which could negatively affect our stock price, our ability to attract additional capital and our development program.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing product candidates for wet AMD or DME. In addition, other companies have developed products for wet AMD and DME, including product candidates administered in combination with anti-VEGF-A therapies, and have suffered setbacks and clinical trial failures in the past, including failures of primary endpoints in Phase 3 pivotal clinical trials following positive data from Phase 1 and 2 trials. Lack of efficacy, adverse events or undesirable side effects experienced by subjects in third party clinical trials currently being conducted or previously conducted could negatively affect our stock price, our ability to attract additional capital and our development of sozinibercept or even the viability of sozinibercept as a product candidate. In addition, any such adverse events or undesirable side effects may lead to increased regulatory requirements for, or additional regulatory review of, sozinibercept, which may result in delays in development and commercialization of sozinibercept and harm our business, financial condition and results of operations.

The results of completed clinical trials may not be predictive of future results. Data from our clinical trials to date may not be indicative of results obtained when these trials are completed or in later-stage trials.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of completed clinical trials of sozinibercept or any future product candidate may not be predictive of the results of later-stage clinical trials, including our Phase 3 trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD, and the results of trials in certain patients may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier stage clinical trials. In addition, data obtained from clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval.

The results of our Phase 2b clinical trial of sozinibercept combination therapy may not be predictive of the results of our Phase 3 clinical program due, in part, to the fact that we have no clinical data on sozinibercept in combination with anti-VEGF-A therapy in any clinical trial longer than 24 weeks and that we are conducting our Phase 3 clinical trials at many clinical centers that were not included in our Phase 2b clinical trial. The number of patients exposed to product candidates and the average exposure time in prior clinical trials may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. Any approved label for sozinibercept combination therapy may also be limited if our Phase 3 clinical trial results do not show long-term clinically significant efficacy results, including for over 12 months or in combination with either of the approved anti-VEGF-A therapies. In addition, if a combination of sozinibercept with an anti-VEGF-A therapy in our Phase 3 clinical program for the treatment of wet AMD does not achieve clinically significant superiority over anti-VEGF-A monotherapy with statistical significance on the primary endpoints of our Phase 3 clinical trials, or the FDA or a comparable non-U.S. regulatory authority requires additional clinical trials beyond our Phase 3 clinical program to support an approved label of sozinibercept used in combination with multiple anti-VEGF-A therapies, our ability to successfully commercialize sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD would be harmed.

For example, masked data from patients that have completed the week 52 visit in the ongoing Phase 3 clinical trials show greater mean BCVA increases from baseline than results with standard of care anti-VEGF-A monotherapy from our Phase 2b study. Masked data represent pooled data from both sozinibercept combination and standard of care monotherapy treatment arms. However, the Phase 3 clinical trial masked data are incomplete and subject to additional analysis once unmasked and the majority of patients enrolled in the trial had not completed the week 52 visit at the time of the analysis. There is no assurance that standard of care monotherapy in our Phase 3 clinical trials will yield similar results to our prior clinical trials or previously published clinical trials with anti-VEGF-A monotherapies. As a result, there can be no assurance that top-line results for sozinibercept from the Phase 3 clinical trials, if completed, will be consistent with results from masked data available to date.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same trials or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available.

In addition, adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors in the future could also result in volatility in the price of the ADSs and our ordinary shares. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, sozinibercept or any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of sozinibercept or any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of wet AMD and DME or have commercially approved products for the treatment of wet AMD or DME, including Roche, Regeneron and Novartis. The current standard of care for wet AMD is monotherapy administration of anti-VEGF-A therapies, including ranibizumab, aflibercept and faricimab, as well as off-label use of bevacizumab. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to sozinibercept combination therapy. In addition to competition from other companies directly targeting wet AMD or DME, any products we may develop may also face competition from other types of therapies or patient and physician preferences. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as sozinibercept or any future product candidates progress through development to potential commercialization.

If our competitors market products that are more effective, safer or cheaper than our products, are more durable, have reduced injection burden compared to our products (including sozinibercept), or reach the market sooner than our products, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Clinical trials for the treatment of wet AMD and DME may be relatively costly and time-consuming. The requirements for approval by the FDA and comparable non-U.S. regulatory authorities may change over time and this may require changes to ongoing or future clinical trial designs that could impact timelines and cost. Further, many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our

product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would negatively affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our inability to compete effectively in any of these aspects of our business could harm our business, financial condition, results of operations and prospects.

A Fast-Track designation by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast-Track designation for a particular indication. Sozinibercept in combination with anti-VEGF-A therapy was granted Fast-Track designation for the treatment of wet AMD in July 2021 and we may seek Fast-Track designation for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our future product candidates. If granted, Fast-Track designation makes a product eligible for more frequent interactions with the FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of products candidates with Fast-Track designation may qualify for Priority Review under the policies and procedures offered by the FDA, but the Fast-Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast-Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast-Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast-track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast-Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast-Track designation at any time.

Sozinibercept and any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Given the number of drugs in development or currently approved for the treatment of wet AMD and DME, if we are unsuccessful in achieving a differentiated profile with sozinibercept, including in combination with existing therapies, based on efficacy, safety and tolerability, dosing and administration, market acceptance will be limited. For example, current treatments for wet AMD, including ranibizumab, aflibercept and low-cost, off-label use of bevacizumab, are well established in the medical community and perceived as demonstrating meaningful clinical response in many cases. As a result, doctors may continue to rely on these treatments without sozinibercept or may continue to use such existing treatments as first-line therapies. The medical community may also resist adopting a combination therapy over monotherapy for any of our targeted indications. In particular, recent clinical development has focused on maintaining vision gains with a VEGF-A inhibitor while reducing the number of injections. While we plan to evaluate the potential for co-formulation of sozinibercept with approved and/or biosimilar forms of VEGF-A inhibitors to provide flexibility of treatment options for physicians and to reduce the frequency and number of injections for patients, there can be no assurance that we will be successful or that any co-formulated product will have a favorable safety profile. If we are unable to reduce the injection burden of sozinibercept combination therapy or demonstrate sufficient efficacy improvements with a comparatively higher frequency and number of injections over standard of care anti-VEGF-A therapies, develop a co-formulation of sozinibercept for patients or otherwise increase the duration of efficacy of sozinibercet doses, or if physicians determine that a more frequent regimen is necessary, the market acceptance of sozinibercept may be limited which would harm our business, financial condition and results of operations.

In addition, the potential market opportunity for sozinibercept is difficult to estimate precisely. If sozinibercept receives marketing approval for the treatment of wet AMD, it will be approved solely for use in combination with one or more anti-VEGF-A therapies, and may be limited to use with only one anti-VEGF-A

therapy for the treatment of wet AMD depending on whether the results from each of our Phase 3 clinical trials support an approved label for use of sozinibercept in combination with more than one anti-VEGF-A therapy. The market opportunity for sozinibercept will be dependent upon the continued use of anti-VEGF-A therapies in the treatment of wet AMD and the market share of such anti-VEGF-A therapies for which sozinibercept is approved as a combination therapy. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy, safety and dosing profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the imposition of a REMS which may include distribution or use restrictions;
- any restrictions on the use of our products to a subgroup of patients;
- acceptance of the product candidate as a safe and effective treatment by physicians and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost-effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost-effective as compared with competing treatments.

Efforts to educate the medical community and third-party payors on the benefits of sozinibercept combination therapy may require significant resources and may not be successful. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products.

If the market opportunities for any product that we or our strategic collaborators develop are smaller than we believe they are, our revenue may be negatively affected and our business may suffer.

We intend to focus our product candidate development on therapies for the treatment of wet AMD and additional retinal disease indications such as DME or retinal vein occlusion, or RVO. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidate are

based on estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse impact on our business.

If sozinibercept is approved by the FDA as a combination therapy for the treatment of wet AMD, the approval will be limited to this specific indication and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing sozinibercept for other indications. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of sozinibercept for unapproved or "off-label" uses, resulting in damage to our reputation and business.

If sozinibercept receives marketing approval for the treatment of wet AMD, it will be approved solely for use in combination with one or more anti-VEGF-A therapies, and may be limited to only one anti-VEGF-A therapy for the treatment of wet AMD depending on the results of our ongoing pivotal Phase 3 clinical trials. Although we are also developing sozinibercept for other retinal diseases, any regulatory approval of sozinibercept for wet AMD would not cover the treatment of any other indication. As a result, we would be prohibited from promoting sozinibercept for the treatment of DME unless we are granted FDA approval for such indication.

The FDA strictly regulates the promotional claims that may be made about prescription products. While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically approved by the FDA or comparable non-U.S. regulatory authorities. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or pharmaceutical companies on off-label use. If the FDA determines that our promotional activities constitute promotion of an off-label use, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

Sozinibercept is being developed to be used as a combination therapy for use with anti-VEGF-A therapies, which exposes us to additional risks.

We are developing sozinibercept to be used in combination with VEGF-A inhibitors. Even if sozinibercept were to receive marketing approval or be commercialized, we would continue to be subject to the risks that the FDA or similar regulatory authorities could revoke approval of some or all approved anti-VEGF-A therapies for safety, efficacy, manufacturing or supply issues. This could result in sozinibercept being restricted from commercialization or being less commercially successful.

We may also evaluate sozinibercept or other future product candidates in combination with one or more other product candidates that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell sozinibercept or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other product candidates or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with sozinibercept or any product candidate we develop, we may be unable to obtain approval of or market sozinibercept or any product candidate we develop.

If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.

Although the development and commercialization of sozinibercept is currently our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other therapies related to retinal diseases. The success of this strategy depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize new drugs and biologics. Our research efforts may initially show promise in discovering potential new drugs and biologics, yet fail to yield product candidates for clinical development for a number of reasons, including:

- we may need to rely on third parties to generate molecules for some of our product candidate programs;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of manufacturing our product candidates, cause delays or make our product candidates unmarketable;
- product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our future collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could harm our business, operating results and prospects and could potentially cause us to cease operations. Future research programs to identify new product candidates may require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Product candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or comparable non-U.S. regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace or be more effective than other commercially available alternatives.

Our business was and may in the future be negatively affected by the effects of health epidemics, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Health epidemics in regions where we have concentrations of clinical trial sites or other business operations could negatively affect our business, including by causing significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. For example, the novel coronavirus disease 2019, or COVID-19, negatively impacted our ability to initiate clinical trial sites, maintain patient enrollment and enroll new patients. Our ability to attract additional clinical trial sites and principal investigators to conduct our clinical trials and to conduct the necessary clinical trial site initiation procedures were negatively impacted by quarantines, shelter-in-place and similar restrictions imposed by federal, state and local governments.

Moreover, we rely on third-party CROs, CDMOs and other third parties to assist us with clinical development activities. We experienced significantly increased costs and delays in connection with the activities conducted by third-party CROs CDMOs and other third parties to prepare for and progress our Phase 3 clinical trials, due in part to the COVID-19 pandemic and its related effects. The outbreak of health epidemics in the future could cause significant disruptions to our clinical development timelines, which would harm our business, financial condition, results of operations and growth prospects.

Risks Related to Legal and Regulatory Compliance Matters

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, otherwise prevent new products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, in March 2020, the FDA temporarily postponed inspections of manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures or issue guidance materially affecting the conduct of clinical trials. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we commercialize sozinibercept or any future product candidate, we may face challenges to achieving profitability such as our products becoming subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations are essential for most patients to be able to afford medical services and pharmaceutical products such as sozinibercept or any our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors are essential for most patients to be able to afford treatments such as sozinibercept .

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Other countries have equivalent authorities who play a similar role. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, no uniform policy for coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Government authorities and other third-party payors in the United States and abroad have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications and for newly approved products, and as a result, they may not cover or provide adequate reimbursement for sozinibercept and future product candidates. Increasingly, certain third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our future collaborators commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our future collaborators obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our future collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained. A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or therapies using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States will be available for sozinibercept and any future product candidates and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require

approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize sozinibercept or any future product candidates with significant market potential at an adequate profit margin after cost of goods sold and other expenses. Commercialization of sozinibercept or any future product candidates may entail a substantial cost of goods sold and there can be no assurance that we will be able to achieve a suitable gross margin with respect to sales of sozinibercept or any future product candidates.

Changes in U.S. healthcare law and implementing regulations, as well as changes in healthcare policy, and equivalent changes in the laws and policies in other countries may impact our business in ways that we cannot currently predict and may harm our business and results of operations.

There have been, and likely will continue to be, several executive, legislative and regulatory changes and proposed and enacted changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy-makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access, and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws.

On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in the Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to additional challenges in the future. It is unclear how any such challenges and future healthcare reform measures will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect until 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three (3) to five (5) years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially negatively affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product-pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug-pricing reform and sets

out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the HHS Secretary to establish a Drug Price Negotiation Program (the "Program") to lower prices for certain high-expenditure, single-source prescription drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least seven (7) years for prescription drugs and at least eleven (11) years for biologics. Under the Program, the HHS Secretary will publish a list of "selected drugs," and will then negotiate maximum fair prices ("MFP") with their manufacturers. The Program will be implemented in stages. Beginning in 2026, ten (10) Medicare Part D "selected drugs" will be subject to price negotiations. By 2029, and in subsequent years thereafter, the number will increase to twenty (20) drugs and biologics covered under Medicare Part B and Part D. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and potential civil monetary penalties. Further, effective October 2023, the IRA requires manufacturers that increase prices of certain Medicare Part B and Part D drugs or biologics at a rate greater than inflation to pay rebates to CMS or be subject to civil monetary penalties. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product-pricing, including price or patient-reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk-purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product-pricing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement and put additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs once marketing approval is obtained. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

As a company with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with substantial operations in Australia with headquarters in Melbourne, and an international clinical trial program, our business is subject to risks associated with conducting business outside the United States. Many of our suppliers and clinical-trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;

- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates, Australian dollar, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

If we fail to comply with non-U.S. regulatory requirements governing clinical trials and marketing approval for drugs, we could be prevented from selling our product candidates in non-U.S. markets, which may negatively affect our operating results and financial condition.

The requirements governing the conduct of clinical trials, product-licensing, pricing and reimbursement for marketing our product candidates outside the United States vary greatly from country to country and may require additional testing. We expect that our future clinical development of our product candidates will involve a number of clinical trials in non-U.S. jurisdictions. We have no direct experience as a company in obtaining non-U.S. regulatory approvals. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. Approval by the FDA does not guarantee approval by comparable non-U.S. regulatory authorities, and approval by one non-U.S. regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop non-U.S. markets for our product candidates and may harm our results of operations and financial condition.

Price controls may be imposed in non-U.S. markets, which may negatively affect our future profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost-containment measures. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference-pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party

payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues, or profitability could be harmed.

We have received tax incentives under the Research and Development Tax Incentive scheme in Australia that may become repayable if we did not or do not comply with the rules of the scheme, or we may become ineligible for tax incentives in our current or future tax years, which could harm our business, financial condition and results of operations.

We have received cash incentives in the past under the Research and Development Tax Incentive scheme, or the R&D Scheme, to offset the costs of our clinical trials and other qualifying expenses incurred both in Australia and other jurisdictions. Certain research and development costs that we incur in the future may be ineligible for cash incentives under the R&D Scheme. For example, costs incurred outside Australia in connection with our future clinical trials are generally not eligible for cash incentives under the R&D Scheme. In addition, the federal government of Australia and the Australian Taxation Office, or ATO, could change the rules of the regulatory regime or amend past tax returns and, as a result, amounts paid to us may become repayable to the ATO including the amount of tax incentives in respect to our fiscal year ended June 30, 2024, included as current receivables in our consolidated financial statements. We have received an aggregate of US$36.1 million (A$44.4 million) in cash tax incentives during the five fiscal years ended June 30, 2024, under the R&D Scheme. As of June 30, 2024, our current tax receivable under the R&D Scheme was US$10.4 million. This receivable amount as of June 30, 2024, is based on Australian legislation as enacted as of June 30, 2024. Any proposed changes to the legislation, such as rate changes to eligibility requirements, may have a retrospective impact on our current tax receivable under the R&D Scheme - currently, no such legislative changes have occurred. Any rule changes made to reduce the amount we are able to claim under the R&D Scheme currently or in the future and any retrospective changes made to the R&D Scheme that reduce the incentives that we have claimed in past tax years could harm our business, financial condition and results of operations.

The withdrawal of the United Kingdom, or the U.K., from the European Union, or the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the U.K. or the EU and may require us to incur additional expenses to develop and commercialize our product candidates in the U.K. or the EU or receive clinical supply of our product candidates from manufacturing partners in the U.K.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the "Transition Period"), during which EU rules continued to apply. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidate is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, approval and commercialization of our product candidate in the U.K. or the EU. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidate in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, would delay or prevent us from commercializing our product candidate in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the U.K. and the E.U. there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the U.K. diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and,

in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, or others using our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- product recalls or a change in the indications for which products may be used;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class-action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or harm our ability to obtain physician endorsement of our products or expand our business.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to broadly applicable healthcare laws and regulations, which could expose us to civil penalties, criminal sanctions, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain regulatory approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations

may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

Such laws include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal criminal and civil false claims laws, including the False Claims Act, which can be enforced through civil whistleblower or qui tam actions, which imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health-care clearing-houses, and certain healthcare providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personally identifiable information, or personal information or personal data, in certain circumstances, many of which differ from one another in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) certain other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the ownership and investment

interests held by such physicians and their immediate family members and payments or other “transfers of value” to such physicians (covered manufacturers are required to submit reports to CMS by the 90th day of each calendar year);. and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers or other interactions with healthcare providers and other potential referral sources, state or non-U.S. laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the national or federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, state, non-U.S., and local laws that require the registration of pharmaceutical sales representatives, and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as providing free trips, free or discounted goods, improper consulting fees and grants and other monetary benefits to prescribers reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any actions are instituted against us for violation of these laws or regulations, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could harm our ability to operate our business and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations (or that of the third parties with whom we work) could lead to regulatory investigations or actions; litigation (including class actions); mass arbitration demands; fines and penalties; a disruption of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information including proprietary and confidential business data. trade secrets. intellectual property, data we collect about trial participants in connection with clinical trials. and other sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations. such as various laws, regulations guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws. personal data privacy laws, consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and

ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR")(collectively, "GDPR"), Brazil's General Data Protection Law (Lei Geral de Protecão de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to 20 million Euros / 17.5 million pounds sterling, or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator. In Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. We may be subject to new and emerging data privacy and security regimes, including Australia's Privacy Act China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

In the ordinary course of business. we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners. vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Our employees and personnel may use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups. We are also bound by contractual obligations related to data privacy and

security. and our efforts to comply with such obligations may not be successful. For example, certain data privacy laws. such as the GDPR and the CCPA, require covered businesses to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies. materials or statements are found to be deficient, lacking in transparency. deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties with whom we work. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) or mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity, or substantial changes to our business model or operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize sozinibercept or any future product candidate, and our ability to generate product revenue will be impaired.

Sozinibercept and any future product candidate that we may develop, as well as the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for, and thus commercialize any product candidate, could negatively impact our ability to generate any revenue from product sales.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that our lead product candidate will never obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any collaborator is permitted to market our product candidate in the United States or any other jurisdiction until we receive regulatory approval of a BLA from the FDA or similar application from regulatory authorities outside of the United States.

The time required to obtain approval of a BLA by the FDA or similar application from regulatory authorities outside of the United States is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. Prior to submitting a BLA to the FDA or any comparable application to any other non-U.S. regulatory authorities for approval of any product candidate, we will need to complete pivotal Phase 3 clinical trials and demonstrate favorable results with respect to safety, tolerability and efficacy. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of our product candidate for the specified indications. We expect to rely on third-party CROs, consultants and our collaborators to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and

inspection of manufacturing facilities by, regulatory authorities. Errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidate and generate product revenue.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

If we succeed in developing any products, we intend to market them in non-U.S. jurisdictions in addition to the United States. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be negatively affected.

Even if sozinibercept combination therapy or any future product candidate receives regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable non-U.S. regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable non-U.S. regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA, or comparable non-U.S. regulatory authorities, become aware of new safety information after approval of any of our product candidates, it may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations and standards. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to

comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- revise labeling, including adding limitations on approved uses or the additions of additional warnings, contraindications or other safety information including boxed warnings;
- impose a REMS which may include distribution on or use restrictions;
- require that we conduct post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate product revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and significant civil and criminal sanctions by the government. In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil and criminal penalties. Additionally, comparable non-U.S. regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would negatively affect our business, prospects and ability to achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We have relied on, and expect to continue to rely on, third-party manufacturers to produce sozinibercept or any future product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to

initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

The manufacturing of biologic drugs such as sozinibercept is complex and the process of identifying the qualifying suppliers takes a significant investment of time and money. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply us with sozinibercept or any future product candidates.

We currently have a sole-source relationship with Patheon N.V.("Patheon"), a division of Thermo Fisher Scientific Inc., pursuant to which it supplies us with sozinibercept drug substance. If there should be any disruption in our supply arrangement with Patheon, including any adverse events affecting Patheon or Thermo Fisher Scientific, it could have a negative effect on the clinical development of sozinibercept and other operations while we work to identify and qualify an alternate supply source. In addition, we do not have a long-term supply arrangement to purchase anti-VEGF-A therapy for use in combination with sozinibercept in our clinical trials and acquire such drug product on a purchase-order basis. Any complications with our existing suppliers of anti-VEGF-A therapies could considerably delay our clinical trials for sozinibercept, including our Phase 3 pivotal clinical program of sozinibercept for the treatment of wet AMD, or the regulatory approvals of sozinibercept .

Reliance on third-party suppliers and manufacturers entails risks to which we would not be subject if we manufacture product candidates or products ourselves. For example, if we do not maintain our key manufacturing relationships, including with Patheon, we may fail to find replacement manufacturers or develop our own manufacturing capabilities in a timely manner or at all, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us in a timely manner, if at all, and there could be a substantial delay before new facilities could be qualified and registered with or licensed by the FDA and other comparable non-U.S. regulatory authorities.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of the third party to manufacture product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture product candidates in accordance with our product specifications);
- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- misappropriation of our proprietary information, including our trade secrets and know-how;
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third-party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

The FDA and other comparable non-U.S. regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable non-U.S. regulatory authorities also inspect these facilities to confirm compliance with cGMP. Contract manufacturers may face manufacturing or quality control

problems causing drug-substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Failure by our third-party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Any failure to comply with cGMP requirements or other FDA or comparable non-U.S. regulatory requirements could negatively impact our clinical research activities and our ability to develop sozinibercept or any future product candidates and market our products following approval.

If sozinibercept or any future product candidates are approved by the FDA or other comparable non-U.S. regulatory authorities for commercial sale, we may need to manufacture such product candidate in larger quantities. We intend to use third-party manufacturers for commercial quantities of sozinibercept to the extent we advance this product candidate and other product candidates. Our manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate.

In addition, the operations of our third-party manufacturers may be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may negatively affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and the manufacturer may be required to obtain applicable licenses or approvals. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget.

The manufacture of biologic products is complex and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The manufacture of biologic products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. We cannot assure you that any stability or other issues relating to the manufacture of sozinibercept will not occur in the future.

The process of manufacturing sozinibercept is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be negatively affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, and for any approved products, product withdrawals, or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

To date, sozinibercept drug substance has been manufactured by a single third-party manufacturer, Patheon, solely for preclinical studies and Phase 1, 2 and 3 trials. Any such failure will require us to seek alternative manufacturing sources, which may result in considerable additional expense and delays in our clinical trials. We have limited process-development capabilities and have access only to external manufacturing capabilities. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. Any delay or interruption in the supply of clinical trial materials, including as a result of breach by us or Patheon of our agreement with Patheon, or our inability to agree to the terms of supply or related services in any statement of work, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause sozinibercept or any future product candidate to perform differently and affect the results of clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of sozinibercept or any future product candidate or jeopardize our ability to commence sales and generate revenue.

We rely on third parties to conduct our clinical trials and some aspects of our research and development activities, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and development activities. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and such alternative arrangements may not be available on terms acceptable to us.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and clinical trial protocols. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and

reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements, standard operating procedures or clinical trial protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for sozinibercept or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development, marketing approval and/or commercialization of sozinibercept or any future product candidates, producing additional losses and depriving us of potential revenue.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. We intend to conduct research programs in a range of therapeutic areas, but our pursuit of these opportunities could result in conflicts with the other parties to these agreements that may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

We work with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

We may seek to establish commercial collaborations for our product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable non-U.S. regulatory authorities, the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Employee Matters and Managing Our Growth

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

We may not be able to attract or retain qualified personnel and consultants due to the intense competition for such individuals in the biotechnology and pharmaceutical industries. In particular, we have hired and may in the future hire employees, including senior employees, in the United States as we continue clinical development of sozinibercept and prepare for potential commercialization. The hiring environment in the United States for such candidates is extremely competitive. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment at any time with three months' notice, subject to certain exceptions, and replacing such individuals may be difficult and time-consuming because of the limited number of individuals in our industry with the necessary breadth of skills and experience. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, contractors, vendors, principal investigators, consultants and future partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors, principal investigators, consultants or future partners. Misconduct by these parties could include failures to comply with FDA or comparable non-U.S. authority regulations, to provide accurate information to the FDA or comparable non-U.S. regulators, to comply with U.S. federal and state and non-U.S. healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a Code of Conduct, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws

or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we or our future partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our future partners violate government price reporting laws, we or our future partners may be subject to administrative civil and/or criminal penalties, among other sanctions.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our future partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

We may encounter difficulties in managing our growth, which could negatively impact our operations.

As we advance our clinical development programs for product candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. In particular, as we progress our Phase 3 clinical trials for sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD, we will require additional key staff for clinical development operations as well as additional key financial and administrative personnel. We will also need to establish commercial capabilities in order to commercialize any product candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We currently have no experience as a company in or infrastructure for sales, marketing and distribution, and our operations are currently limited to clinical development activities and as our operations expand, we likely will need to manage additional relationships with such third parties. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

If sozinibercept or any future product candidate is approved, we intend either to establish a sales and organization with technical expertise and supporting distribution capabilities to commercialize sozinibercept or any future product candidate or to outsource such functions to one or more third parties. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of sozinibercept or any future product candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be harmed.

Risks Related to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success will depend in significant part on our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our owned and licensed intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. In addition to taking other steps to protect our intellectual property, we hold issued patents, we have applied for patents, and we intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. We have filed patent applications both in the United States and in certain non-U.S. jurisdictions to obtain patent rights to inventions we have developed, with claims directed to compositions of matter, methods of use and other technologies relating to our programs. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, that the claims of the patents will exclude others from making, using or selling our product candidates or products that compete with or are similar to our product candidates. In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. For a description of our patent portfolio, see "Item 4B Business Overview" of this annual report.

Any changes we make to sozinibercept or any future product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is potentially crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to sozinibercept or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Similar to the patent rights of other biotechnology companies, the scope, validity and enforceability of our owned and licensed patent rights generally are highly uncertain and involve complex legal and factual questions. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent

applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by those third parties.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, with extended rights limited to the approved product, its approved uses and/or its manufacture. During the period of patent term extension, the claims of a patent are not enforceable for their full scope, but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable non-U.S. regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many non-U.S. countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some non-U.S. countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with sozinibercept or any future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could place our patent applications at risk of not issuing and could provoke third parties to assert claims against us or our collaborator. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ and certain countries have heightened requirements for patentability, requiring more disclosure in the patent application. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect sozinibercept and any future product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in non-U.S. jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and a change allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. The Leahy-Smith Act and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize sozinibercept or any future product candidates.

The patent landscape around our programs is complex, and there may be one or more third-party patents and patent applications containing subject matter that might be relevant to sozinibercept. Depending on what claims may ultimately issue from these patent applications, and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of sozinibercept or any future product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable

to develop and commercialize one or more of our product candidates, which would harm our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under the relevant license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to the technologies licensed under those agreements.

The licensing or acquisition of third-party intellectual property rights is an area in which many companies operate that have interests that are in conflict with ours, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could harm our business, financial condition, results of operations and prospects.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a negative effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendants usually assert counterclaims alleging invalidity or unenforceability. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the subject matter alleged to be infringing on the grounds that our patents do not cover that subject matter. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party in such a case does not offer us a license on commercially reasonable terms, or at all. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and our defense may distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many non-U.S. jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could negatively affect the price of the ADSs and our ordinary shares.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell sozinibercept or any future product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing sozinibercept or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of all third-party intellectual property rights potentially relating to sozinibercept or any future product candidates and technologies. We are not aware of any facts that would lead us to conclude that the valid and enforceable claims of any third-party patents would reasonably be interpreted to cover our product candidates. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and negatively affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we and other commercialization partners may be prevented from commercializing our product candidates, or may be

required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would harm our business, financial condition and operating results.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

We may be subject to claims by third parties asserting misappropriation of intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we seek to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or the services of personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could harm our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and product candidates, we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our trade secrets and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our trade secrets will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any technology or information that we protect as trade secret, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to sozinibercept and any future product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we exclusively license or may own in the future;
- we, our licensors or our future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we exclusively license or may own in the future;
- we, our licensors or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or exclusively licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future, including those that we have licensed, will not result in issued patents;
- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in major commercial markets in which we do not have sufficient patent rights to stop such sales;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may be asserted against our product candidates and technologies in a manner that harms our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not maintained and adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be negatively affected.

Failure to obtain trademark registrations in the future, could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce any future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time consuming and can strain the financial resources of a company of our size, and we may not be successful in enforcing our trademark rights. In addition, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Future trademark applications in the United States and in other non-U.S. jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are

unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be negatively affected.

Our product candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

There is a risk that any exclusivity we may be afforded if any of our product candidates are approved as a biologic product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to market it until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Risks Related to Ownership of the ADSs

The trading price and volume of the ADSs may be volatile, and ADSs holders could incur substantial losses.

The price and trading volumes of our ordinary shares and ADSs may be significantly affected by events such as announcements regarding scientific and clinical results concerning product candidates currently being developed by us, our collaboration partners or our main competitors, changes in market conditions related to our sector of activity, announcements of new contracts, technological innovations and collaborations by us or our main competitors, developments concerning intellectual property rights, as well as the development, regulatory approval and commercialization of new products by us or our main competitors and changes in our financial results.

In addition, equity markets may be subject to considerable price and trading volume fluctuations, and often, these movements do not reflect the operational and financial performance of the listed companies concerned. In particular, biotechnology companies' share prices have been highly volatile in the past and may continue to be highly volatile in the future. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry. Fluctuations in the stock market as well as the macroeconomic environment

could significantly affect the price of the ADSs. As a result of this volatility, investors may not be able to sell their ADSs at or above the price originally paid for the security. The market price and trading volume for the ADSs may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, divestitures, spin-offs, strategic partnerships, joint ventures, collaborations, capital commitments or changes in business strategy;
- adverse results of delays in our or any of our competitors' preclinical studies or clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination of a strategic alliance or the inability to establish additional strategic alliances;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- ADS price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs;
- price and volume fluctuations in trading of our ordinary shares on the ASX;
- short selling or other market manipulation activities;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- additions or departures of key management or scientific personnel;
- disruptions in our supply or manufacturing arrangements;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent and other intellectual property protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- litigation involving our company;
- announcement or expectation of additional debt or equity financing efforts;
- natural disasters or other calamities or disease outbreaks, such as the COVID-19 pandemic;
- sales of the ADSs by us, our affiliates or our other shareholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for the ADSs to fluctuate, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of the trading market for the ADSs.

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ADSs.

We have not declared or paid any cash dividends on our ordinary shares since February 2005 and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our operations and growth. Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in the ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of the ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased them. Investors seeking cash dividends should consider not purchasing the ADSs.

While we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may negatively impact the value of your ADSs. In addition, exchange rate fluctuations may affect the amount of Australian dollars that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in Australian dollars, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

Future sales of ordinary shares or ADSs by existing holders could depress the market price of the ordinary shares or ADSs.

We had a total of 1,091,466,771 ordinary shares outstanding as of June 30, 2024.

In August 2023, Opthea announced a non-underwritten institutional placement (“2023 Placement”) and fully underwritten accelerated non-renounceable entitlement offering (“2023 ANREO”) of A$90.0 million (approximately US$58.2 million), which was completed in September 2023. Existing shareholders were entitled to purchase new shares at a ratio of 1 for 3.07 pro-rata. The 2023 Placement and the fully underwritten institutional component of the 2023 ANREO, which closed in August 2023, together raised approximately A$73.7 million (approximately US$47.7 million), and the fully underwritten retail component of the 2023 ANREO, which closed in September 2023, raised approximately A$16.3 million (approximately US$10.5 million).

Participants in the 2023 Placement and 2023 ANREO receive one option, each exercisable at A$0.80 per option and expiring on August 31, 2025 (“2023 New Investor Options”), for every two new shares issued under the 2023 Placement and 2023 ANREO. A total of approximately 98 million 2023 New Investor Options were issued in connection with the 2023 Placement and 2023 ANREO, of which approximately 97.8 remain outstanding.

In June 2024, Opthea announced a non-underwritten institutional placement (“2024 Placement”) and partially underwritten accelerated non-renounceable entitlement offering (“2024 ANREO” and together with the 2024 Placement, the "2024 Equity Offering") of A$227.3 million (approximately US$151.9 million), which completed in July 2024. The 2024 Placement and the partially underwritten institutional component of the 2024 ANREO, which closed in June 2024, together raised approximately A$171.5 million (approximately US$114.3 million) and the fully underwritten retail component of the 2024 ANREO (the "2024 Equity Retail Offering"), which closed in July 2024, raised approximately A$55.9 million (approximately US$37.6 million). Total shares outstanding as of the date of this report is 1,231,094,617 .

Participants in the 2024 Placement and 2024 ANREO received one option, each exercisable for an ordinary share at A$1.00 per option and expiring on June 30, 2026 (2024 New Options), for every three new shares issued under the 2024 Equity Offering. A total of approximately 189.4 million 2024 New Investor Options were issued in connection with the 2024 Equity Offering.

As of the date of this annual report, the exercise of all outstanding investor options/rights exercisable for ordinary shares would enable the subscription of new ordinary shares representing approximately 18.9% of the diluted share capital. The ordinary shares subject to subscription under outstanding options exercisable for ordinary shares will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the ordinary shares in the public market could depress the market price of the ADSs. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ordinary shares and ADSs could decline substantially, which could impair our ability to raise additional capital through the issuance of ordinary shares, ADSs or other securities in the future.

The dual listing of our ordinary shares and the ADSs may negatively impact the liquidity and value of the ADSs.

Our ADSs are listed on Nasdaq and our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may negatively impact the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be negatively impacted by trading in our ordinary shares on the ASX.

We have incurred and will continue to incur significant increased costs as a result of operating as a company with ADSs that are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a company whose ADSs are publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the United States Securities and Exchange Commission, or SEC, and Nasdaq have imposed various requirements on public companies listed in the United States including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company listed in the United States, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of senior management and the experts named in this annual report.

Certain members of our senior management and board of directors named in this annual report are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. As a result, it may be impracticable to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the United States. An award for monetary damages under U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and Australia do not currently have a treaty or statute providing for recognition and enforcement of the judgments of the other country (other than arbitration awards) in civil and commercial matters.

As a result, our public shareholders may have more difficulty in protecting their interests through actions against us, our management or our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States. In addition, as a company incorporated in Australia, the provisions of the *Corporations Act 2001(Cth)*, or the Corporations Act, regulate the circumstances in which shareholder derivative actions may be commenced which may be different, and in many ways less permissive, than for companies incorporated in the United States.

Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' opportunity to sell their ordinary shares and may further restrict the ability of our shareholders to obtain a premium from such transactions. See Exhibit 2.3 "Description of Securities" as well as our Constitution, which is included as an exhibit to this annual report.

Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Corporations Act, sets forth various rights and obligations that apply to us as an Australian company and which may not apply to a U.S. corporation. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under Exhibit 2.3 "Description of Securities" as well as our Constitution, which is included as an exhibit to this annual report, prior to investing in our securities.

Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in ordinary shares may be limited, which may cause dilution to your holdings.

The deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act of 1933, as amended, or the Securities Act or exempted from registration under the Securities Act. If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (i) the notice of the meeting or solicitation of consent or proxy sent by us and (ii) a statement as to the manner in which instructions may be given by the holders.

You may instruct the depositary to vote the ordinary shares underlying your ADSs. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the ordinary shares underlying the ADSs you hold. However, you may not know about the meeting far enough in advance to withdraw those ordinary shares. If we

ask for your instructions, the depositary, upon timely notice from us, will notify you of the upcoming vote and arrange to deliver our voting materials to you and will try to vote ordinary shares as you instruct. We cannot guarantee you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares or to withdraw your ordinary shares so that you can vote them yourself. If we do not ask for your instructions, you can still send voting instructions to the depository and the depository may try to carry out those instructions, but it is not required to do so.

Under our Constitution, any resolution to be considered at a meeting of the shareholders shall be decided on a show of hands unless a poll is demanded in accordance with the terms of our Constitution. A poll may be demanded before a vote is taken, or, in the case of a vote taken on a show of hands, immediately before or immediately after, the declaration of the result of the show of hands. Under voting by a show of hands, multiple "yes" votes by ADS holders will only count as one "yes" vote and will be negated by a single "no" vote, unless a poll is demanded.

You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying ordinary shares.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to surrender your ADSs and receive the underlying ordinary shares. Temporary delays in the surrendering of your ADSs and receipt of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to surrender your ADSs and receive the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities. See "Item 12D —Description of American Depositary Shares."

Holders of ADSs are not treated as holders of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares, unless they surrender the ADSs to receive the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying the ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement. See "Item 12D —Description of American Depositary Shares."

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs provides that holders and beneficial owners of ADSs, including those holders and owners who acquired ADSs in secondary transactions, irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including in respect of claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs.

No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with such matters, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

As the jury trial waiver relates to claims arising out of or relating to the ADSs or the deposit agreement, we believe that the waiver would likely continue to apply to ADS holders or beneficial owners who withdraw the ordinary shares from the ADS facility with respect to claims arising before the cancellation of the ADSs and the withdrawal of the ordinary shares, and the waiver would likely not apply to ADS holders or beneficial owners who subsequently withdraw the ordinary shares represented by ADSs from the ADS facility with respect to claims arising after the withdrawal. However, to our knowledge, there has been no case law on the applicability of the jury trial waiver to ADS holders or beneficial owners who withdraw the ordinary shares represented by the ADSs from the ADS facility.

We currently report our financial results under IFRS, which differs in certain significant respect from U.S. generally accepted accounting principles, or U.S. GAAP.

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related, share-based compensation expense, and income tax. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our senior management and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on the ASX and expect to file financial reports on an annual and semi-annual basis, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year. Accordingly, there may be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

As a foreign private issuer listed on Nasdaq, we are subject to its corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of their home country. Some corporate governance practices in Australia may differ from Nasdaq corporate governance listing standards. For example, we could include non-independent directors as members of our Remuneration and Nomination committees, and our independent directors may not necessarily hold regularly scheduled meetings at

which only independent members of the board of directors are present. Currently, we follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. For an overview of our corporate governance practices, see "Item 16G—Corporate Governance."

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made on December 31, 2024. In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if 50% or more of our securities are held by U.S. residents and more than 50% of our senior management or directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP rather than IFRS, and modify certain of our policies to comply with corporate governance practices required of U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

We are an "emerging growth company" under the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our ordinary shares ADSs less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and if we were to lose our foreign private issuer status, -exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find the ordinary shares or ADSs less attractive because we may rely on these exemptions. If some investors find the ordinary shares or ADSs less attractive as a result, there may be a less active trading market for the ordinary shares or ADSs and the price of the ordinary shares or ADSs may be more volatile. We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than US$1.235 billion in annual revenue; (ii) the last day of the fiscal year in which we qualify as a "large accelerated filer"; (iii) the date on which we have, during the previous three-year period, issued more than US$1.0 billion in non-convertible debt securities; and (iv)June 30, 2026.

It is likely that we will be classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences for U.S. holders.

In general, a non-U.S. company will be considered a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets is attributable to assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation.

We believe we were a PFIC for our taxable year ended June 30, 2024, and based on the nature and composition of our income, assets, activities and market capitalization, we may be a PFIC in future taxable years. However, our PFIC status is based on an annual determination and may change from year to year. Our status as a PFIC will depend on the composition of our income and the composition and value of our assets, which may be volatile, from time to time. Our status may also depend, in part, on how quickly we utilize the cash we raise in any offering of our securities. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

If we are a PFIC for any taxable year during which a U.S. holder (as defined below in the section titled "Item 10E – Taxation") holds ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. We will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a valid and timely qualified electing fund (QEF) or mark-to-market election, or makes a deemed sale election once we cease to be a PFIC; however, we do not currently intend to provide the information necessary for a U.S. holder to make a QEF election. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see "Item 10E—Taxation."

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder is treated as owning (directly, indirectly or constructively,) at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated, for U.S. federal income tax purposes, as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Because our group includes a U.S. subsidiary (Opthea US Inc.), certain of our current and future non-U.S. subsidiaries will be treated as controlled corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro-rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and payment obligations described above. Failure to comply with such obligations may subject a United States shareholder to significant monetary penalties and stall the beginning of the statute of limitations period for relevant U.S. federal income tax returns. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in the ADSs.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

Our tax treatment is subject to the enactment of, or changes in, tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related to the Organization for Economic Co-Operation and Development's Base Erosion and Profit Shifting Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our position and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangement and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

General Risk Factors

We may be subject to securities litigation, which is expensive and could divert management's attention.

The market price of the ordinary shares or ADSs may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and their trading volume could decline.

The trading market for the ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. As a public listed company in Australia since 1985, our equity securities are currently subject to coverage by a number of analysts. If fewer securities or industry analysts cover our company, the trading price for the ADSs could be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of the ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for the ADSs could decrease, which could cause the price of the ADSs or their trading volume to decline.

If our information technology systems or data, or those of the third-parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations' reputational harm' loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process confidential sensitive, and/or proprietary information, including intellectual property, business information, personal data, and health information (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitations nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential

harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, adware, telecommunications failures, earthquakes, fires, floods and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent, particularly for companies like ours in the biopharmaceutical space, and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cyber security risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, as it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitations, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third-party with whom we work have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information of our information technology systems, or those of the third parties with whom we work. A security incident or other interruptions could disrupt our ability (and that of third parties with whom we work) to develop and provide our products. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective.

We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis.[1]Further, we may experience delays in developing and deploying remedial measures designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions are costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Our insurance policies are expensive and only protect us from some business risks, leaving us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. We believe that we maintain insurance customary for businesses of our size and type, including clinical trial liability insurance. However, there are types of losses we may incur that cannot be insured against or that we believe are not economically reasonable to insure. Moreover, any loss incurred could exceed policy limits and policy payments made to us may not be made on a timely basis. Such losses could negatively affect our business prospects, results of operations, cash flows and financial condition. We do not know if our current levels of coverage are adequate or if we will be able to obtain insurance with adequate levels of coverage in the future, if at all. Any significant uninsured liability may require us to pay substantial amounts, which could negatively impact our financial position and results of operations.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or fail to implement and maintain an effective system of internal control over financial reporting, which may result in us being unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of the ADSs may be negatively impacted.

Section 404(a) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that our management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. During the year ended June 30, 2024 and 2023, we identified a material weakness in our internal controls over financial reporting because we did not design and maintain effective controls in relation to accounting for non-routine transactions and its related note disclosures which resulted in our failure to prevent and detect material errors which were corrected in our consolidated financial statements as of and for the year ended June 30, 2024 related to the (1) remeasurement of the financial liabilities in connection with our Funding Agreement and (2) the accounting application and related disclosures of investor options issued during the year. Although we are taking certain measures to remediate this material weakness, this material weakness will not be considered remediated until management completes the design and implementation of the remediation measures and the controls operate for a sufficient period of time and management concludes, through testing, that these controls are effective. If in the future, we fail to maintain effective internal controls, as such standards are modified, supplemented or amended from time to time, we may

not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404(a).

Section 404(b) also requires an attestation report on the effectiveness of internal control over financial reporting be provided by our independent registered public accounting firm beginning with our annual report following the date on which we are no longer an "emerging growth company", which may be up to five fiscal years from the initial public offering of our ADSs. If we are unable to attest to the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, and the market price of our ordinary shares and ADSs could decline. Failure to maintain effective internal control over financial reporting could also restrict our future access to the capital markets and subject each of us, our directors and our officers to both significant monetary and criminal liability. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial position, results and prospects may be adversely affected.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, which could require us to restate our operating results or result in our auditors issuing a qualified audit report. In order to establish and maintain effective disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Developing, implementing and testing changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in establishing and maintaining adequate internal controls.

If in the future we conclude that we have ineffective internal controls over financial reporting or when applicable, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on Nasdaq.

Item 4. Information on the Company

4A. History and Development of Opthea Limited

We were incorporated under the laws of Australia in 1984 under the name Circadian Technologies Limited. In 1985, we completed an initial public offering of our ordinary shares and the listing of our ordinary shares on the Australian Securities Exchange, or the ASX. In December 2015, we changed the name of our company to Opthea Limited. Our headquarters and registered offices are located at Suite 0403, Level 4, 650 Chapel Street, South Yarra, VIC 3141, Australia. Our telephone number is +61 3 9826 0399. Our agent for service of process in the United States is Corporation Service Company, located at 1180 Avenue of the Americas, Suite 210, New York, NY 10036. Our website address is www.opthea.com. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not part of this annual report. The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

For a description of our principal capital expenditures and divestitures for the three years ended June 30, 2024, and for those currently in progress, see Item 5 “Operating and Financial Review and Prospects”.

4B. Business Overview

We are a clinical-stage biopharmaceutical company developing a novel therapy for the treatment of highly prevalent and progressive retinal diseases. We are developing our Phase 3-product candidate, sozinibercept, a biologic designed to inhibit VEGF-C and VEGF-D, to complement VEGF-A inhibitors for the treatment of ophthalmic diseases. Anti-VEGF-A therapies represent the standard of care for wet age-related macular degeneration, or AMD, and other retinal diseases; however, there remains a significant unmet medical need as many patients experience suboptimal vision outcomes with these treatments. As the only biologic inhibitor of VEGF-C and VEGF-D in clinical development for ophthalmology, sozinibercept differs from standard of care therapies and when administered in combination with a VEGF-A inhibitor, is designed to achieve broader inhibition of the vascular endothelial growth factor, or VEGF, family of growth factors and target a mechanism of clinical resistance to improve visual acuity. Our lead indication for sozinibercept combination therapy is wet AMD, a chronic, progressive eye disease and the leading cause of vision loss for individuals over the age of 50. In a 366-patient Phase 2b clinical trial for the treatment of wet AMD, 2.0 mg sozinibercept, in combination with a standard of care anti-VEGF-A therapy, ranibizumab (Lucentis®), met the primary endpoint of a statistically significant superior mean gain in visual acuity over ranibizumab monotherapy at week 24. We initiated two pivotal Phase 3 clinical trials, COAST (Combination OPT-302 with Aflibercept Study) and ShORe (Study of OPT-302 in combination with Ranibizumab), in treatment-naive patients with wet AMD to evaluate the efficacy and safety of sozinibercept in combination with anti-VEGF-A therapies compared to anti-VEGF-A monotherapy. We completed patient recruitment in COAST in February 2024 and in ShORe in May 2024. The 52-week top-line data readout of COAST is anticipated early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025. In addition to our clinical trials in wet AMD, we have observed evidence of improved clinical outcomes in a Phase 1b/2a clinical trial of sozinibercept in combination with another standard of care anti-VEGF-A therapy, aflibercept (Eylea®), in patients with treatment-refractory diabetic macular edema, or DME. We retain worldwide rights to develop and commercialize sozinibercept for the treatment of wet AMD and DME and believe that the novel treatment mechanism of sozinibercept has the potential to provide therapeutic benefit for other progressive eye diseases.

Wet AMD is a rapidly progressing disease with loss of central vision developing over a period of weeks to months in which abnormal new blood vessels form in the back of the eye in a process called choroidal neovascularization, or CNV. These newly formed vessels are highly permeable, leaking exudate leading to fluid accumulation and retinal lesion formation. This, in turn, adversely affects sensory cells in the retina and if left untreated, results in rapid loss of visual acuity.

Wet AMD affects approximately one million people in the United States and 2.5 million people in Europe. The standard of care for wet AMD and other ocular neovascular diseases is the administration of monotherapies that primarily inhibit VEGF-A. These therapeutic agents, which include ranibizumab, aflibercept, and faricimab, prevent VEGF-A molecules from binding to, and activating, VEGF receptors and thereby inhibit the formation and permeability of blood vessels. As the risk of developing wet AMD increases with age, it is predicted that the overall aging of the population will result in a significant increase in the number of wet AMD cases, both in the United States and worldwide. In 2023, branded anti-VEGF-A monotherapies had combined annual worldwide sales in excess of US$14 billion. In addition, it is estimated that ~35% of wet AMD patients are treated with off-label bevacizumab as a lower cost alternative anti-VEGF-A therapy. Despite receiving anti-VEGF-A monotherapy, many wet AMD patients also experience suboptimal vision outcomes and as a result, we believe there is a significant and expanding market opportunity for novel therapies that can improve vision in patients with wet AMD, which has the potential to lead to sales greater than the combined annual sales of ranibizumab, aflibercept and faricimab.

Despite the widespread use and commercial success of VEGF-A inhibitors, at least 45% of wet AMD patients treated with a VEGF-A inhibitor experience some degree of suboptimal clinical response, with a majority of patients failing to achieve 20/40 vision after 12 months of treatment, providing further opportunity for visual acuity improvement. Furthermore, many patients have persistent retinal fluid and insufficient gains in visual acuity to resume routine daily activities such as driving and reading following regular treatment with a VEGF-A inhibitor. In addition, improvements in visual acuity following regular administration of VEGF-A monotherapy are often not sustained with long-term use.

Sozinibercept is designed to improve patient outcomes with superior vision gains for patients with wet AMD and other retinal diseases, such as DME, by targeting alternate members of the VEGF family, namely VEGF-C and VEGF-D, which are not targeted by current standard of care therapies. VEGF-C and VEGF-D function in parallel with VEGF-A to drive neovascularization and vascular leakage, which are key hallmarks of both wet AMD and DME. In addition, treatment with VEGF-A inhibitors leads to upregulation of VEGF-C and VEGF-D to compensate for VEGF-A inhibition, which may represent an important mechanism of clinical resistance to anti-VEGF-A monotherapy. We are developing sozinibercept to be used in combination with standard of care anti-VEGF-A monotherapies to achieve broader inhibition of the VEGF family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone

In our completed Phase 2b wet AMD clinical trial, 2.0 mg sozinibercept in combination with ranibizumab demonstrated a statistically significant superior mean gain in visual acuity at week 24 compared to patients treated with ranibizumab with a sham injection, which we refer to as ranibizumab monotherapy. The trial was an international, multi-center, double-masked trial in 366 treatment-naive patients with wet AMD. Patients were randomized into three groups and received intravitreal injections every four weeks of either 0.5 mg or 2.0 mg sozinibercept in combination with 0.5 mg ranibizumab or 0.5 mg ranibizumab monotherapy. Treatments were administered by intravitreal injections once every four weeks for 24 weeks (six treatments in total). The primary endpoint was the mean change at week 24 in best corrected visual acuity, or BCVA, from baseline on the Early Treatment of Diabetic Retinopathy Study, or ETDRS, standardized eye chart, which we refer to as visual acuity. Patients treated with 2.0 mg sozinibercept combination therapy demonstrated a statistically significant improvement in visual acuity compared to patients treated with ranibizumab monotherapy. In the patients that received 2.0 mg sozinibercept combination therapy, visual acuity improved at week 24 from baseline by a mean of +14.2 letters compared to +10.8 letters for those treated with ranibizumab monotherapy, a statistically significant benefit of +3.4 letters(p=0.0107). Patients that received 2.0 mg sozinibercept combination therapy also demonstrated improvements in retinal anatomy which were consistent with the visual acuity gains observed in the trial, including reductions in retinal fluid and lesion size by week 24. In a pre-specified subgroup analysis of patients without retinal angiomatous proliferation (RAP) who had occult or minimally classic lesions, which are considered more difficult to treat with anti-VEGF-A therapy and are present in the majority of wet AMD patients, the mean visual acuity gain from baseline to week 24 was +16.1 letters with sozinibercept combination therapy (n=88) compared to +10.3 letters for those treated with ranibizumab monotherapy (n=87), a benefit of +5.7 letters (p=0.0002). Our clinical experience to date, which includes administration of sozinibercept to patients enrolled in our Phase 3 clinical trials, as well as administration of over 1,800 doses of sozinibercept to 399 patients with retinal disease in our Phase 1 and Phase 2 clinical trials, indicates that sozinibercept intravitreal injections are well tolerated, with the incidence of treatment-emergent adverse events, or TEAEs, comparable to anti-VEGF-A monotherapy in our clinical trials

In August 2020, we successfully completed End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA), and a Scientific Advice meeting with the European Medicines Agency (EMA). The regulatory engagement provided us with guidance on our Phase 3 clinical program for sozinibercept in wet AMD and associated manufacturing processes that we believe will support the submission of a Biologics License Application in the U.S. and Marketing Authorization Application in Europe. Further regulatory milestones were achieved during the year, firstly with our successful application to the FDA for an initial Pediatric Study Plan (iPSP) waiver, which was received in March 2021. The receipt of the waiver means that we will not have to conduct an additional study of sozinibercept in the pediatric population for use of sozinibercept in this U.S. population. Furthermore, in July 2021, the FDA granted Fast-Track designation for sozinibercept in combination with anti-VEGF-A therapy for the treatment of patients with wet AMD. We believe the FDA's Fast-Track designation acknowledges the significant unmet medical need in the management of wet AMD, and the potential role that sozinibercept may have in addressing it. The FDA's Fast-Track Designation for sozinibercept offers benefits to expedite the Phase 3 clinical program and subsequent potential approval process, including more frequent communication and meetings with the FDA, and a Rolling Review of completed sections of its BLA.In December 2023, we received further feedback from the FDA in a Type C meeting on our manufacturing, chemistry and controls program required to support the BLA filing

We initiated two concurrent pivotal Phase 3 clinical trials for the treatment of wet AMD. These double-masked, sham-controlled Phase 3 clinical trials enrolled treatment-naive patients and assessed the efficacy and safety of 2.0 mg of sozinibercept in combination with ranibizumab (Lucentis®) (referred to as ShORe) or aflibercept (Eylea®) (referred to as COAST), compared to ranibizumab or aflibercept monotherapy in each respective trial. In addition, each trial is comparing the clinical efficacy of sozinibercept administered in combination with the applicable VEGF-A inhibitor on an every four-week and every eight-week dosing regimen to understand the durability of sozinibercept treatment effect with less frequent dosing. For consistency, the ShORe and COAST Phase 3 trials built upon and maintain key features of our Phase 2b clinical trial of sozinibercept combination therapy for the treatment of wet AMD, while evaluating the administration of sozinibercept combination therapy over a longer treatment period and in a greater number of patients. The primary endpoint of both trials will be the mean change in visual acuity from baseline to week 52. Patients will continue to be dosed until week 96 to further assess long-term safety at week 100. In total, we enrolled 1,984 patients across the COAST (n=998) and ShORe (n=986) trials, with patients recruited from more than 20 countries worldwide. Based on the completion of enrollment in COAST in February 2024 and ShORe in May 2024, the 52-week top-line data readout of COAST is anticipated early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025. Pending the results of the primary efficacy phase at week 52 of the Phase 3 clinical trials, we intend to submit Biologics License and Marketing Authorization Applications with the FDA and EMA respectively

In addition to our pivotal Phase 3 clinical trials, we plan to develop a co-formulation of sozinibercept with an approved and/or biosimilar anti-VEGF-A therapy designed to achieve VEGF-A, VEGF-C and VEGF-D inhibition following the administration of a single intravitreal injection of the co-formulated product. Sozinibercept is currently administered as a combination therapy, consisting of a sequential injection of sozinibercept following intravitreal administration of a VEGF-A inhibitor. We believe that a co-formulated sozinibercept and VEGF-A inhibitor product could provide an additional treatment option for physicians to reduce the frequency and number of injections for patients. We intend to file an investigative new drug application, or IND, for the co-formulated product prior to initiation of clinical trials.

While we intend to focus our development efforts on seeking commercialization of sozinibercept for the treatment of wet AMD, we are also investigating the therapeutic potential of sozinibercept for DME. DME is a progressive eye disease and a complication of diabetic retinopathy, or DR, a condition caused by chronically elevated glucose levels in diabetics that damages the retina. DME can cause blurred vision, severe vision loss and blindness. Wet AMD and DME share a similar underlying pathophysiology, including retinal neovascularization and increased vascular permeability, and as a result, VEGF-A inhibitors are also considered the standard of care treatment for DME. Based on its mechanism of action and clinical results to date, we believe that sozinibercept also has the potential to deliver therapeutic benefit in DME patients. In our Phase 1b/2a clinical trial of sozinibercept in combination with aflibercept in patients with treatment-refractory DME, we observed evidence of improved clinical outcomes following sozinibercept combination therapy in this indication.

We also believe that our novel treatment mechanism has the potential to provide therapeutic benefit for other progressive retinal diseases beyond wet AMD and DME. We may further investigate the efficacy of sozinibercept to improve clinical outcomes in patients with polypoidal choroidal vasculopathy, or PCV, a form of wet AMD that is highly prevalent in Asian populations and less responsive to anti-VEGF-A therapy than other wet AMD subtypes. Beyond wet AMD and DME, we may explore applications of sozinibercept in other retinal diseases in which a VEGF-C or VEGF-D inhibitor could have therapeutic potential, such as retinal vein occlusion, or RVO.

Our Company

We are a public company listed on the Australian Securities Exchange and Nasdaq. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in neovascular disease. In October 2023, Frederic Guerard, PharmD, and Peter Lang, joined as our Chief Executive Officer and Chief Financial Officer, respectively.

Dr. Guerard brings over 25 years of pharmaceutical leadership experience in strategic and commercial roles. Dr.Guerard served as the Chief Executive Officer of Graybug Vision, Inc., a clinical-stage pharmaceutical company developing potentially transformative therapies for ocular diseases. Prior to Graybug, Dr.Guerard acted as the Worldwide Business Franchise Head of Ophthalmology at Novartis. In this role, he successfully led the integration of Novartis retina and Alcon Pharmaceuticals and accelerated the rejuvenation of the product pipeline through strategic acquisitions and licensing transactions in dry eye, presbyopia, and inherited retinal diseases. Prior to this role, he served as Global Franchise Head of Pharmaceuticals at Alcon. He has also held multiple leadership positions at Novartis, including Head of United Kingdom and Ireland.

Mr. Lang has over 25 years of experience delivering strategic, operational, and financial solutions, with expertise in the healthcare and biopharmaceutical sectors. Prior to joining Opthea, Mr. Lang served as the Chief Financial Officer of Aerie Pharmaceuticals, Inc., a fully integrated pharmaceutical company focused on the discovery, development, and commercialization of first-in-class ophthalmic therapies for the treatment of patients with eye diseases. Before Aerie, Peter was Managing Director and Partner at Ridge Advisory, LLC, a boutique advisory and banking firm, and also served in various leadership roles in the healthcare investment banking divisions of well-respected firms, including HSBC, Bank of America Merrill Lynch, UBS Investment Bank, and Leerink Partners.

Megan Baldwin, Ph.D., our Founder, Chief Innovation Officer and Executive Board Director, has over 25 years of research and development and biopharmaceutical industry experience on neovascularization and therapeutic strategies in ophthalmic indications and cancer. Prior to her current role at Opthea, Dr. Baldwin was CEO of Opthea Limited for 10 years, having founded the ophthalmology and sozinibercept program at the company and progressing sozinibercept from preclinical studies through to Phase 3 pivotal trials. Prior to joining our company, she was a postdoctoral research fellow and an associate market planning manager at Genentech, where she conducted angiogenesis research before joining the anti-angiogenic therapy commercial group.

Judith Robertson, our Chief Commercial Officer, was previously Chief Commercial Officer of Eleusis Ltd and Chief Commercial Officer of Aerie Pharmaceuticals. Prior to Aerie, Ms. Robertson was Vice President Immunology and Ophthalmology Global Commercial Strategy Leader at Johnson and Johnson, Janssen Pharmaceutical and Vice President, Ophthalmology Global Business Franchise Head at Novartis (formerly Alcon).

Our Strategy

Our goal is to become a leader in developing and commercializing therapeutics for the treatment of retinal diseases. The key elements of our strategy are to:

- **Advance sozinibercept through two concurrent Phase 3 trials for the treatment of wet AMD**. Based on the statstically superior results of our Phase 2b trial in wet AMD, we initiated two concurrent pivotal Phase 3 clinical trials in treatment-naive patients with wet AMD to evaluate the efficacy and safety of sozinibercept in combination with anti-VEGF-A therapy. Pending the results of the primary efficacy phase at week 52 of the Phase 3 clinical trials, we intend to file for marketing approval for sozinibercept for the treatment of wet AMD in the United States, the European Union and other territories.

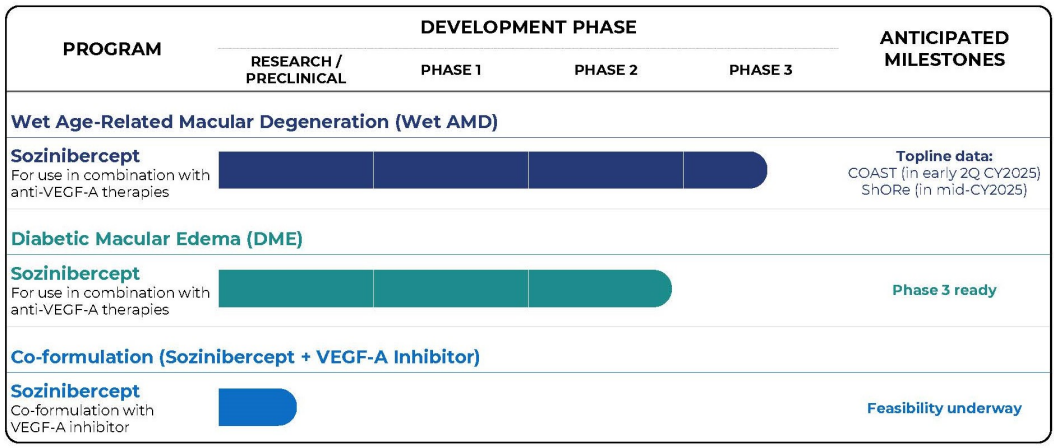
- **Optimize sozinibercept administration and develop a co-formulation to reduce injection burden for patients and provide treatment flexibility**. Currently, sozinibercept is administered as an injection following intravitreal administration of a VEGF-A inhibitor. In our Phase 3 clinical trials, we are investigating the efficacy and durability of sozinibercept administered every 4-weeks and administered less frequently on an every 8-week dosing schedule. Based on sozinibercept's pharmacokinetic profile, structural similarity to aflibercept and potential for improved and prolonged clinical efficacy over time, additional studies to investigate extended dosing regimens and durability of clinical benefit beyond every 8-week dosing may be also conducted. In addition, we plan to develop a co-formulation of sozinibercept with an approved and/or biosimilar anti-VEGF-A therapy to provide a treatment option for physicians to reduce the frequency and number of injections for patients.

- **Expand clinical development of sozinibercept in DME and other retinal diseases**. Due to similarities in the underlying pathophysiology, we anticipate that sozinibercept in combination with VEGF-A inhibitors may provide therapeutic benefit to patients with other neovascular ophthalmic diseases, such as DME. We reported positive data from a Phase 1b/2a trial of sozinibercept in combination with aflibercept for the treatment of DME, and we plan to continue further development in this indication. We also continue to explore the potential benefit of sozinibercept in PCV and other ocular diseases, such as RVO and DR, in which there is a strong scientific and clinical rationale.

- **Maximize the commercial potential of sozinibercept**. We retain worldwide rights for the development and commercialization of sozinibercept. If sozinibercept receives marketing approval in the United States and the European Union for wet AMD or any other retinal indications we are pursuing, we intend to establish our own commercial organization in these key territories. We may also enter into collaborations where we believe there is an opportunity to accelerate the development and commercialization of sozinibercept in select territories.

Our Pipeline

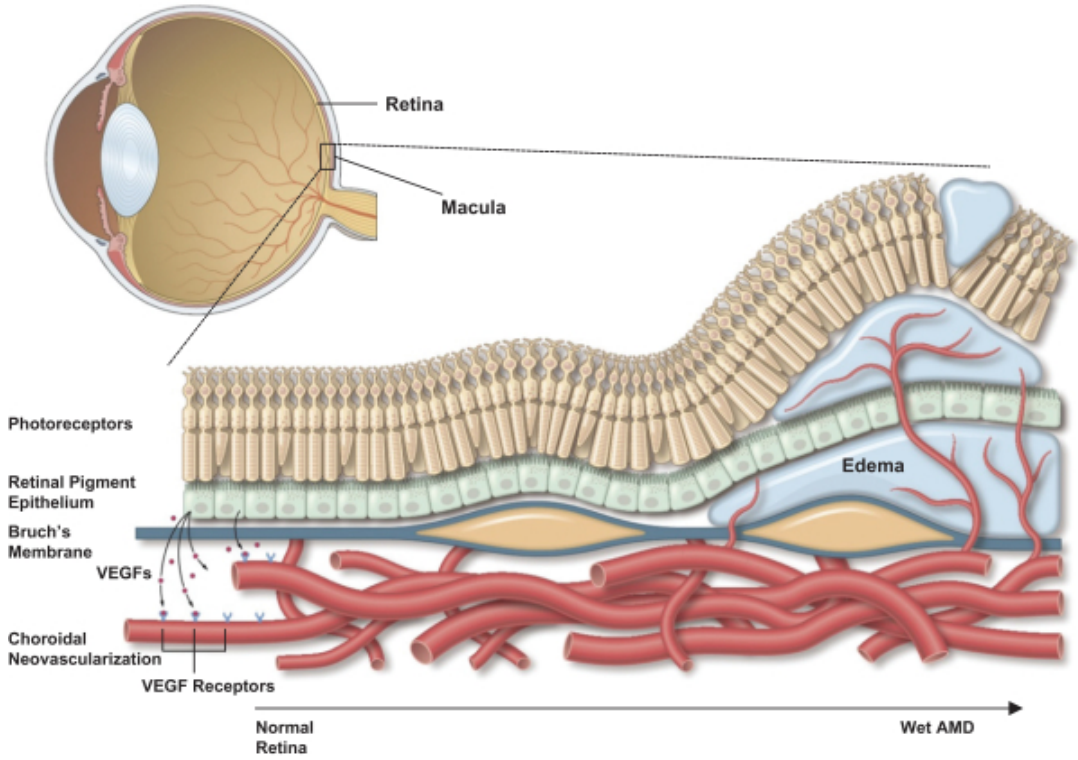
The following table summarizes the stage of clinical development and status of our product candidate, sozinibercept :



VEGFs in Ocular Diseases

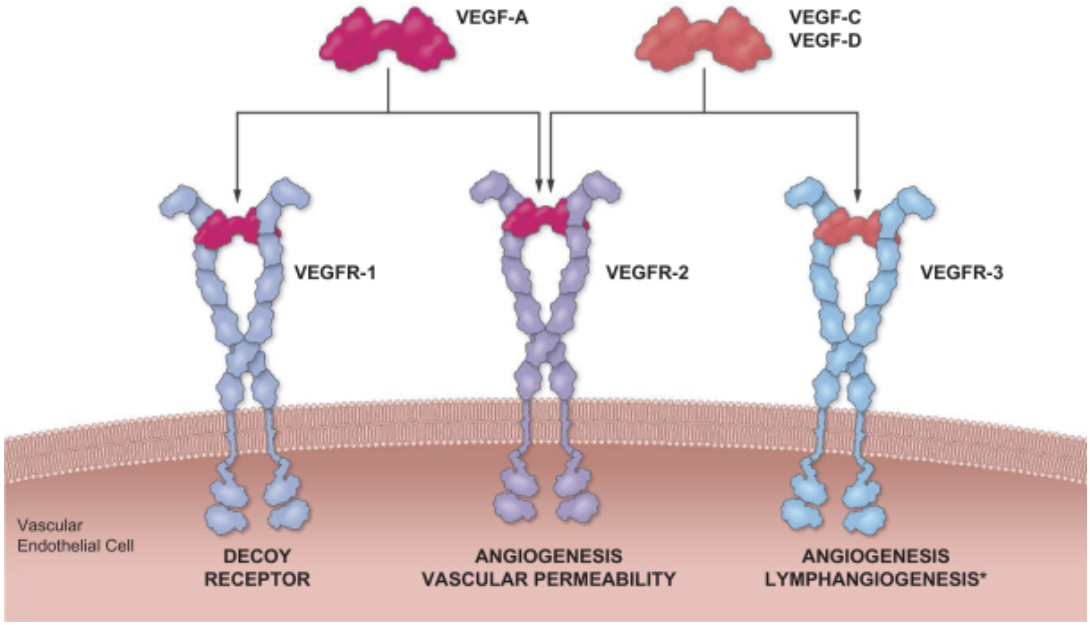
Multiple ophthalmic diseases and conditions, including wet AMD and DME, involve aberrant blood vessel formation and growth, as well as vascular permeability and resulting leakage that contributes to disease progression. In wet AMD, lesions consist of newly formed blood vessels that are typically fragile and leak, leading to the accumulation of fluid in the retinal tissue at the back of the eye. As shown in the figure below, if left untreated, this fluid can cause retinal swelling that disrupts the local architecture and function of sensory cells and neurons in the eye, resulting in vision loss. In patients with DME, high blood glucose levels drive physiological changes resulting in vascular permeability that also result in fluid accumulation, or edema, in the macula, the central region of the retina, and loss of visual acuity.

Neovascularization and Vascular Permeability are Key Hallmarks of a Number of Retinal Diseases, Leading to Lesion Formation, Edema and Distortion of the Retina Photoreceptor Layer Causing Loss of Vision



Neovascularization and vascular permeability associated with retinal disease progression are driven by a family of related growth factors known as VEGFs. Members of the VEGF family, including VEGF-A, VEGF-C and VEGF-D, exert their activity by binding and activating VEGF receptors referred to as VEGFR-1, VEGFR-2, and VEGFR-3. Receptor activation triggers signaling pathways that lead to the development of new blood vessels, a process known as angiogenesis, as well as vascular permeability.

Members of the VEGF Family of Growth Factors Have Overlapping but Distinct Specificities for VEGFRs



* Lymphangiogenesis refers to the proliferation of lymphatic vessels from pre-existing lymphatic vessels.

VEGF-A

VEGF-A is the most well-characterized member of the VEGF family of growth factors and was the first to be targeted for therapeutic intervention. VEGF-A is a potent growth factor and its relevance in ophthalmic neovascularization has been well-established. Overexpression of VEGF-A in animal models has shown VEGF-A to be a causal factor in the development of neovascularization and vascular permeability, which are key hallmarks in the progression of wet AMD. In wet AMD patients, VEGF-A levels are shown to be elevated in the aqueous humor fluid of the eye. VEGF-A binds to VEGFR-1, which acts to regulate VEGF-A activity, and VEGFR-2, which is a key driver of neovascularization and vascular permeability. Several inhibitors of VEGF-A have been approved to treat a number of neovascular ocular diseases. The leading ocular VEGF-A inhibitors by revenue, ranibizumab, aflibercept and faricimab, had combined annual worldwide sales in excess of US$14 billion in 2023.

VEGF-C and VEGF-D

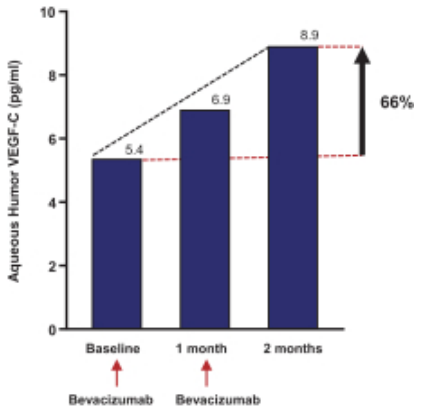
VEGF-C and VEGF-D contribute to the development and persistence of neovascular diseases, as evidenced by their elevated levels in multiple pathological conditions. Both VEGF-C and VEGF-D can stimulate neovascularization and VEGF-C can induce permeability by binding to VEGFR-2, independent of VEGF-A activity. Additionally, VEGF-C and VEGF-D bind to VEGFR-3, a receptor that is not activated by VEGF-A, which confers biological activities to both VEGF-C and VEGF-D that are distinct from those of VEGF-A. Activation of VEGFR-3 can stimulate vascular proliferation and modulate vascular permeability, vascular leakage and edema formation. The receptor binding profiles, and the distinct biological activities of VEGF-C and VEGF-D suggest that inhibiting VEGF-C and VEGF-D may have therapeutic potential in ocular diseases by acting independently of, and in tandem with, the activity of VEGF-A inhibitors.

Resistance to VEGF-A Therapies May be Driven by VEGF-C and VEGF-D

Standard of care treatments for wet AMD and DME inhibit VEGF-A activation of its receptors that are typically expressed on vascular endothelium. This can lead to inhibition of blood vessel growth and leakage which can stabilize disease and improve clinical outcomes, including visual acuity, in patients with retinal eye conditions. However, not all patients fully respond to VEGF-A inhibition. A substantial proportion of patients with wet AMD and DME have further opportunity for visual acuity gain and/or a need for resolution of persistent retinal fluid following anti-VEGF-A treatment. Furthermore, gains in visual acuity are often not sustained over the long term, even when anti-VEGF-A therapies are administered regularly. This resistance may occur as anti-VEGF-A monotherapies do not fully address the multifactorial pathogenesis of wet AMD and DME, including having no activity to block VEGF-C and VEGF-D.

VEGF-C and VEGF-D are implicated in the development of resistance to clinical use of anti-VEGF-A therapies. Levels of VEGF-C and/or VEGF-D have been observed to be unregulated in response to anti-VEGF-A therapies, most notably in patients with wet AMD. In a study conducted by third-party researchers in wet AMD patients, a 66% increase in the level of VEGF-C in the aqueous humor fluid in eyes was observed following two monthly doses of the VEGF-A inhibitor, bevacizumab (Avastin). This is illustrated in the figure below.

VEGF-C Levels are Increased in Aqueous Fluid of the Eye in Wet AMD Patients Treated with Monthly Intravitreal Bevacizumab



Study conducted by Cabral et al. (2018)

Upregulation of VEGF-C and VEGF-D can continue to drive signaling through VEGFR-2, even in the presence of a VEGF-A inhibitor, as well as signal through VEGFR-3, both of which may contribute to ongoing angiogenesis and vascular permeability associated with persistent wet AMD. VEGF-C and VEGF-D mediated activation of VEGFR-2 and VEGFR-3, as well as their compensatory elevation following VEGF-A inhibition, may contribute to sub-optimal clinical response to anti-VEGF-A monotherapy. We believe sozinibercept in combination with a VEGF-A inhibitor can address a key mechanism of clinical sub-responsiveness to standard of care treatments for serious retinal eye diseases by broad blockade of the VEGF family of growth factors which is not achieved by anti-VEGF-A monotherapies.

Sozinibercept

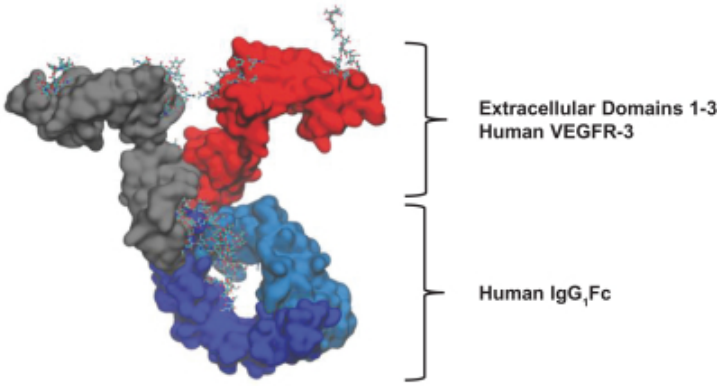
We are developing our Phase 3 product candidate, sozinibercept, a biologic designed to inhibit VEGF-C and VEGF-D, to complement existing VEGF-A inhibitors for the treatment of ophthalmic diseases, including wet AMD and DME. Anti-VEGF-A therapies represent the standard of care for wet AMD and other retinal diseases. However, there remains a significant unmet need as many patients have suboptimal vision outcomes with these treatments. As the only biologic inhibitor of VEGF-C and VEGF-D in clinical development for ophthalmology, sozinibercept differs from standard of care VEGF-A inhibitors, and in combination with a VEGF-A inhibitor, is designed to address patients' suboptimal clinical responses to anti-VEGF-A monotherapies by achieving broader inhibition of the VEGF family to improve visual acuity over standard of care anti-VEGF-A monotherapies.

In 2019, we completed a 366-patient Phase 2b clinical trial of sozinibercept in combination with ranibizumab for the treatment of wet AMD, which met the primary endpoint of a statistically significant superior mean gain in visual acuity over ranibizumab monotherapy at week 24. We initiated two pivotal Phase 3 clinical trials, COAST and ShORe, in treatment-naive patients with wet AMD to evaluate the efficacy and safety of sozinibercept in combination with anti-VEGF-A therapy compared to a standard of care monotherapy. We initiated these two pivotal Phase 3 clinical trials in treatment-naive patients with wet AMD to evaluate the efficacy and safety of sozinibercept in combination with anti-VEGF-A therapy compared to anti-VEGF-A monotherapy. We completed patient recruitment in COAST in February 2024 and in ShORe in May 2024. The 52-week top-line data readout of COAST is anticipated early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025. In addition, in our Phase 1b/2a clinical trial of sozinibercept in combination with aflibercept for the treatment of persistent DME, we observed evidence of clinical activity and improvements in visual acuity outcomes compared to aflibercept monotherapy. sozinibercept was observed to be well tolerated across Phase 1 and Phase 2 clinical trials in two disease indications following intravitreal administration of over 1,800 doses of sozinibercept to 399 patients either as monotherapy or in combination with standard of care VEGF-A inhibitors

Sozinibercept Mechanism of Action

We have designed sozinibercept to function as a ligand trap, capable of binding and sequestering VEGF-C and VEGF-D, thereby preventing these growth factors from activating VEGFR-2 and VEGFR-3. sozinibercept is comprised of the first three extracellular domains of human VEGFR-3, fused to the Fc domain, or the constant fragment of human immunoglobulin G_1, or IgG_1, as illustrated in the figure below. VEGF-C and VEGF-D function independent of, but in parallel with, VEGF-A to drive neovascularization and vascular leakage, key hallmarks of both wet AMD and DME. In addition, treatment with VEGF-A inhibitors leads to upregulation of VEGF-C and VEGF-D to compensate for VEGF-A inhibition, which may represent an important mechanism of clinical resistance to VEGF-A monotherapy.

Structure of sozinibercept



Ligand trap therapeutics that include the receptor-binding domains for other ligands have been approved for a number of indications. One such agent is aflibercept, marketed as Eylea, a ligand trap consisting of extracellular domains of VEGFR-1 and VEGFR-2, which primarily mediates its activity by binding and inhibiting VEGF-A. Aflibercept has marketing approval for the treatment of wet AMD, DME, macular edema secondary to RVO and DR. In rabbits, sozinibercept has been shown to have a comparable ocular biodistribution and intravitreal pharmacokinetic profile as aflibercept, with low systemic exposure.

Wet AMD

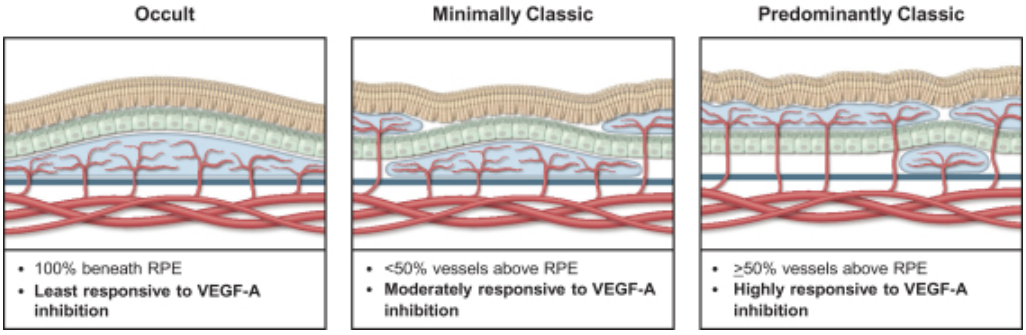
AMD is a chronic, progressive disease of the macula, a part of the retina containing the greatest concentration of light-sensing cells responsible for detailed, high visual acuity and central vision. The development of AMD is strongly associated with age, affecting up to 40% of individuals over the age of 75. There are two forms of AMD, dry AMD and wet AMD. Dry AMD is the most common form, representing approximately 85% to 90% of all AMD cases. However, dry AMD can develop into wet AMD, and wet AMD accounts for 90% of the severe vision loss associated with the disease.

Wet AMD is a rapidly progressing disease with loss of central vision developing over a period of weeks to months, and is the leading cause of vision loss for individuals over the age of 50. The most common symptoms of wet AMD are loss of central vision, distortion of objects or blurred vision. Peripheral vision usually remains intact. The disease typically affects patients initially in one eye, with a high likelihood of it occurring in the second eye over time. If left untreated, wet AMD can lead to rapid loss of visual acuity and blindness, adversely impacting the patient's ability to conduct daily activities, such as driving and reading.

Wet AMD occurs when new blood vessels in the choroid, or the vascular layer in the eye just under the retina, intrude into the retinal layers and leak fluid. The formation of these new blood vessels is referred to as CNV. These newly formed vessels are highly permeable, which can lead to fluid accumulation and adversely affect sensory cells in the retina.

Wet AMD can be classified as occult or classic, based on the neovascular pattern within lesions. In occult lesions, all of the blood vessels are below the retinal pigment epithelium, or RPE, and the areas on angiograms have a stippled appearance. Classic lesions, by contrast, appear as well-demarcated areas on angiograms due to neovascular blood vessels being located above the RPE. Classic lesions are further subdivided into predominantly classic if 50% or more of the blood vessels are above the RPE, and minimally classic, if greater than 0% and less than 50% of the blood vessels are above the RPE. Classic-containing lesions tend to be the most responsive to anti-VEGF-A therapies.

Classifications of Wet AMD Based on Neovascular Lesion Pattern



There is a further sub-type of wet AMD lesion referred to as retinal angiomatous proliferation, or RAP. RAP lesions are a type of CNV in which neovascularization in the retina protrudes into the sub-retinal space and connects to the choroidal circulation. Between 10% and 21% of wet AMD patients have RAP lesions. Although there are no therapies specifically approved to treat RAP lesions, patients are typically treated with VEGF-A inhibitors.

PCV is a further sub-type of wet AMD. PCV is an abnormality of inner choroidal vessels that causes dilations in the blood vessels in the retina that resemble polyps, known as polypoidal protrusions. PCV typically does not respond well to VEGF-A inhibitor therapies and many patients are diagnosed with PCV only after they fail to respond to these therapies. There is a high prevalence of PCV in Asian countries, with between 23% and 54% of patients with presumed cases of wet AMD in Japan having PCV. Prevalence rates of between 4% and 10% have been reported in Caucasian patients with presumed cases of wet AMD.

Current Treatments for Wet AMD and Their Limitations

There are five VEGF-A inhibitors approved by the U.S. Food and Drug Administration, or FDA, for the treatment of wet AMD, all of which are administered by regular intravitreal injections as monotherapy. These VEGF-A inhibitors include: the VEGF-A specific antibody ranibizumab (Lucentis®), the antibody fragment brolucizumab (Beovu®), the bispecific antibody faricimab (Vabysmo®) and the VEGFR-based ligand trap aflibercept (Eylea®). The VEGF-A antibody, bevacizumab (Avastin®), an FDA approved therapy for colorectal and other cancers, is also used off-label by many physicians to treat wet AMD, comprising approximately 35% of anti-VEGF-A injections administered globally. Recent clinical development has focused on maintaining vision gains with a VEGF-A inhibitor whilst reducing the number of injections.

VEGF-A inhibitors stabilize loss vision in over 90% of wet AMD patients. However, the effectiveness of these therapies in many patients is limited. Improvements of ≥15 letters of visual acuity typically occur in less than 40% of treated patients. In addition, despite regular treatment with a VEGF-A inhibitor, many patients have insufficient gains in visual acuity to resume routine daily activities such as driving and reading. Chronic vision loss can also occur despite ongoing treatment with an anti-VEGF-A inhibitor. Retrospective and prospective analyses of patients treated with VEGF-A inhibitor therapies for five years have found that, after initial gains in visual function following one year of treatment, many patients then had a gradual decline in visual acuity in subsequent years, resulting in the eventual reversal of the majority of gains. In addition, in clinical settings, up to two-thirds of patients treated with VEGF-A inhibitor therapies continue to have retinal fluid following treatment and approximately 25% experience further vision loss 12 months following treatment. Treatment options are limited for patients who do not respond adequately or experience visual decline despite ongoing therapy with standard of care VEGF-A inhibitors, and typically involve switching treatment from one anti-VEGF-A monotherapy to another with minimal additional visual benefit achieved.

Market Opportunity for the Treatment of Wet AMD

Wet AMD affects approximately one million people in the United States and 2.5 million in Europe. As the risk of developing wet AMD increases with age, it is predicted that the overall aging of the population will result in a significant increase in the number of wet AMD cases, both in the United States and worldwide. Branded anti-VEGF-A monotherapies had combined annual worldwide sales in excess of US$14 billion in 2023. In addition, it is estimated that ~35% of wet AMD patients are treated with off-label bevacizumab as a lower cost alternative anti-VEGF-A therapy. Despite receiving anti-VEGF-A monotherapy, many wet AMD patients experience suboptimal vision outcomes and as a result, we believe there is a significant and expanding market opportunity for novel therapies that can improve vision in patients with wet AMD, which has the potential to lead to sales greater than the combined annual sales of ranibizumab and aflibercept.

We believe that sozinibercept, used in combination with standard of care VEGF-A inhibitors, can address the significant unmet need for wet AMD patients by providing improved vision outcomes over that which can be achieved by inhibiting VEGF-A alone.

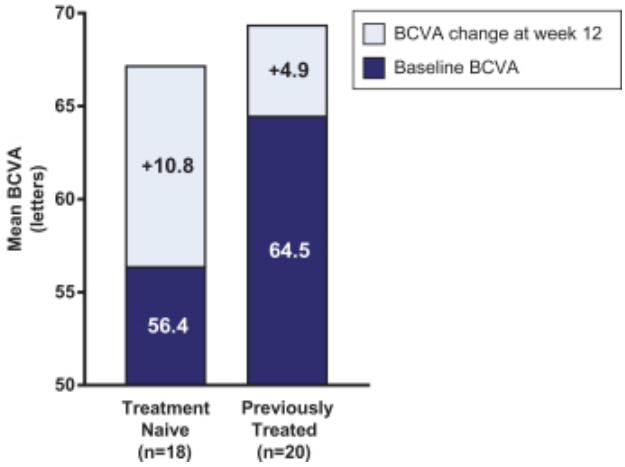
Phase 1/2a Clinical Trial Results in Wet AMD

In 2017, we completed a Phase 1/2a clinical trial of sozinibercept for the treatment of wet AMD patients under an investigational new drug, or IND, application accepted by the FDA in 2015. The trial was divided into two parts. Part 1 was a Phase 1 first-in-human 20-patient dose-escalation study in which sozinibercept was administered at three escalating doses (0.3 mg, 1.0 mg or 2.0 mg), either in combination with 0.5 mg ranibizumab or alone as a 2.0 mg monotherapy, once every four weeks for a total of three doses, with a follow-up visit at week 12. Part 2 was a Phase 2a 31-patient dose-expansion trial in which 2.0 mg sozinibercept was administered in combination with ranibizumab or as a monotherapy once every four weeks for a total of three doses, with a follow-up visit at week 12. Of the 51 patients dosed, 49% were treatment naive and 51% were previously treated with anti-VEGF-A therapy. The previously-treated patients received an average of 17 prior treatments, equating to prior treatment over an average of 1.3 years, of an intravitreal VEGF-A inhibitor prior to enrolling in the trial. The Phase 1/2a trial was conducted at 14 trial sites in the United States.

Sozinibercept was well tolerated up to the highest dose tested both in combination with ranibizumab and as a monotherapy. No dose-limiting toxicities, or DLTs, were observed and the maximum tolerated dose, or MTD, was not reached. There were no treatment-related serious adverse events, or SAEs. The most common TEAEs were conjunctival hemorrhage, eye pain and corneal inflammation mainly related to the intravitreal injection procedure. TEAEs did not lead to permanent discontinuation of the study for any patient. The pharmacokinetic profile of sozinibercept was similar in the absence or presence of ranibizumab, and there was no evidence of sozinibercept immunogenicity in this clinical trial.

Although the focus of this trial was safety, we also observed preliminary signals of clinical benefit. Improvements in visual acuity were observed in treatment-naive patients as well as patients previously treated with anti-VEGF-A therapy, as measured by the number of letters that could be read on a standard eye chart following sozinibercept monotherapy and sozinibercept combination therapy. As illustrated in the figure below, after 12 weeks, in patients across all dose groups, the mean change in visual acuity from baseline increased by +10.8 letters in treatment-naive patients and +4.9 letters in previously treated patients who received sozinibercept combination therapy.

Mean Change in Visual Acuity from Baseline to Week 12 in Treatment-Naive and Previously-Treated Wet AMD Patients Administered sozinibercept in Combination with Ranibizumab

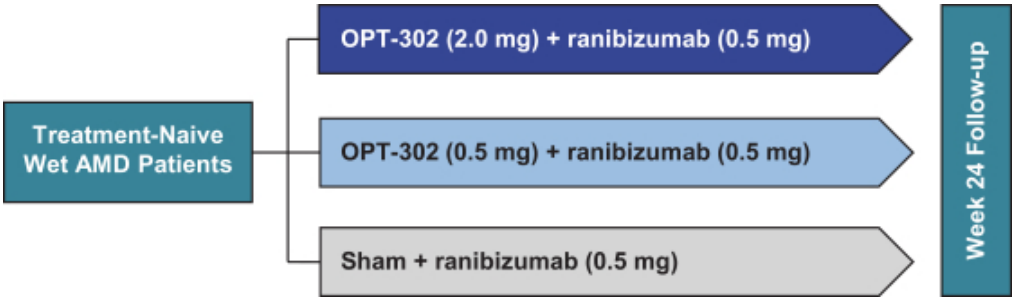


In addition, improvements in visual acuity following treatment with sozinibercept combination therapy were consistent with anatomical outcomes, such as reductions in intraretinal and subretinal fluid. Retinal thickness, which is assessed by spectral domain optical coherence tomography, or SD-OCT, using a standard criterion called central subfield thickness, or CST, was also reduced following sozinibercept combination therapy.

Phase 2b Clinical Trial Results in Wet AMD

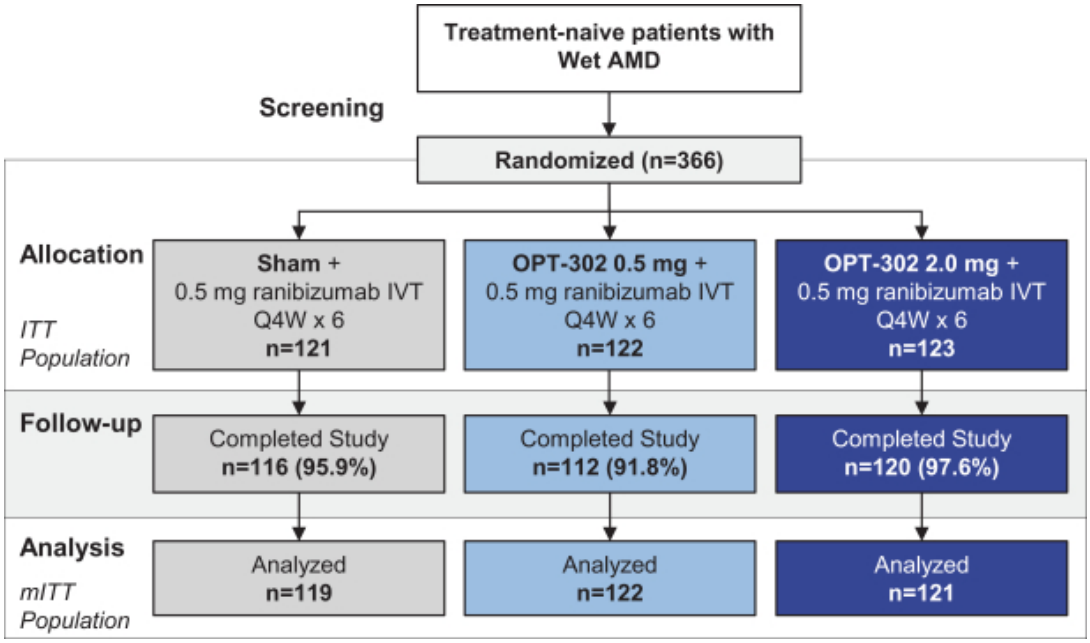
Based on the positive results of the Phase 1/2a trial, we completed an international, multi-center, double-masked Phase 2b clinical trial of sozinibercept in combination with ranibizumab in a total of 366 treatment-naive patients in 2019. As illustrated in the figure below, patients were randomized into three groups to receive either 0.5 mg or 2.0 mg sozinibercept with 0.5 mg ranibizumab or ranibizumab monotherapy, which included a sham injection. A sham intravitreal injection involves pressing a syringe hub against the surface of the eye to mimic an intravitreal injection so that the patient remains masked to the treatment group to which they have been randomized. Administration was by intravitreal injection once every four weeks for 20 weeks (six treatments in total). The primary endpoint of the clinical trial was the mean change in BCVA from baseline on the ETDRS standardized eye chart at week 24. Secondary outcome measures included the proportion of patients gaining ≥15 letters in BCVA, changes in retinal thickness, change in intraretinal and subretinal fluid and proportion of patients losing ≥15 letters in BCVA.

Design of the Phase 2b Clinical Trial of sozinibercept with Ranibizumab in Wet AMD



As illustrated in the figure below, 366 treatment-naive patients were randomized 1:1:1 to each of the three treatment groups. We used data from the 362 patients who had a baseline assessment of their visual acuity and completed at least one post-dose visit as the modified intent to treat population, or mITT, in all analyses. Key inclusion criteria for patients in the trial included CNV classified as either occult, minimally classic or predominantly classic, and BCVA on the ETDRS standardized eye chart of ≥25 and ≥60 letters. The Phase 2b trial was conducted at 109 trial sites in the United States, Europe, Israel and the United Kingdom.

Patient Distribution in the Phase 2b Clinical Trial in Wet AMD



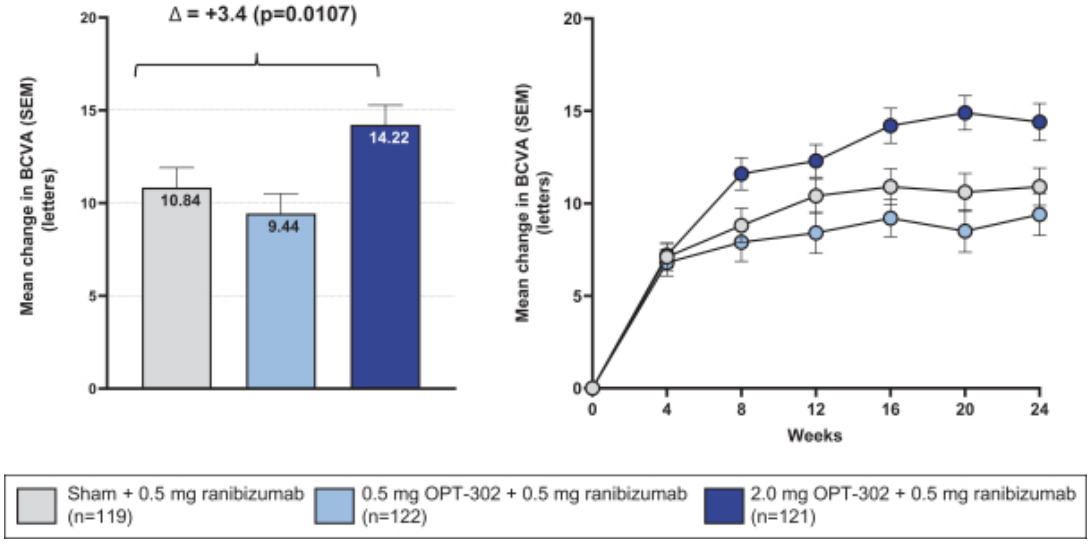
Q4W refers to administration every four weeks. IVT refers to administration by intravitreal injection.

In presentations of statistical results in this annual report, a p-value is a measure of statistical significance of the observed results, or the probability that the observed results were achieved purely by chance. By convention, a p-value of 0.05 or lower is commonly considered statistically significant. The FDA and comparable non-U.S. regulatory authorities utilize the reported statistical measures when evaluating the results of a clinical trial, including statistical significance as measured by p-value, to evaluate the reported evidence of a drug product's safety and efficacy.

Improvements in Visual Acuity

The Phase 2b clinical trial met the primary endpoint, demonstrating a statistically significant superior mean gain in visual acuity at week 24 compared to baseline in the 2.0 mg sozinibercept combination therapy group compared to the ranibizumab monotherapy group. The figure below illustrates patients in the 2.0 mg sozinibercept combination therapy group had a mean visual acuity improvement of +14.2 letters relative to baseline, compared to +10.8 letters for those treated with ranibizumab monotherapy at week 24 (p=0.0107). This represents a statistically significant benefit of +3.4 letters and a greater than 30% relative improvement in vision outcomes in the sozinibercept combination group compared to ranibizumab monotherapy. Evidence of improved visual acuity was observed beginning as early as week 8 and continued throughout the course of the trial to week 24. Mean visual acuity in the lower dose 0.5 mg sozinibercept combination therapy group was not significantly different from the ranibizumab monotherapy group. However, evidence of a dose response was observed between the 2.0 mg and 0.5 mg sozinibercept combination therapy groups on several anatomical outcomes, such as retinal thickness and the proportion of patients with intraretinal and subretinal fluid at week 24.

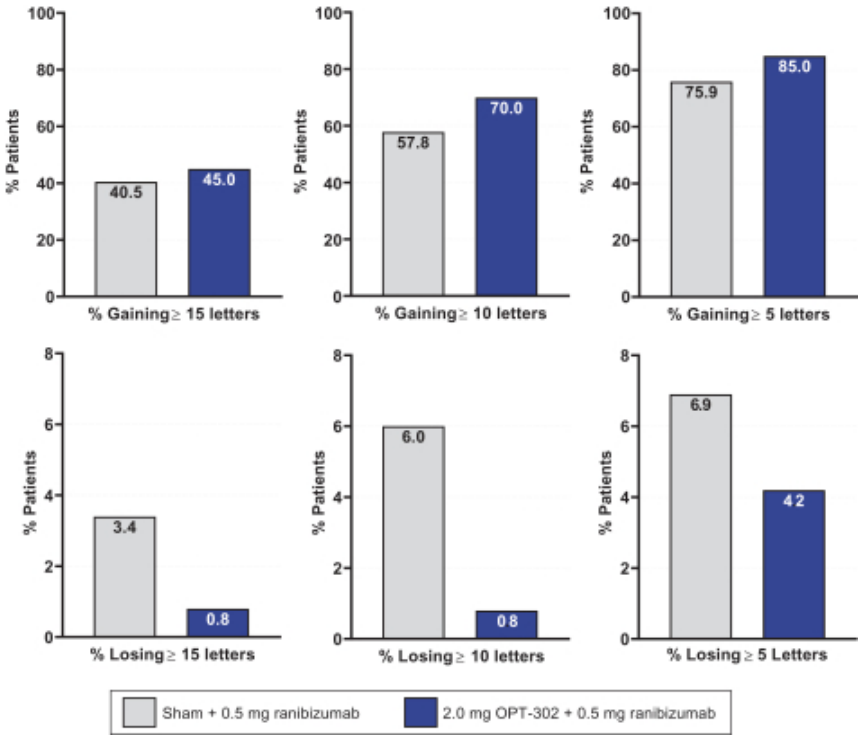
Mean Change in Visual Acuity from Baseline to Week 24 in Treatment-Naive Wet AMD Patients Administered Ranibizumab Monotherapy or Sozinibercept Combination Therapy



Error bars shown in all figures represent the SEM, or the standard error of the mean.

Secondary outcome measurements from the trial were also supportive of the primary endpoint. As illustrated in the figure below, we observed a greater proportion of patients gaining 15, 10 and 5 letters in the 2.0 mg sozinibercept combination therapy group compared to the ranibizumab monotherapy group. In addition, the proportion of patients losing 15, 10 and 5 letters was lower in the 2.0 mg sozinibercept combination therapy group compared to the ranibizumab monotherapy group. The Phase 2b trial was not designed for statistical significance on secondary and exploratory endpoints and was not powered to detect statistically significant differences in secondary outcome measurements.

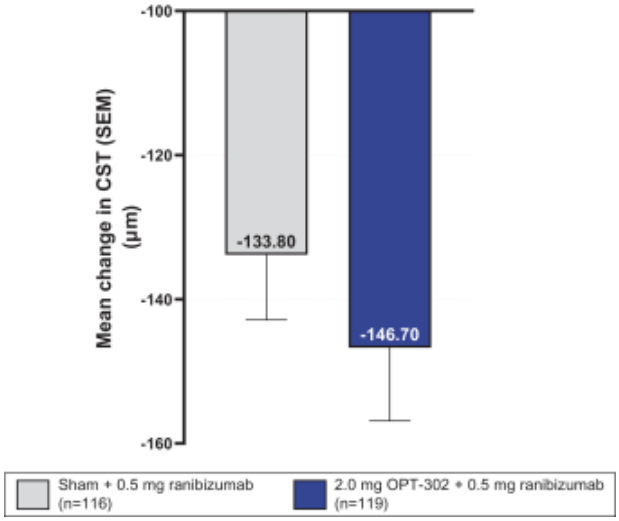
Greater Proportion of Patients Gaining, and Fewer Patients Losing, 15, 10 and 5 Letters with Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



Reductions in Retinal Thickness and Fluid

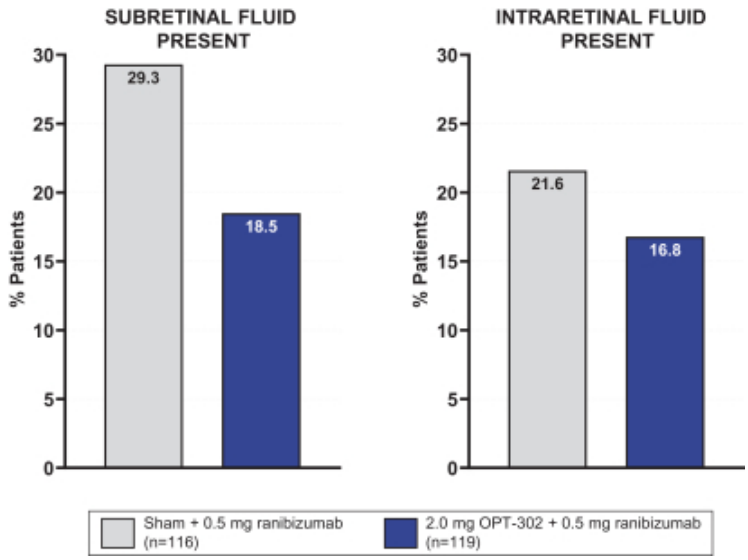
In addition to the statistically significant improvement in visual acuity, treatment with sozinibercept combination therapy led to greater reductions in retinal thickness. The reductions in retinal thickness in patients is consistent with less fluid accumulation in the retina and reduced disease severity as increased fluid accumulation in the retina is associated with the loss of visual acuity in wet AMD patients. The figure below depicts the greater mean reduction in retinal thickness in the sozinibercept combination therapy group compared to the ranibizumab monotherapy group at week 24.

Greater Reduction in Retinal Thickness from Baseline to Week 24 following Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



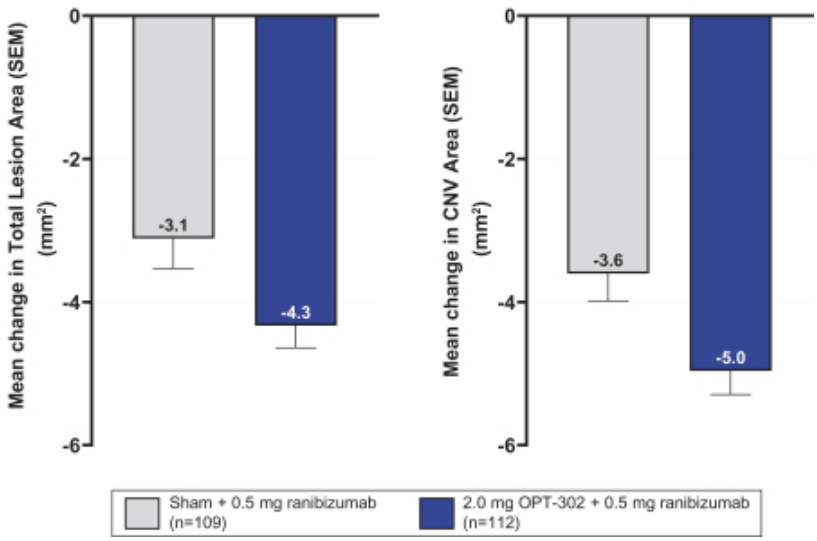
Fewer patients in the sozinibercept combination therapy group had subretinal fluid and intraretinal fluid present compared to the ranibizumab monotherapy group. The presence of subretinal fluid is a hallmark of wet AMD and its resolution is referred to as "drying" of the retina while intraretinal fluid is a prognostic biomarker for poor visual acuity and sub-optimal response to anti-VEGF-A therapies. As illustrated in the figure below, there were approximately 10% fewer patients with subretinal fluid and 5% fewer patients with intraretinal fluid following administration of sozinibercept combination therapy compared to ranibizumab monotherapy.

Fewer Patients with Subretinal and Intraretinal Fluid Present at Week 24 Following Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



Greater improvements in anatomical indicators of disease severity, including on exploratory endpoints of mean reduction in total lesion area and CNV area, were observed in the sozinibercept combination therapy group compared to ranibizumab monotherapy. As illustrated in the figure below, the patients treated with sozinibercept combination therapy had an approximately 39% further reduction in both total lesion area and CNV area compared to ranibizumab monotherapy.

Greater Reduction in Total Lesion Area and CNV Area from Baseline to Week 24 following Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



Improved Therapeutic Outcomes in Wet AMD Lesion Subtypes

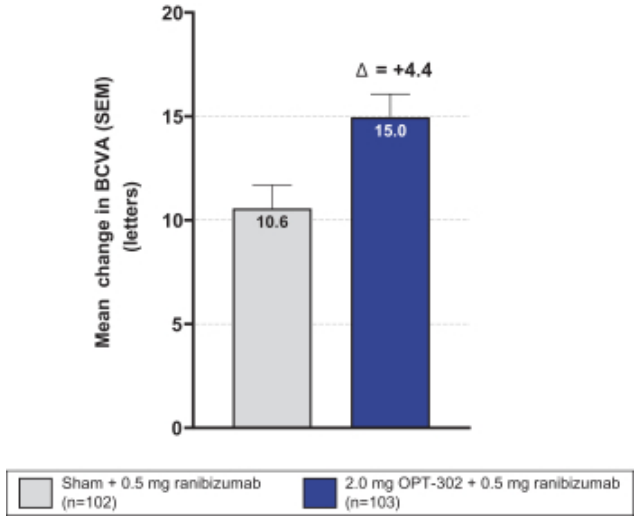
A number of pre-specified subgroup and exploratory analyses were incorporated into the Phase 2b trial design in order to identify those wet AMD patients who may respond best to sozinibercept. The Phase 2b trial randomized patients with a broad range of lesion morphologies including occult, minimally classic and predominantly classic lesions. In addition, the Phase 2b trial investigated efficacy in post-hoc analyses in other wet AMD subtypes, including PCV and RAP. This trial was not designed for statistical significance on these subgroup and exploratory analyses and was not powered to detect statistically significant differences in related measurements.

Patients enrolled in our Phase 2b trial consisted of 44% occult, 43% minimally classic and 13% predominantly classic lesion types, which is similar to the distribution reported in treatment-naive wet AMD patients. Predominantly classic patients typically respond well to VEGF-A inhibitor therapy and an additive benefit of sozinibercept combination therapy could not be discerned in this small patient group of only 15 patients per treatment arm. The majority of patients randomized in the Phase 2b trial had occult or minimally classic lesions. These patients did not respond as well to ranibizumab monotherapy as those with predominantly classic lesions. Patients with occult and minimally classic lesions treated with sozinibercept combination therapy experienced improvement in visual acuity beginning at week 8 and persisting through week 24 compared to ranibizumab monotherapy. The figure below illustrates the mean change in visual acuity over 24 weeks in each of the lesion classifications treated with sozinibercept combination therapy compared to ranibizumab monotherapy.

RAP and PCV Lesion Subtypes

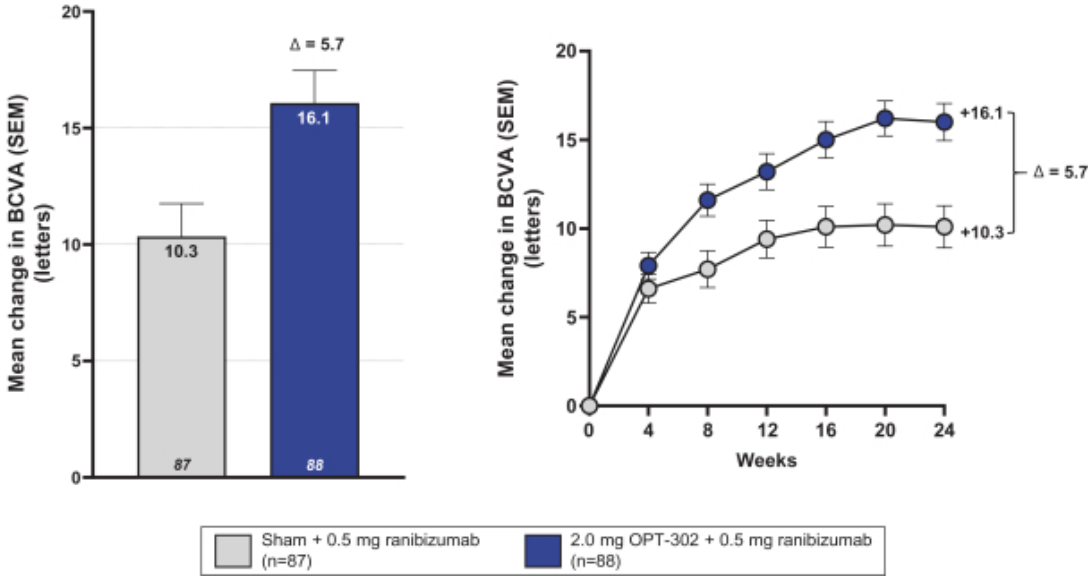
In our Phase 2b clinical trial, over 85% of patients enrolled did not have RAP lesions detected at randomization and these patients responded better to sozinibercept than patients with RAP lesions. In patients without RAP lesions, the mean visual acuity gain from baseline to week 24 was +15.0 letters (n=103) with sozinibercept combination therapy, compared to +10.6 letters for those treated with ranibizumab monotherapy (n=102), a benefit of +4.4 letters.

Mean Change in Visual Acuity from Baseline to Week 24 in Patients Without RAP Lesions Following Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



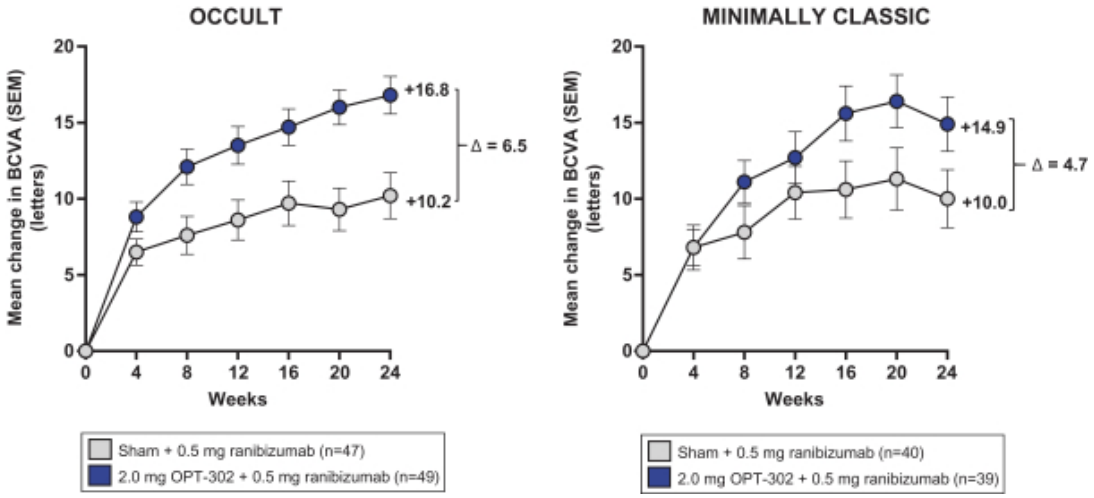
In patients without RAP lesions who had occult or minimally classic lesions, representing the majority of wet AMD patients, the mean visual acuity gain from baseline to week 24 was +16.1 letters with sozinibercept combination therapy (n=88) compared to +10.3 letters for those treated with ranibizumab monotherapy (n=87), a benefit of +5.7 letters (p=0.0002). This represents the patient population for which the primary analysis of the primary endpoint of the Phase 3 trials of sozinibercept combination therapy for the treatment of wet AMD will be first conducted, followed by analysis of the total patient population and the every eight week dosing groups.

Mean Change in Visual Acuity from Baseline to Week 24 in the combined group of RAP Absent Occult and Minimally Classic Lesions Following sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



Patients with RAP absent occult lesions demonstrated a mean visual acuity gain at week 24 of +16.8 letters with sozinibercept combination therapy (n=49) compared to +10.2 letters for those treated with ranibizumab monotherapy (n=47), a gain of +6.5 letters. Patients with RAP absent minimally classic lesions demonstrated a mean visual acuity gain at week 24 of +14.9 letters with sozinibercept combination therapy (n=39) compared to +10.0 letters for those treated with ranibizumab monotherapy (n=40), a gain of +4.7 letters.

Mean Change in Visual Acuity from Baseline to Week 24 in RAP Absent Occult and Minimally Classic Lesions Following Sozinibercept Combination Therapy Compared to Ranibizumab Monotherapy



Improved Therapeutic Outcomes of Sozinibercept in PCV Lesions

In patients with PCV lesions, the mean visual acuity gain from baseline to week 24 in the sozinibercept combination therapy group was +13.5 letters (n=22), compared to +6.9 letters in the ranibizumab monotherapy group (n=20). This equates to a benefit of +6.7 letters and is almost a two-fold improvement in visual acuity gain observed from baseline following sozinibercept combination therapy. Ranibizumab monotherapy was not observed to be as effective in patients with PCV compared to other wet AMD subtypes.

Safety and Tolerability

Sozinibercept was well tolerated in this Phase 2b trial with a very low incidence of ocular inflammation and no safety issues identified with the addition of sozinibercept to ranibizumab intravitreal therapy. The incidence of ocular TEAEs was similar in sozinibercept combination groups compared to the ranibizumab monotherapy group. TEAEs were considered potentially treatment related in approximately 15% of patients. The most common treatment-related TEAEs were eye pain, vitreous floaters, eye irritation and raised intraocular pressure. One patient discontinued from the trial due to a TEAE, which was not considered treatment related. Three patients treated with sozinibercept combination therapy had potentially treatment-related SAEs: one case each of vitritis, endophthalmitis and myocardial infarction.

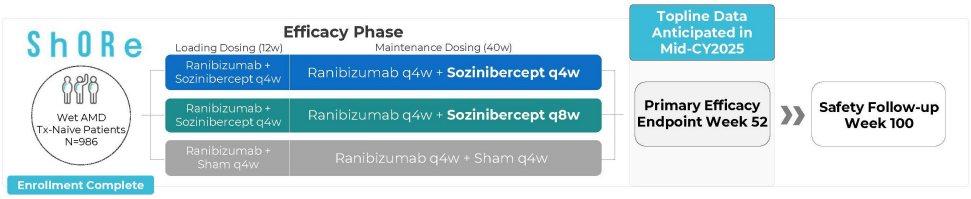
Pivotal Phase 3 Clinical Trials in Wet AMD

We initiated two concurrent pivotal Phase 3 clinical trials for the treatment of wet AMD. These double-masked, sham-controlled Phase 3 clinical trials enroll treatment-naive patients to assess the efficacy and safety of 2.0 mg sozinibercept in combination with anti-VEGF-A therapy for treatment-naive patients with wet AMD compared to a standard of care anti-VEGF-A monotherapy. In addition, each trial is comparing the clinical efficacy of sozinibercept, administered in combination with the applicable VEGF-A inhibitor on an every 4-week and every 8-week dosing regimen to understand the durability of sozinibercept treatment effect with less frequent dosing. The primary endpoint of both trials will be the mean change in visual acuity from baseline to week 52. Patients will continue to be dosed until week 96 to further assess long-term safety at week 100. Based on the completion of enrollment in COAST in February 2024 and ShORe in May 2024, the 52-week top-line data readout of COAST is anticipated early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025. Pending the results of the primary efficacy phase at week 52 of the Phase

3 clinical trials, we intend to submit Biologics License and Marketing Authorization Applications with the FDA and EMA respectively.

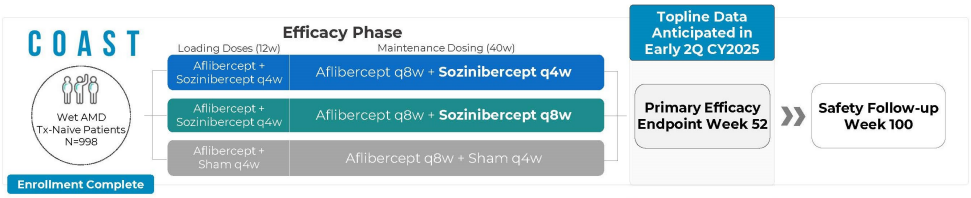
Study of Sozinibercept in Combination with Ranibizumab (ShORe) Phase 3 Trial

In the Study of sozinibercept in combination with Ranibizumab, or ShORe, Phase 3 trial, 986 treatment-naive patients with wet AMD were randomized to one of three treatment groups. Patients randomized to the standard dosing arm will receive standard of care 0.5 mg ranibizumab every four weeks in combination with 2.0 mg sozinibercept on a standard every four weeks dosing regimen. In the extended dosing arm, 0.5 mg ranibizumab is administered every four weeks to week 52, in combination with 2.0 mg sozinibercept administered every four weeks for three total doses over 12 weeks, followed by sozinibercept dosing every eight weeks to week 52, with a sham injection administered at visits where sozinibercept is not administered. Patients randomized to the control arm receive 0.5 mg ranibizumab administered in combination with sham intravitreal injections administered every four weeks to week 52. The primary and secondary efficacy outcomes are determined at the end of the efficacy phase at week 52. Each patient continues to be treated for an additional year in the safety phase to reach week 100 to evaluate safety and tolerability over a total two-year period.



Combination of Sozinibercept with Aflibercept STudy (COAST) Phase 3 Trial

In the Combination Sozinibercept with Aflibercept STudy, or COAST, Phase 3 trial, 998 treatment-naive wet AMD patients were randomized to one of three treatment groups. Patients randomized to the standard dosing arm receive 2.0 mg aflibercept administered every four weeks for three total doses over 12 weeks, followed by aflibercept dosing every eight weeks to week 52, in combination with 2.0 mg sozinibercept administered every four weeks to week 52. In the extended dosing arm, 2.0 mg aflibercept in combination with 2.0 mg sozinibercept is administered every four weeks for three total doses over 12 weeks, followed by dosing every eight weeks to week 52, with a sham injection administered at visits where sozinibercept and aflibercept are not administered. Patients randomized to the control arm, will receive 2.0 mg aflibercept administered every four weeks for three total doses over 12 weeks, followed by dosing every eight weeks to week 52, in combination with sham intravitreal injections administered every four weeks to week 52. Similar to ShORe, the primary and secondary efficacy outcomes of COAST are assessed at the end of the efficacy phase at week 52. Each patient continues to be treated for an additional year in the safety phase to reach week 100 to evaluate the safety and tolerability over a total two-year period.



For consistency, the ShORe and COAST Phase 3 trials build upon and maintain key features of our Phase 2b clinical trial of sozinibercept combination therapy for the treatment of wet AMD, while evaluating the administration of sozinibercept combination therapy over a longer treatment period and in a greater number of patients. In addition, the results of our Phase 2b clinical trial has informed the design of the Phase 3 trials. Analysis of the Phase 2b trial demonstrated that sozinibercept combination therapy increased visual acuity by a further +5.7 letters over ranibizumab monotherapy in wet AMD patients with RAP absent minimally classic and occult lesions, representing the majority of wet AMD patients. Based on these positive data, patients with RAP lesions are not eligible for randomization into COAST and ShORe and primary analysis of the primary endpoint of the Phase 3 trials will be first conducted in patients with minimally classic and occult lesions administered sozinibercept every four weeks and every eight weeks, followed by analysis on the total patient population.

Development of Co-Formulation

Sozinibercept is currently administered as a combination therapy consisting of a sequential injection of sozinibercept following intravitreal administration of a VEGF-A inhibitor. We plan to develop a co-formulation of sozinibercept with an approved and/or biosimilar anti-VEGF-A therapy to achieve VEGF-A, VEGF-C and VEGF-D inhibition following the administration of a single intravitreal injection of the co-formulated product. We believe that a co-formulated sozinibercept and VEGF-A inhibitor product could provide a treatment option for physicians to reduce the frequency and number of injections for patients.

We are currently assessing the feasibility of co-formulating sozinibercept with anti-VEGF-A therapy and intend to advance a co-formulated product through non-clinical studies, including IND-enabling safety and tolerability studies. We intend to file an IND for the co-formulated product prior to the initiation of clinical trials.

Diabetic Macular Edema

Diabetic macular edema is a complication of DR, a disease affecting the blood vessels of the retina in diabetics. Chronically elevated blood glucose levels, or hyperglycemia, causes damage to the small blood vessels or capillaries in the retina in patients with diabetes. The consequent chronic decrease in oxygen supply to retinal cells results in tissue damage that is referred to as DR. Approximately one-third of patients with DR or up to 10% of diabetics develop DME, which is characterized by accumulation of fluid and retinal thickening within the macula and is responsible for most of the central visual loss experienced in the diabetic population. Central-involved DME is diagnosed when swelling or edema occurs from fluid leaking into the central fovea region of the macula.

Current Treatments for DME and Their Limitations

VEGF-A inhibitor therapy is the first-line standard of care therapy for DME. Ranibizumab, aflibercept and faricimab are approved for the treatment of DME, and similarly to wet AMD, many patients receive bevacizumab as an off-label, lower cost alternative VEGF-A inhibitor therapy. Many patients with central-involved DME require near-monthly administration of intravitreal VEGF-A inhibitors during the first 12 months of treatment, with fewer injections needed in subsequent years to maintain clinical benefit. VEGF-A inhibitors have largely replaced the use of laser photocoagulation as a treatment for DME.

The anti-inflammatory corticosteroid implant therapies dexamethasone (Ozurdex®) and fluocinolone acetonide (Illuvien®) are also approved for use in central-involved DME. These agents, however, are rarely used as first-line therapy due to inferior visual acuity outcomes compared to anti-VEGF-A therapy. Patients with persistent DME and who are insufficiently responsive to anti-VEGF-A therapy have shown some treatment benefit with intravitreal corticosteroids. However, as intravitreal corticosteroids are associated with high rates of ocular adverse events including cataract progression and intraocular pressure elevation, switching to corticosteroids from an anti-VEGF-A therapy with a sub-optimal response needs to be carefully considered.

Despite the widespread use of treatments targeting VEGF-A in the management of DME, there is still a significant unmet need as many patients demonstrate a sub-optimal response, remain treatment refractory or require frequent injections for persistent leakage in the macula. Up to two-thirds of patients with central-involved DME treated with VEGF-A inhibitors do not show reductions in the fluid or clinically meaningful improvement in visual acuity. In addition, approximately 25% of DME patients treated with VEGF-A inhibitors continue to have macula thickening and swelling following treatment. This resistance may occur as treatment selective anti-VEGF-A monotherapies do not fully address all of the factors involved in the pathogenesis of DME. As such, combination therapies targeting alternative factors and pathways have the potential for improved clinical outcomes in DME patients.

Market Opportunity for the Treatment of DME

It is estimated that between 1.3 million and 2.0 million people worldwide, including 14% of Type 1 diabetics and 6% of Type 2 diabetics, have DME. The risk of developing DME increases with time. According to the Wisconsin Epidemiologic Study of Diabetic Retinopathy, after 10 years of follow-up, 20% of patients with Type 1 diabetes and 25% of those with Type 2 diabetes will have developed DME. Ranibizumab and aflibercept, two VEGF-A inhibitors approved for the treatment of DME, generated combined annual worldwide sales approaching US$13 billion in 2022. Historically, approximately 20% of these sales are attributable to the treatment of DME.

Potential for sozinibercept in DME

We believe that as a potent inhibitor of VEGF-C and VEGF-D, sozinibercept has the potential to provide significant therapeutic benefit to patients affected by DME. Although the underlying causes of wet AMD and DME differ, members of the VEGF family play a role in the progression of both diseases. VEGF-C and VEGF-D and their receptors are specifically implicated in the progression of diabetes. For example, patients with diabetes have higher levels of VEGF-C and VEGF-A and increased expression of both VEGFR-2 and VEGFR-3 in the retina compared to non-diabetics. The VEGF-A inhibitors ranibizumab and aflibercept, originally approved for treatment of wet AMD patients, have also been approved for treatment of DME patients. Similar to wet AMD, bevacizumab is also frequently used off-label as a treatment for DME. Faricimab was approved in 2022 for wet AMD and DME.

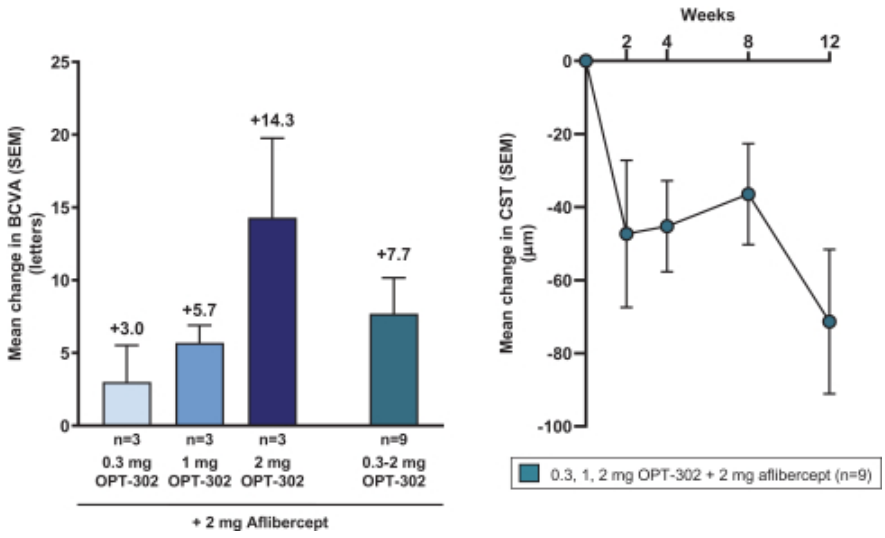
In our completed Phase 1b dose escalation clinical trial in patients with persistent DME, we observed what we believe to be promising evidence of a dose response of sozinibercept in combination with aflibercept, including further improvements in visual acuity despite patients' having been previously treated with anti-VEGF-A therapy. In our completed Phase 2a clinical trial, we observed improved visual acuity outcomes and evidence of a reduction in retinal thickness in treatment-refractory DME patients following sozinibercept combination therapy.

Phase 1b Clinical Trial of sozinibercept in DME

In 2018, we completed a Phase 1b dose-escalation clinical trial of sozinibercept in combination with aflibercept in nine patients with persistent DME that were previously treated with anti-VEGF-A therapies. Patients were administered three escalating doses (0.3 mg, 1.0 mg or 2.0 mg) of sozinibercept in combination with 2.0 mg aflibercept by intravitreal injections once every four weeks for a total of three doses. The primary analysis was conducted at week 12, four weeks after the final dose.

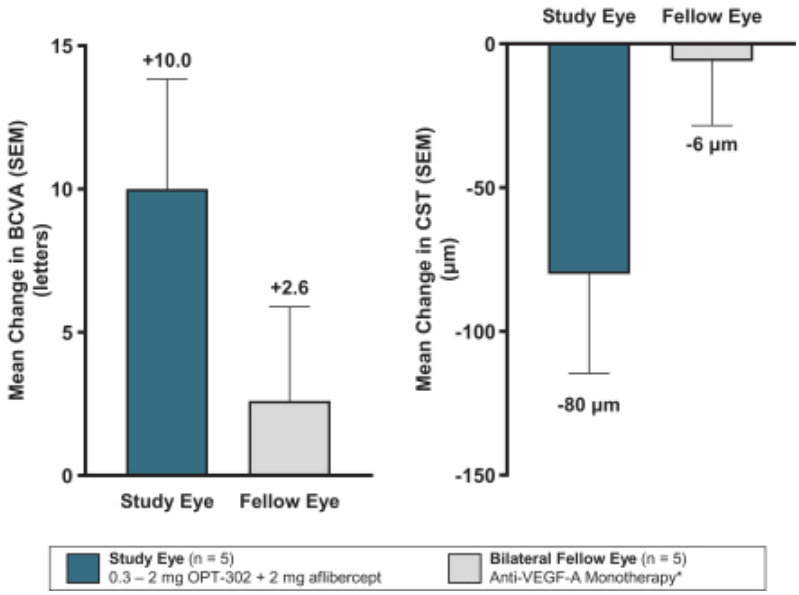
Across all nine patients in the Phase 1b trial, a mean gain in visual acuity of +7.7 letters from baseline to week 12 was observed across all dose groups, with a clear dose response of improved visual acuity with increasing doses of sozinibercept. There was a corresponding mean decrease in retinal thickness at week 12 of -71 µm from baseline and six of nine (67%) patients had a 50% reduction in excess foveal thickness.

Dose-dependent Increases in Visual Acuity and Reduction in Retinal Thickness at Week 12 Following Treatment with Sozinibercept in Combination with Aflibercept



Five of the nine patients in the Phase 1b trial had bilateral, persistent treatment-refractory DME. In these patients, study eyes received sozinibercept in combination with aflibercept, and fellow eyes received standard of care anti-VEGF-A monotherapy. In these bilateral disease patients, the mean change in visual acuity from baseline to week 12 was +10.0 letters in the study eye and +2.6 letters in the fellow eye. The corresponding reduction in retinal thickness from baseline to week 12 was -80 µm for sozinibercept combination treated study eyes, compared to -6 µm in fellow eyes that received anti-VEGF-A monotherapy.

In Patients with Bilateral DME, Sozinibercept Combination Therapy Improved Visual Acuity and Reduced Retinal Thickness Compared to Fellow Eyes Treated with Anti-VEGF-A Monotherapy



* Patients with bilateral disease and persistent DME in the fellow eye receiving anti-VEGF-A (ranibizumab or aflibercept) monotherapy. Prior anti-VEGF-A therapy in Fellow Eyes BL to Week 12 (5 patients): 3x Aflibercept, 3x Ranibizumab, 1x Ranibizumab, 4x Ranibizumab, 3x Aflibercept.

Sozinibercept in combination with aflibercept was well tolerated at all dose levels, with no DLTs and the MTD was not reached. There were no treatment-related clinically significant changes in intraocular pressure, electrocardiograms or vital signs. The most common AEs were related to the intravitreal injection procedure.

Phase 2a Clinical Trial of Sozinibercept in DME

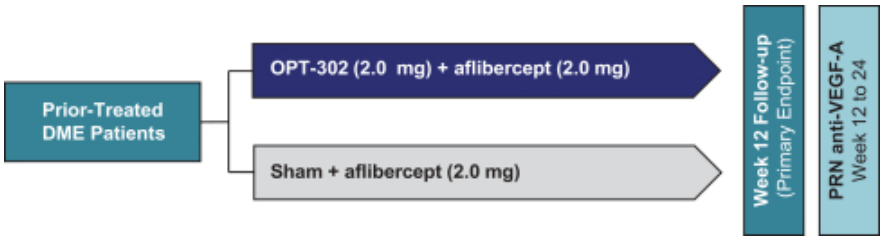
Based on the positive results of our Phase 1b trial, we reported outcomes from a Phase 2a trial in persistent DME patients refractory to anti-VEGF-A therapy in June 2020. Similar to the Phase 1b trial, this proof-of-concept trial was designed to investigate the ability of sozinibercept to improve outcomes in persistent DME patients. The primary endpoints were clinical response rate in visual acuity as well as safety and tolerability.

Clinical Trial Design

This Phase 2a trial was a randomized, double-masked, dose expansion trial that enrolled patients diagnosed with persistent center-involved DME despite regular administration of prior anti-VEGF-A monotherapy. These patients are considered to be a difficult-to-treat patient population since they have received prior anti-VEGF-A therapy and experienced a suboptimal clinical response. In our trial, these patients were defined as having visual acuity between 20/40 and 20/320 Snellen equivalent, or 73 and 24 BCVA letters on the ETDRS standardized eye chart, and retinal thickness of 320 µm on SD-OCT. In this Phase 2a trial, the mean number of prior intravitreal anti-VEGF-A injections was eight in each of the treatment groups, reflecting that the patients recruited into this trial were heavily pre-treated, with a mean of 39 days since the immediate prior injection to the start of the trial.

The Phase 2a trial was conducted at 53 trial sites in the United States, Israel, Australia and Latvia. Of the 144 patients randomized in the trial, 115 patients conformed sufficiently with the trial protocol and were included in our analyses of clinical efficacy. Patients were randomized 2:1 to receive either 2.0 mg sozinibercept in combination with 2.0 mg aflibercept or a sham injection and 2.0 mg aflibercept. Patients received intravitreal injections once every four weeks for a total of three doses. The primary analysis was conducted at week 12, four weeks after the final dose.

Design of the Phase 2a Clinical Trial of Sozinibercept in Combination with Aflibercept in Persistent Diabetic Macular Edema



PRN refers to *pro re nata*, or treatment on an as needed basis.

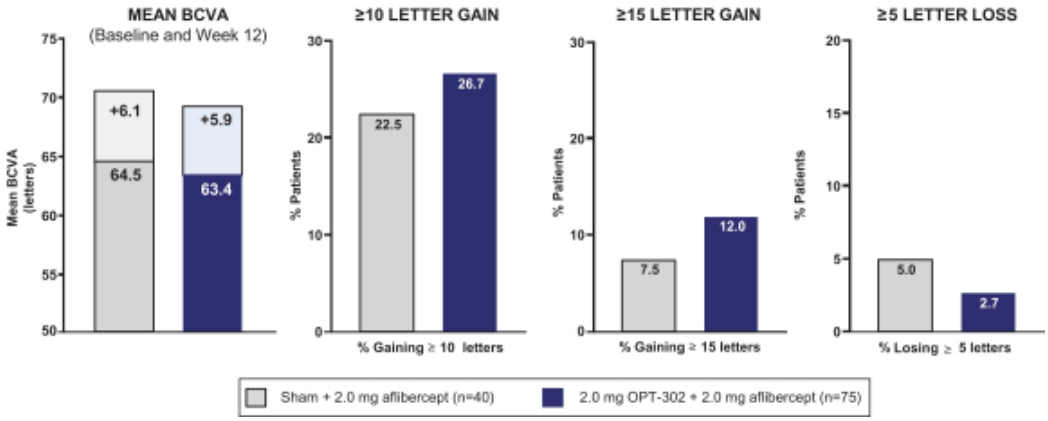
Improvements in Visual Acuity

The primary efficacy endpoint of the trial was the clinical response rate, defined as the proportion of patients receiving sozinibercept combination therapy that achieved a 5 letter gain in visual acuity at week 12 compared to baseline. Our predefined measure of success was a response rate of greater than or equal to 38%, based on historical observations that show limited ability to achieve a 5 letter improvement in DME patients on long-term anti-VEGF-A monotherapy. As an exploratory trial, this Phase 2a was not powered to detect statistical significance of sozinibercept combination therapy compared to aflibercept monotherapy.

We observed that 52.8% of patients treated with sozinibercept combination therapy achieved a 5 letter improvement in visual acuity at week 12 compared to baseline, meeting the pre-specified primary efficacy endpoint for this trial.

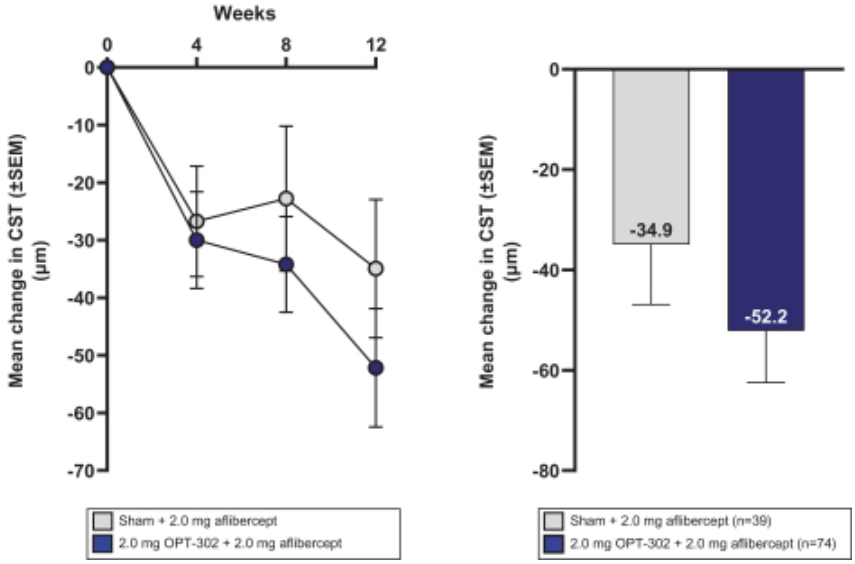
The mean change in visual acuity at week 12 compared to baseline was +5.9 letters in patients receiving sozinibercept combination therapy and +6.1 letters in the aflibercept monotherapy group. In the sozinibercept combination therapy group, the percentage of patients with visual acuity gains of 10 and 15 letters was higher, and the percentage of patients who lost 5 letters was lower than that in the aflibercept monotherapy group. These measures of visual function are shown in the figure below.

Measures of Visual Acuity at Week 12 Following sozinibercept Combination Therapy and Aflibercept Monotherapy



Patients treated with sozinibercept combination therapy also had decreased retinal thickness compared to aflibercept monotherapy, as shown in the figure below.

Greater Reduction in Retinal Thickness from Baseline to Week 12 Following Sozinibercept Combination Therapy Compared to Aflibercept Monotherapy



Prior Treatment History in Persistent DME Patients

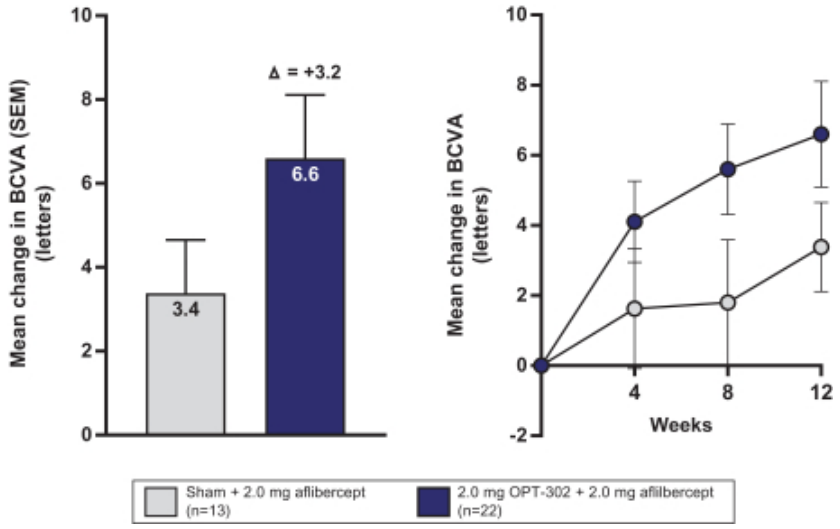
Prior trials have shown that DME patients with mild visual acuity loss of 20/40 or better at baseline, show similar outcomes to any of the VEGF-A therapies: ranibizumab, aflibercept and bevacizumab. However, in patients with poorer baseline vision of 20/50 or worse, aflibercept has better outcomes compared to ranibizumab and bevacizumab over the first 12 months of treatment. It has also been shown that DME patients who experience inadequate responses to ranibizumab have achieved further anatomical and functional improvements upon switching to aflibercept.

Due to the challenge of enrolling a large group of patients with identical prior treatment histories, we designed our Phase 2a trial to accelerate enrollment by randomizing patients with variable prior treatment histories. This strategy allowed us to more broadly understand the prior treatment history in persistent DME patients, which will inform the design of our future trials in DME.

In order to explore the importance of differences in prior treatment history, we collected detailed anti-VEGF-A treatment histories for patients enrolled in our Phase 2a DME trial. Patients randomized into our Phase 2a trial had variable prior treatment histories which included infrequent or irregular dosing and/or therapy with aflibercept, ranibizumab and bevacizumab. Approximately one third of patients had a prior treatment history of having received only aflibercept, or aflibercept for their three anti-VEGF-A treatments immediately before trial enrollment. Approximately 11% of patients had a prior treatment history of having received only ranibizumab, or ranibizumab for their three anti-VEGF-A treatments immediately before trial enrolment, whereas approximately 44% of patients had received only bevacizumab prior to trial enrollment. Patients with a prior treatment history of bevacizumab were required to receive at least one injection of either aflibercept or ranibizumab immediately prior to randomization into the trial. Post-hoc analyses of the results from our Phase 2a trial suggest that some patients may have benefited from the increased efficacy of aflibercept and/or from the switch to aflibercept therapy as administered in our trial on an every four-week dosing cycle. In the subset of patients who had only received aflibercept, or received aflibercept for their three anti-VEGF-A treatments immediately before trial enrollment, referred to as treatment history of prior aflibercept, the mean improvement in visual acuity observed for the aflibercept monotherapy group was +3.4 letters (n=13), compared to a mean improvement of +7.4 letters for those patients with more variable prior treatment history who received aflibercept monotherapy (n=27) following randomization into the trial. This suggests that the majority of patients enrolled in the trial had not achieved a maximal response to all anti-VEGF-A therapies prior to enrolling in the trial.

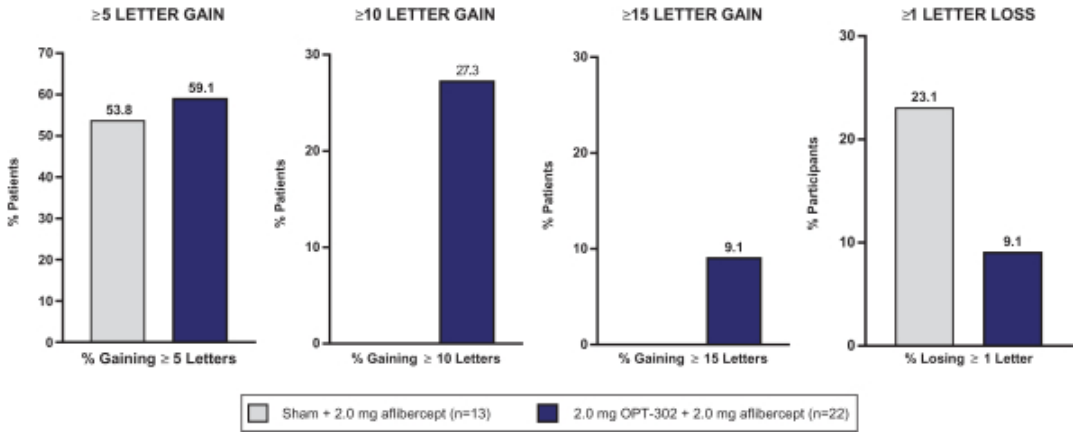
Due to the observed increase in treatment benefit for patients with a variable treatment history who then received aflibercept every four weeks in the trial, the subset of patients with a treatment history of prior aflibercept may represent the most stringent and least variable patient population in which to test the ability of sozinibercept to provide additional benefit. In this more homogeneous patient population, as shown in the figure below, patients administered sozinibercept combination therapy demonstrated a mean improvement in visual acuity of +6.6 letters (n=22) from baseline to week 12, compared to +3.4 letters (n=13) in the aflibercept monotherapy group.

Greater Gains in Visual Acuity following Sozinibercept Combination Therapy in Patients with a Treatment History of Prior Aflibercept



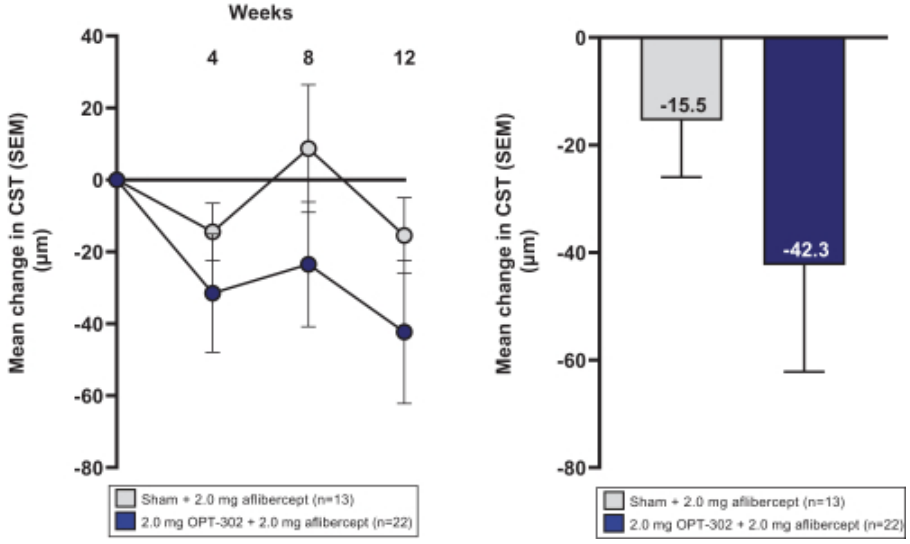
In addition, 27.3% of patients gained 10 letters and 9.1% gained 15 letters of visual acuity from baseline to week 12 following sozinibercept combination therapy. There were no patients with a treatment history of prior aflibercept that gained 10 letters of visual acuity in the aflibercept monotherapy group. Furthermore, the proportion of patients who lost 1 letters was 9.1% in the sozinibercept combination therapy group and 23.1% in the aflibercept monotherapy group. We believe that these results, as shown in the figures below, strongly support the potential of sozinibercept to improve the visual acuity in patients with persistent DME despite prior treatment with anti-VEGF-A monotherapy.

Proportion of Patients with a Treatment History of Prior Aflibercept Who Gained and Lost Visual Acuity from Baseline to Week 12



In this subgroup of patients with a treatment history of prior aflibercept, anatomical changes were consistent with functional visual acuity outcomes. As shown in the figure below, a greater mean reduction in retinal thickness was observed in the sozinibercept combination therapy group compared to the aflibercept monotherapy group at week 12. In particular, 22.7% of patients in the sozinibercept combination therapy group experienced at least a 300 µm reduction in retinal thickness at week 12, compared to 7.7% of patients in the aflibercept monotherapy group.

Greater Mean Reduction in Retinal Thickness following Sozinibercept Combination Therapy in Patients with a Treatment History of Prior Aflibercept



Safety and Tolerability

Sozinibercept combination therapy was well tolerated. There was one potentially treatment-related SAE of cerebrovascular accident, or stroke, resulting in one patient discontinuing treatment and withdrawing from the trial. The most common TEAEs were conjunctival hemorrhage and increased intraocular pressure and were mainly related to the intravitreal injection procedure. TEAEs did not lead to discontinuation of the trial for any patient. The incidence of intra-ocular inflammation was low, occurring in one patient for each treatment group, and the observed events were manageable and able to be resolved.

We now have extensive global clinical dosing experience demonstrating a favorable tolerability profile following repeated intravitreal administration of sozinibercept in 399 patients, with over 1,800 doses of sozinibercept administered across three completed international clinical trials in two disease indications and in combination with the two leading standard of care anti-VEGF-A therapies, ranibizumab and aflibercept. In particular, across our clinical trials, the incidence of intra-ocular inflammation was similar across all treatment groups. In addition, we continue to collect safety and tolerability information from our ongoing Phase 3 clinical trials with sozinibercept.

Retinal Vein Occlusion

Based on the positive clinical data from our clinical trials of sozinibercept in wet AMD and DME, we intend to prioritize future development in these two indications while exploring potential opportunities to develop sozinibercept in other ophthalmic indications such as RVO, DR and other diseases involving aberrant CNV.

RVO is a sight-threatening visual disorder resulting from blockage of one of the veins carrying blood out of the retina. This blocked vein can leak blood and fluid resulting in swelling that can cause macular edema. Persistent, inadequately-treated macular edema associated with RVO can blur vision, cause significant loss in visual acuity and eventually lead to blindness. Macular edema is the most common cause of vision loss in people who suffer from RVO.

Similar to wet AMD and DME, the first-line standard of care to treat macular edema associated with RVO is intravitreal anti-VEGF-A monotherapy. VEGF-A inhibitors however, are only effective in significantly improving vision in approximately 30% to 40% of patients with macular edema associated with RVO above sham control. The prevalence of RVO in people over the age of 50 has been reported to be 0.7%, or approximately 1.8 million people in the United States and Europe. Over 500,000 individuals in the United States and Europe have macular edema associated with RVO. We believe that sozinibercept has the potential to bring therapeutic benefit to patients suffering from macular edema secondary to RVO.

Competition

The biotechnology and pharmaceutical industries, and the ophthalmic disease subsector, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and a strong emphasis on intellectual property. While we believe that sozinibercept and our knowledge and experience provide us with certain competitive advantages, we face substantial potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical studies, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing our product candidates.

We are developing sozinibercept for the treatment of wet AMD and additional retinal disease indications, such as DME and RVO, together with certain combination agents. Companies that have products that may compete with sozinibercept include Roche Group, Regeneron Pharmaceuticals, Inc. and Novartis AG, which have marketed anti-VEGF-A therapies including ranibizumab (Lucentis) and aflibercept (Eylea), each a standard of care treatment for wet AMD, and brolucizumab (Beovu). Faricimab (Vabysmo) is approved for wet AMD and DME. A higher dose version (8 mg) of aflibercept(Eylea HD) was recently approved that allow some patients less frequent dosing. Companies with products in development for the treatment of wet AMD and DME - include 4D Molecular Therapeutics Inc, RevOpsis Therapeutics, Ocugen, Inc., Ocular Therapeutix, Inc., EyePoint Pharmaceuticals, Inc., Clearside Biomedical, Inc., and Outlook Therapeutics, Inc. We are also aware of other companies that are working on therapies for the whole eye, including Santen, Inc. and Ocular Therapeutix, Inc. In addition, bevacizumab (Avastin), marketed by Genentech, Inc., is used off-label to treat wet AMD.

It is possible that our competitors will succeed in developing technologies that are more effective than our product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar or interchangeable products for our product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other retinal therapies continue to accelerate, particularly once ranibizumab and aflibercept approach loss of exclusivity. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products or our product candidates.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance the development of sozinibercept and any other product candidates;
- license additional technology;
- complete clinical trials which position our products for regulatory and commercial success;

- maintain a proprietary position in our products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- establish efficient manufacturing processes and supply chain;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to our business, including the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

Our Commercial License Arrangement with Selexis SA

In October 2013, we entered into a commercial license agreement, or the Selexis Agreement, with Selexis SA, or Selexis, under which Selexis granted us a non-exclusive, worldwide, sublicensable license under certain patents, know-how and other intellectual property controlled by Selexis to use certain cell lines, deliverables and materials provide by Selexis to manufacture sozinibercept and related products and to use, sale and otherwise exploit such products.

We paid Selexis a nominal upfront payment upon entering into the Selexis Agreement. We are also required to make certain payments under the Selexis Agreement totaling approximately US$1.3 million upon the achievement of certain development and commercial milestones. We are also obligated to pay a low single-digit running royalty on worldwide net sales of the licensed products. Our royalty obligations will continue, on a product-by-product and country-by-country basis, until the expiration of the relevant patents, but will not extend beyond October 2024 in any event. After the expiration of the royalty term, our license will continue and become full paid, perpetual and irrevocable.

The Selexis Agreement will expire on the date of expiration of the last-to-expire of the license patents. Either party may terminate the Selexis Agreement for the other party's uncured material breach or bankruptcy. We may also terminate the Selexis Agreement at any time upon prior notice to Selexis.

Intellectual Property

As of June 30, 2024, we have rights to 15 issued U.S. patents, five U.S. patent applications, 66 issued non-U.S. patents and four pending non-U.S. applications. Our current issued patents and patent applications began expiring in September 2022 all are projected to expire between March 2025 and November 2034 although our most recent PCT and Taiwanese applications, do not expire until September 2043. National phase entry of our pending PCT application is due by 1 March 2025.

With respect to soluble forms of VEGFR-3, we own and have licensed rights to patent families including issued patents in the United States and Europe (Switzerland, France, Germany and the UK), which began expiring in 2022 and are expected to continue expiring until 2031. These patents cover composition of matter and/or method of use claims, including claims directed at the treatment of eye diseases associated with abnormal blood vessel growth, such as wet AMD.

With respect to sozinibercept, we own a patent family with three issued U.S. patents, an issued European patent validated in 38 countries and non-U.S. patents granted in Australia, Brazil, Canada, China, Colombia, Indonesia, Israel, India, South Korea, Mexico, Malaysia (2), New Zealand, Russia, Singapore and South Africa. Patent applications are pending in the United States and in Europe and Philippines. The three issued U.S. patents have claims covering the composition of matter of sozinibercept and its uses in treating ocular disorders and/or

nucleic acids, vectors, and host cells for producing it. These issued patents and pending patent applications, if issued, are expected to expire in 2034, not including any patent term extension.

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. The information in the above list is based on our current assessment of patents that we own or control or have exclusively licensed. The information is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside the United States. We expect that litigation will likely be necessary to determine the term, validity, enforceability and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated.

Patents expire, on a country by country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term adjustment, patent term extension and supplemental protection certificates and requirements for terminal disclaimers. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application or its foreign equivalent in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. In the United States, a patent may also be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process in the US. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, with extended rights limited to the approved product, its approved uses, and/or its manufacture.

Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes or obtain patents from pending patent applications. In the event of patent issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our partners. Our current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we have or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in USPTO *inter partes* review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality and invention assignment agreements with its commercial partners, collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant it ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter its development or commercial strategies for our product candidates or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that it may require to develop or commercialize its future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

As of June 30, 2023, we or our subsidiaries have registered and own "Opthea" as a trademark in ten jurisdictions, including the United States and Europe. Other than the registered trademark listed above, we currently rely on our unregistered trademarks, trade names and service marks, as well as our domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in non-U.S. countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record-keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of sozinibercept or any future product candidate.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market regulations may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates and any future biological product candidates we develop must be approved by the FDA through a biologics license application, or BLA, process before they may be legally marketed in the United States. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The FDA review and approval process generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and contain an Investigator's Brochure that must be updated annually or when significant changes are made;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials; satisfactory completion of an FDA advisory committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current good manufacturing practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCP; and

- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for specific indications supported by the data from clinical trials that support use in specific indications in the United States.

Nonclinical Trials and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. For new indications, a separate new IND may be required. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical study results to public registries. For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 trials may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission, Review and Approval

Assuming successful completion of the clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing (a 60-day process), or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process can be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as Priority Review, Fast-Track, Breakthrough Therapy and Accelerated Approval.

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review). In July 2021, sozinibercept was granted Fast-Track Designation by the FDA for the treatment of wet AMD.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. The benefits of breakthrough therapy designation include the same benefits as Fast-Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review and approval will not be shortened. Furthermore, priority review, Fast-Track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review or approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee. A designated orphan product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or

other safety information about the product, or complete withdrawal of the product from the market or product recalls;

- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or Affordable Care Act signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, transparency and price reporting laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA and similar state laws, each as amended, as applicable. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and transparency laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback statute is violated. Violations of the Anti-Kickback Statute can result in significant civil and criminal fines and penalties for each violation, imprisonment, and exclusion from federal healthcare programs. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or the FCA, as discussed below.

The federal false claims laws, including the FCA, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that create, maintain, transmit, receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include (doctors, dentists, optometrists, podiatrists and chiropractors) certain other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. Certain state and local laws also require the registration of pharmaceutical sales representatives. We may be subject to state and foreign laws governing the privacy and security of health information, some of which may be more stringent than those in the United States (such as the GDPR, which was adopted by the EU and subsequently became effective in May 2018). These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to

pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Canada or the EU, we may be subject to additional regulation.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect its ability to operate our business and results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage, Pricing and Reimbursement in the U.S.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, which decide which therapeutics they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

We may develop products that, once approved, may be administered by a physician. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act among other things contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws.

Since its enactment, there have been executive, legal and political challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Cuts and Jobs Act, or TCJA, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to

judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect until 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the HHS Secretary to establish a Drug Price Negotiation Program (the "Program") to lower prices for certain high-expenditure, single-source prescription drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for prescription drugs and at least 11 years for biologics. Under the Program, the HHS Secretary will publish a list of "selected drugs," and will then negotiate maximum fair prices ("MFP") with their manufacturers. The Program will be implemented in stages. Beginning in 2026, 10 Medicare Part D "selected drugs" will be subject to price negotiations. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Medicare Part B and Part D. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and potential civil monetary penalties. Further, beginning in October 2023, the IRA will require manufacturers that increase prices of certain Medicare Part B and Part D drugs or biologics at a rate greater than inflation to pay rebates to CMS or be subject to civil monetary penalties. HHS has and will continue to issue and update guidance as these programs are implemented, although the IRA may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue

from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

European Union Product Approval Process

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported, and archived in accordance with the GLP principles, as set forth in Directive 2004/10/EC, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice, or GCP, and the related national implementing provisions of the individual EU member states currently govern the system for the approval of clinical trials in the EU.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations of EU members states and the International Conference on Harmonization, or ICH, guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and increasingly in EU member states, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

Under the applicable regulatory system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a related favorable opinion. The application for authorization of a clinical trial must be accompanied by, among other documents, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation as prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the related implementing national provisions of the individual EU member states, and further detailed in applicable guidance documents. Any substantial changes to the trial protocol or to other information submitted with the clinical trial application must be notified to and approved by the relevant competent national authorities and ethics committees. Medicinal products used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP).

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. The Regulation came into effect in the EU on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU member states, repealing the Clinical Trials Directive 2001/20/EC. A three-year transition period is in place to move from the previous European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, SI No 190 of 2004 which transposed into law the provision of Council Directive 2001/20/EC. The transition period sets out the following key timelines:

- *From 31 January 2022 until 31 January 2023 - All initial clinical trial applications can be submitted under either the Directive or the Clinical Trial Regulation.*
- *From 31 January 2023* - All initial clinical trial applications need to be submitted under the Clinical Trial Regulation.
- *From 31 January 2022 until the end of the transition period* - Ongoing clinical trials previously authorized under the Directive can remain under the Directive, or they can transition to the Clinical Trial Regulation.

- *By 31 January 2025* all ongoing clinical trials will be required to have transitioned to the Clinical Trial Regulation and will need to be migrated to CTIS.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed first by a single "reference" member state whose conclusions are then assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted to "concerned" member states. Part II is assessed separately by each concerned EU member state. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation, which provides Sponsors a reliable timeline to evaluate the approval of the clinical trial throughout Europe.

Marketing Authorizations

To obtain a marketing authorization, or MA, for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU member states (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions, and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional on the related approval of the EMA.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for conducting the assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU member states who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU member state cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU member states.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU member states of the MA of a medicinal product by the competent authorities of other EU member states. The holder of a national MA may submit an application to the competent authority of an EU member state requesting that this authority recognize the MA delivered by the competent authority of another EU member state.

In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU member states may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU member state within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicable does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the Union. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate

authorizations for distribution granted by the competent authorities of the EU member states. MA holders and/or manufacturing and import authorization, or MIA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric trials for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Coverage, Pricing and Reimbursement outside the United States

Outside the U.S., pharmaceutical companies, products and distributors are also generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in EEA and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems that fund a large part of the cost of those products to consumers. Some countries operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of comparative trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional price controls in foreign countries or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors abroad, as in the U.S., to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

If we are unable to establish or sustain coverage and adequate reimbursement for any of products from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

In various EEA countries, we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper products as an alternative. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including countries representing major markets. The HTA process, which is currently governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EEA Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EEA level for joint clinical assessments in these areas. In June 2021, the European Parliament and Council reached a provisional agreement on the draft regulation. Entry into application of the Regulation could impose stricter and

more detailed procedures to be followed by MAHs concerning conduct of HTA in relation to their products which may influence related pricing and reimbursement decisions.

Advertising Regulation

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU rules, the details are governed by regulations in individual EU member states and can differ from one country to another. Applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA, therefore all off-label promotion is prohibited. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

We are also subject to numerous federal, state and local laws and foreign laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

In addition to regulation in the United States and the EEA, a variety of foreign regulations govern clinical trials, commercial sales and distribution of drugs. Pharmaceutical firms who wish to market their medicinal drugs outside the EEA and the United States must submit marketing authorization application to the national authorities of the concerned countries, such as the Pharmaceutical and Medical Device Agency, or PMDA in Japan. The approval process varies from jurisdiction to jurisdiction and the time to approval may be longer or shorter than that required by the FDA or European Commission.

Manufacturing and Supply

We are dependent on specialized third parties, who are subject to cGMP requirements and regulations, for the supply and manufacture of sozinibercept drug substance and drug product. We do not have any internal manufacturing and control capabilities. We source the drug substance for sozinibercept and our clinical trials on a purchase order basis. However, we believe that competitive pricing is achieved because there are a number of potential long-term replacements for our suppliers of drug substance.

In October 2013, we entered into a biopharmaceutical manufacturing agreement, or the Patheon Agreement, with Patheon Biologics Company, Australia Pty Ltd. and Patheon Biologics Company B.V., or collectively Patheon now part of ThermoFisher Scientific. The Patheon Agreement establishes the general terms and conditions pursuant to which Patheon or its affiliates will manufacture sozinibercept drug product for us in accordance with cGMP requirements. Under the Patheon Agreement, Patheon granted us a perpetual, royalty-free, fully paid-up, non-exclusive, worldwide, transferable and sublicensable license, under all of Patheon's intellectual property rights embedded in the development and manufacture process to the extent necessary for developing, making, using and selling sozinibercept.

The Patheon Agreement will expire on the date that all of the manufacturing services to be performed by Patheon are completed. We may terminate the Patheon Agreement for any reason upon prior written notice. Patheon may terminate the Patheon Agreement upon prior written notice if Patheon has not performed any activities under the Patheon Agreement for certain period of time or if, despite Patheon's commercially reasonably best efforts, Patheon determines that the services cannot be completed according to specifications approved by us or within a reasonable time after the originally planned timeframe. Either party may terminate the Patheon Agreement for the other party's uncured material breach or bankruptcy. In addition, the Patheon Agreement will terminate if the parties are unable to reach agreement regarding necessary changes to the services based on the results of individual stage of development work. Upon termination of the Patheon Agreement, we are required to pay Patheon for services properly performed, including non-cancelable costs. Based upon the timing of the termination, we may also be required to pay Patheon certain close out cost for canceled services.

Employees

As of June 30, 2024, we had 34 full-time employees, fifteen of whom had an M.D. or Ph.D. degree. None of our employees are represented by collective bargaining agreements. We believe that our management maintains good relations with our employees. As of June 30, 2024, our employees were based in Australia (8) and United States (24), with 27 employees in our research and development and commercialization department and seven employees in our general and administrative department.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are currently not a party to any material legal proceedings.

4C. Organizational Structure

Opthea Limited is the parent company of two wholly-owned subsidiaries for which it holds 100% of the voting power: Vegenics Pty Ltd, incorporated in Australia in January 2006 and Opthea US Inc, incorporated in the United States in May 2021.

4D. Property and Equipment

We occupy approximately 1,938 square feet of office space in South Yarra, Victoria, Australia under a lease that expires in July 2025. We believe that our existing facilities are adequate to meet our current needs and that suitable additional alternative facilities will be available in the future on commercially reasonable terms to meet our future needs.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following "Operating and Financial Review and Prospects" should be read together with our consolidated financial statements and the accompanying notes included elsewhere in this annual report. The following discussion is based on our financial information prepared in accordance with IFRS, as issued by the IASB, which might differ in material respects from accounting principles generally accepted in other jurisdictions, including U.S. GAAP. This discussion includes both historical information and forward-looking information based upon current expectations that involve risk, uncertainties and assumptions. Our actual results may differ materially from management's expectations as a result of various factors, including, but not limited to, those discussed in "Risk Factors" and elsewhere in this annual report.

Overview

We are a clinical-stage biopharmaceutical company developing a novel therapy for the treatment of highly prevalent and progressive retinal diseases. We are developing our Phase 3-ready product candidate, sozinibercept, a biologic drug designed to inhibit VEGF-C and VEGF-D, to complement VEGF-A inhibitors for the treatment of ophthalmic diseases. Anti-VEGF-A therapies represent the standard of care for wet age-related macular degeneration, or AMD, and other retinal diseases; however, there remains a significant unmet medical need as many patients do not adequately respond to these treatments. As the only biologic inhibitor of VEGF-C and VEGF-D in clinical development, sozinibercept differs from standard of care therapies and when administered in combination with a VEGF-A inhibitor, is designed to achieve broader inhibition of the vascular endothelial growth factor, or VEGF, family and target a mechanism of clinical resistance to improve visual acuity. Our lead indication for sozinibercept combination therapy is wet AMD, a chronic, progressive disease and the leading cause of vision loss for individuals over the age of 50. In a 366-patient Phase 2b clinical trial for the treatment of wet AMD, 2.0 mg sozinibercept, in combination with a standard of care anti-VEGF-A therapy, ranibizumab (Lucentis), met the primary endpoint of a statistically significant superior mean gain in visual acuity over ranibizumab monotherapy at week 24. We initiated two pivotal Phase 3 clinical trials in treatment-naive patients with wet AMD to evaluate the efficacy and safety of sozinibercept in combination with anti-VEGF-A therapies compared to anti-VEGF-A monotherapy. In total, we enrolled 1,984 patients across the COAST (n=998) and ShORe (n=986) trials, with patients recruited from more than 20 countries worldwide. Based on the completion of enrollment in COAST in February 2024 and ShORe in May 2024, the 52-week top-line data readout of COAST is anticipated early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025. In addition to our clinical trials in wet AMD, we have observed evidence of improved clinical outcomes in a Phase 1b/2a clinical trial of sozinibercept in combination with another standard of care anti-VEGF-A therapy, aflibercept (Eylea), in patients with treatment-refractory diabetic macular edema, or DME. We retain worldwide rights to develop and commercialize sozinibercept for the treatment of wet AMD and DME and believe that the novel treatment mechanism of sozinibercept has the potential to provide therapeutic benefit for other progressive eye diseases.

We were founded in 1984 and completed our initial public offering and listing of ordinary shares on the Australian Securities Exchange in 1985. In October 2020, we completed a U.S, initial public offering of ADSs on Nasdaq. In April 2007, we acquired intellectual property relating to VEGF receptor 3 and subsequently developed the intellectual property for our lead product candidate, sozinibercept. Our development focus on the treatment of retinal diseases began in 2013. Since then, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, developing and manufacturing our lead product candidate, sozinibercept, conducting research and development activities, including preclinical studies and clinical trials, and providing general and administrative support for these operations. Our operations relating to the development of sozinibercept have been financed primarily through the issuance and sale of new ordinary shares totaling US$377.3 million through June 30, 2024. We have also received an aggregate of US$36.1 million (A$44.4 million) in cash tax incentives for the five fiscal years ended June 30, 2024 under the Research and Development, or R&D, Tax Incentive Scheme for the funding of the development of and clinical trials for sozinibercept.

We have incurred operating losses since 2013. Our ability to generate product revenue sufficient to achieve profitability will be dependent on the successful development and eventual commercialization of sozinibercept and any future product candidates. Our total comprehensive loss was US$92.8 million, US$142.5 million, and US$220.2 million for the years ended June 30, 2022, 2023 and 2024, respectively. As of June 30, 2024, we had an accumulated loss of US$579.7 million. We expect to continue to incur significant expenses for at least the next several years as we advance sozinibercept through late-stage clinical development, including our pivotal Phase 3 trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD, and, if these results are favorable, seek regulatory approval for sozinibercept. In addition, we may also pursue development of sozinibercept for the treatment of additional indications, including DME, retinal vein occlusion and other indications in which sozinibercept has the potential to provide therapeutic benefit. In addition, if we obtain marketing approval for sozinibercept, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. As a company whose ADSs are publicly traded in the United States, we have incurred and will continue to incur additional costs associated with operating as a public company in the United States, including significant additional legal, accounting, investor relations, compliance and other expenses.

As a result, we will need substantial additional funding to complete the ongoing Phase 3 trials and report top-line data to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions as well as Australian research and development tax incentives. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of sozinibercept.

Because of the numerous risks and uncertainties associated with the development of biopharmaceutical product candidates, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may never become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to scale back or discontinue our operations.

On August 24, 2023, we announced a A$80.0 million capital raise consisting of an A$10.0 million private placement ("2023 Placement") and a A$70.0 million fully underwritten accelerated non-renounceable entitlement offer (“2023 ANREO”). On August 28, 2023, Opthea announced an increase in the 2023 Placement by a further A$10.0 million to increase the overall raise to A$90.0 million (approximately US$58.2 million). The Placement and the fully underwritten institutional component of the ANREO, which closed on August 25, 2023, together raised approximately A$73.7 million (approximately US$47.7 million) and the fully underwritten retail component of the 2023 ANREO, which closed in September 21, 2023, raised approximately A$16.3 million (approximately US$10.5 million). The A$90.0 million (US$58.2 million) proceeds from the 2023 Placement and 2023 ANREO will be used to continue advancing the clinical development of sozinibercept for the treatment of wet age related macular degeneration (wet AMD) including to progress our Phase 3 clinical trials and for general corporate purposes

In December 2023, we received US$35.0 million from Ocelot SPV LP ("Ocelot"), an affiliate of Carlyle and Abingworth, for the third tranche of funding under the Development Funding Agreement, as amended (the "DFA," or "Funding Agreement"). In addition, we received additional funding of US$50.0 million from a new co-Investor (together with Ocelot, the "Investors"), bringing the total funding received under the Funding Agreement to US$170.0 million, the maximum amount allowed under the terms of the Funding Agreement. As such, we no longer have any committed external source of funds. If sozinibercept is approved in a major market (as defined in the Funding Agreement), within 90 days of approval, we must make a fixed payment to the Investors followed by six annual payments. The Investors will also receive a variable payment of 7% of net sales. To date, the Investors have invested $170 million. If sozinibercept is approved, the Investors will receive four times invested capital, or $680.0 million over approximately six years. We anticipate that profits generated by the sales of sozinibercept should be able to fund this repayment, however there can be no assurances that we will have sufficient cash resources to repay this amount when it is due.

In June 2024, Opthea announced a non-underwritten institutional placement ("2024 Placement") and partially underwritten ANREO of A$227.3 million (approximately US$151.9 million), which was completed in July 2024. On June 14, 2024, we announced the completion of the Placement and the partially underwritten institutional component of the ANREO, which together raised approximately A$171.5 million (approximately US$114.3 million). On June 19, 2024, we announced the opening of the fully underwritten retail component of the 2024 ANREO to raise approximately A$55 million (approximately US$37.6 million), which was completed on July 17, 2024. See Note 39, Events after the Balance Sheet Date, for more information. The proceeds from the 2024 Placement and 2024 ANREO will be used to continue advancing the clinical development of sozinibercept for the treatment of wet-age related macular degeneration (wet AMD), including to progress our Phase 3 clinical trials and for general corporate purposes.

As of June 30, 2024, we had cash and cash equivalents of US$172.5 million. We believe that our existing cash and cash equivalents as of June 30, 2024, as well as proceeds of approximately US$37.6 million from the 2024 fully underwritten retail component of the 2024 ANREO, will enable us to fund our operating and research and development expenses into the third calendar quarter of 2025 and through the anticipated topline data readouts dates for our Phase 3 clinical trials. However, such proceeds will not be sufficient to fully fund all anticipated costs of the Phase 3 clinical trials and Opthea will require additional funding to reach commercialization of Sozinibercept in any indication, including wet AMD. In addition, as a result of among other things, certain obligations under the Funding Agreement and applicable law regarding liquidity, we expect to raise or obtain additional capital from external sources, in on or more transactions, earlier than the third calendar quarter of 2025 or anticipated topline data readout dates of our Phase 3 clinical trials. In addition, the forecast of our cash runway, following receipt of the proceeds from the 2024 Equity Offering, is subject to a number of assumptions, including assumptions and forecasts regarding Clinical Research Organization ("CRO"), CDMO and labor costs, costs to retain and attract any required personnel, and costs to engage additional consultants and advisors. We have in the past incurred significantly increased costs in connection with the activities conducted by third party CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials, and may continue to incur higher than expected costs for such activities in the future, including due to factors outside our control.

The amounts and timings of our expenditures will depend upon and have been impacted in the past, and may continue to be impacted by, numerous factors, including historical or future delays in completing our clinical trials, particularly as it relates to enrollment, the timing of regulatory submissions, the performance and costs efficiency of CROs and any continuing impacts of the COVID-19 pandemic, the global supply chain and macroeconomic challenges. In particular, delays in patient enrollment have in the past resulted, and may in the future result in increased costs or delays and other impacts on the timing of our Phase 3 clinical trials. We have in the past incurred significantly increased costs in connection with the activities conducted by third party CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials, and may continue to incur higher than expected costs for such activities in the future. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We may also experience future delays in our clinical development or commercialization of sozinibercept for an indication, including due to factors and conditions set forth above or other factors that we cannot presently anticipate. We intend to focus our development efforts on achieving commercialization of sozinibercept for the treatment of wet AMD, and we will require additional funding to reach commercialization of sozinibercept in any indication, including wet AMD. In addition, we may require additional external funding to meet the minimum cash condition under the Funding Agreement or to pay for development and commercialization costs in excess of funding received under the Funding Agreement, including prior to the readout of top-line results for our Phase 3 clinical trials for sozinibercept for the treatment of wet AMD.

We will need to raise significant additional funds to complete both trials' two-year efficacy and safety phase, file a biologics license application with the FDA and EMA, potentially launch Sozinibercept, if approved, and meet the obligations under the Funding Agreement including the minimum cash condition and payment of development and commercialization costs in excess of funding received under the Funding Agreement. As a result of, among other things, certain obligations under the Funding Agreement, and applicable law regarding liquidity we expect to raise or obtain additional capital from external sources earlier than the third calendar quarter of 2025 or anticipated topline data readout dates of our Phase 3 clinical trials. See "—Liquidity and Capital Resources."

5A. Operating Results

Components of Our Results of Operations

Revenue

Revenue consists of sales-based royalties in connection with the out-licensing of certain intellectual property assets that are unrelated to our core business and the development of sozinibercept and are not currently under development. These licenses are primarily used by third-party licensees for research purposes, and we expect revenue from these out-licensing arrangements to be nominal in future periods. These are variable consideration amounts and are recognized when the sales by our license partners to third parties occur, as the performance obligation to transfer the intellectual property to the license partner is already satisfied.

To date, we have not generated any revenue from sales of approved products. Because of the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount, timing or whether we will be able to obtain revenue from sales of approved products, and we may never succeed in obtaining regulatory approval for sozinibercept or any other product candidate. If our development efforts for sozinibercept are successful and result in an approved and marketed product, or if we enter into additional collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Other Income

Other income primarily comprises funding under a one-time Australian government grant and the Australian Tax Office.

Operating Expenses

Research and Development Expenses. Research and development expenses comprise the research project costs related to the development programs, including clinical trials, for sozinibercept for the treatment of wet AMD and DME. R&D expenses also include:

- expenses incurred in connection with the clinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing and purchasing drug products for use in our clinical trials, including under agreements with third parties, such as consultants and CDMOs;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent, maintenance of facilities and insurance;
- employee benefit expenses for all R&D staff;
- costs related to compliance with regulatory requirements; and
- clinical trial insurance.

We expense R&D costs as incurred and have not capitalized any amounts of R&D costs as of June 30, 2023 and 2024. In the years ended June 30, 2022, 2023 and 2024, we have made advance payments for R&D activities that will be provided by our CROs in future periods for use in R&D activities.

Our direct R&D expenses are tracked on a program-by-program basis for our product candidate and consist primarily of R&D employee-based benefits, external costs, such as fees paid to CROs, CDMOs, research laboratories and outside consultants in connection with our process development, manufacturing and clinical development activities. We do not allocate laboratory supplies and facilities, including depreciation and other indirect costs, to specific programs because these costs are deployed across multiple development activities and indications for sozinibercept and, as such, are not separately classified. We use internal resources primarily to conduct our research activities as well as for managing our process development, manufacturing and clinical development activities. These employees work across multiple development programs and, therefore, we do not track these costs by program.

R&D expenses in fiscal years after June 30, 2024 are expected to comprise costs of a similar nature to that recorded to date. Product candidates in later stages of clinical development, such as sozinibercept, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our R&D expenses will increase in connection with our planned clinical development, manufacturing and regulatory approval activities in the near term and in the future, including as we continue our pivotal Phase 3 clinical trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD.

At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of sozinibercept and any future product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our planned clinical trials as well as other R&D activities, including any impacts of the COVID-19 pandemic and macroeconomic challenges such as inflationary pressures and supply chain disruptions;
- clinical trial results;
- the terms and timing of regulatory approvals;
- the expense of filing, maintaining, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the ability to raise necessary additional funds;
- the ability to obtain and maintain third-party insurance coverage and adequate reimbursement;
- the ability to market, commercialize and achieve market acceptance for any products that receive regulatory approval;
- a continued acceptable safety profile of sozinibercept combination therapy following approval in any indication; and
- establishing and maintaining agreements with third-party suppliers and manufacturers for clinical supply and commercial manufacturing of sozinibercept, or any other product candidate, if approved.

A change in the outcome of any of these factors with respect to the development of sozinibercept could significantly change the duration, costs and timing associated with clinical trials and development of sozinibercept.

Patent and Intellectual Property Expenses. Patent and Intellectual Property expenses comprise the cost of outside patent attorneys to manage and prosecute our patent portfolio.- license and patent assignment costs in respect of our in-license agreements for certain technologies not currently under development and unrelated to our out-licensing arrangements under which we receive sales-based royalties.

Administrative Expenses. Administrative expenses comprise employee benefit expenses, including share-based payment expenses; investor relations expenses; insurance costs; audit, accountancy and legal fees; other personnel-related expenses; and depreciation expense. We anticipate that our administrative expenses will increase in the future as we increase our headcount to support development of sozinibercept and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company in the United States.

Occupancy Expenses. Occupancy expenses represent the costs relating to our headquarters in Melbourne, Australia, including lease maintenance and incidental costs.

Finance Income – Interest income

Finance income primarily comprises of income from interest on bank deposits.

Net Foreign Exchange Gain (Loss)

Net foreign exchange gain (loss) represents the impact of the variance in exchange rates between the U.S. dollar and the Australian dollar, Euro, British Pound and Canadian dollar on our cash and cash equivalents, financial assets, financial liabilities and foreign currency denominated transactions.

Income Tax Benefit

Income tax benefit represents the cash incentive amount receivable under the R&D Tax Incentive Scheme, an Australian Federal Government program under which eligible companies with annual aggregated revenue of less than A$20.0 million can receive cash amounts equal to 43.5% of eligible R&D expenditures from the Australian Taxation Office, or the ATO. The ATO may also make other changes to the eligibility of R&D expenditures, including placing a cap on the amount of non-clinical trial R&D expenses claimed under the scheme.

The R&D Tax Incentive Scheme incentive relates to eligible expenditures incurred in Australia and, under certain circumstances, in other countries in connection with the development of sozinibercept. The R&D tax incentive is applied annually to eligible expenditures incurred during the fiscal year following an annual application and subsequent filing of our income tax return subsequent to fiscal year end. We estimate the amount of R&D tax incentive after the completion of a fiscal year based on eligible Australia and overseas expenditures incurred during that year. We expect to continue applying for the R&D tax incentive as we further develop sozinibercept. In particular, we intend to apply for the costs expected to be incurred in Australia related to our pivotal Phase 3 clinical trials of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD to be eligible for the R&D tax incentive for future fiscal years once incurred. However, there can be no assurance that the ATO will allow these costs to be eligible for the tax incentive.

Results of Operations for the Fiscal Years Ended June 30, 2022, 2023 and 2024

The following table sets forth a summary of our consolidated statement of profit or loss and other comprehensive income for the periods presented. In the current year the Group changed its presentation in the consolidated statement of profit or loss and other comprehensive income to reflect expenses by business function. Prior year comparative amounts have been reclassified to conform with the updated presentation in the consolidated statement of profit or loss and other comprehensive income.

	2024	2023	2022
	US$	US$	US$
		(in thousands)	
Revenue	125	108	91
Other income	137	277	108
Operating expenses			
Research and development expenses (included amounts owed by related parties $3,042 (2023: $900)) 1	(176,326)	(128,829)	(81,445)
Administrative expenses 1	(15,778)	(21,582)	(15,291)
Total Operating expenses	(192,104)	(150,411)	(96,736)
Operating loss	**(191,842)**	**(150,026)**	**(96,537)**
Finance income	3,395	3,228	235
Interest expense on DFA	(30,263)	(13,462)	—
Gain on remeasurement of financial liability - DFA2	387	12,302	—
Fair value loss on derivative - investor options	(11,224)	—	—
Net foreign exchange(loss)/gain	(107)	(489)	(2,814)
Loss before income tax	**(229,654)**	**(148,447)**	**(99,116)**
Income tax benefit	9,412	5,926	6,299
Loss for the year	**(220,242)**	**(142,521)**	**(92,817)**
Other comprehensive income:			
Other comprehensive income for the period, net of tax	—	—	—
Total comprehensive loss for the year	**(220,242)**	**(142,521)**	**(92,817)**

1. Figures have been reclassified as described in Note 3 to the consolidated financial statements.
2. Figures have been reclassified as described in Note 13 to the consolidated financial statements.

Revenue

Revenue was US$125 thousand for the fiscal year ended June 30, 2024, compared to US$108 thousand for the fiscal year ended June 30, 2023. This increase was due to higher sales-based royalties received under our out-licensing arrangements. Revenue for the years ended June 30, 2024 and 2023 consisted of sales-based royalties in connection with the out-licensing of certain intellectual property assets that are unrelated to our core business and the development of sozinibercept which are not currently under development.

Revenue was US$108 thousand for the fiscal year ended June 30, 2023, compared to US$91 thousand for the fiscal year ended June 30, 2022. This increase was due to higher sales-based royalties received under our out-licensing arrangements. Revenue for the years ended June 30, 2023 and 2022 consisted of sales-based royalties in connection with the out-licensing of certain intellectual property assets that are unrelated to our core business and the development of sozinibercept which are not currently under development.

Other Income

Other income was US$137 thousand for the fiscal year ended June 30, 2024, compared to US$277 thousand for the fiscal year ended June 30, 2023.

Other income was US$277 thousand for the fiscal year ended June 30, 2023, compared to US$108 thousand for the fiscal year ended June 30, 2022.

Research and Development Expenses

Research and development expenses were US$176.3 million for the fiscal year ended June 30, 2024, compared to US$128.8 million for the fiscal year ended June 30, 2023. This increase was primarily due to costs relating to our Phase 3 clinical trial of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD, particularly with the completion of enrollment of the global Phase 3 trials, the expansion of our

clinical team, and chemistry, manufacturing and controls costs incurred during the fiscal year ended June 30, 2024 relative to costs incurred during the fiscal year ended June 30, 2023.

Research and development expenses were US$128.8 million for the fiscal year ended June 30, 2023, compared to US$81.4 million for the fiscal year ended June 30, 2022. This increase was primarily due to costs relating to our Phase 3 clinical trial of sozinibercept in combination with anti-VEGF-A therapy for the treatment of wet AMD and chemistry and manufacturing and controls costs incurred during the fiscal year ended June 30, 2023 relative to costs incurred during the fiscal year ended June 30, 2022.

Our research and development expenses are broken down as set forth in the table below. Both Financial Years 2023 and 2022 have been retrospectively reclassified to conform with the 2024 classification:

	2024	2023	2022
	US$	US$	US$
	(in thousands)	(in thousands)	(in thousands)
Costs related to the ShORe Phase 3 clinical trial of sozinibercept in wet AMD	77,788	59,472	36,675
Costs related to the COAST Phase 3 clinical trial of sozinibercept in wet AMD	69,947	50,544	27,520
Costs related to the Phase 2b clinical trial of sozinibercept in wet AMD	—	18	—
Costs related to the Phase 1b/2a clinical trial of sozinibercept in DME	—	18	—
Chemistry manufacturing and controls	19,394	12,062	14,430
Other direct non-clinical expenses	9,197	6,715	2,820
Total research and development expenses	176,326	128,829	81,445

Administrative Expenses

Administrative expenses were US$15.8 million for the fiscal year ended June 30, 2024, compared to US$21.6 million for the year ended June 30, 2023. This decrease was primarily due to US$5.7 million in professional and advisory fees that were incurred in fiscal year ended June 30, 2023 and a decrease of US$1.2 million for insurance and consultancy costs in fiscal year ended June 30, 2024 offset by an US$1.1 million increase in personnel-related expenses, resulting from increased headcount as we built out the US management team in the fiscal year ended June 30, 2024.

Administrative expenses were US$21.6 million for the fiscal year ended June 30, 2023, compared to US$15.3 million for the year ended June 30, 2022. This increase was primarily due to a US$5.7 million increase in professional and advisory fees and expenses and a US$0.6 million increase in personnel-related expenses, each resulting from increased headcount as we built out the US team to aid continued clinical trial oversight and management and capital raising activities in the fiscal year ended June 30, 2022.

Interest expense on DFA

Interest expense on the DFA was US$30.3 million for the fiscal year ended June 30, 2024, compared to US$13.5 million for the fiscal year ended June 30, 2023. This increase was due to the accretion of the financial liability recognized upon the receipt of payments under the DFA. The interest expense is a non-cash item.

Interest expense on the DFA was US$13.5 million for the fiscal year ended June 30, 2023, compared to US$nil for the fiscal year ended June 30, 2022. This increase was due to the accretion of the financial liability recognized upon the receipt of payments under the DFA. The interest expense is a non-cash item.

Gain on remeasurement of financial liability - DFA

There was a US$0.4 million gain on remeasurement of the DFA for the fiscal year ended June 30, 2024, compared to US$12.3 million for the fiscal year ended June 30, 2023. The small gain in fiscal year ended June 30, 2024 was due to a remeasurement of the financial liability as a result of the additional $50.0 million option

funding above the original committed funding under the DFA and Amended and Restated DFA. The gain on remeasurement on the DFA is a non-cash item.

There was a US$12.3 million gain on remeasurement of the DFA for the fiscal year ended June 30, 2023, compared to no remeasurement adjustment for the fiscal year ended June 30, 2022. This increase was due to the remeasurement of the financial liability regarding the assumptions on the anticipated timing of repayments under the DFA. The gain on remeasurement of the DFA is a non-cash item.

Fair value loss on investor options

There was a US$11.2 million value loss on investor options for the fiscal year ended June 30, 2024, compared to US$nil loss for the fiscal year ended June 30, 2023. This increase was due to the new issues of options in the current financial year. The fair value adjustment on investor options is a non-cash item.

Equity and Investor Options - 2024

On June 14, 2024, the Company offered approximately 139.5 million new shares at the offer price of A$0.40 per new share and approximately 46.5 million new options to eligible shareholders with an exercise price of A$1.00 on the basis of 1 new option for every 3 new shares issued under the retail offer of the 2024 ANREO; and approximately 142.9 million institutional and placement options with an exercise price of A$1.00 to participants in the placement and institutional offer of the 2024 ANREO on the basis of 1 Institutional option for every 3 new shares issued under the Placement ("2024 Investor Options"). Pursuant to the 2024 ANREO, the company raised gross proceeds of A$227.3 million. Each 2024 Investor Option entitles the holder to one ordinary share of the company.

Equity and Investor Options -2023

On August 28, 2023, the Company offered approximately 35.4 million new shares at the offer price of A$0.46 per new share and approximately 18.0 million new options to eligible shareholders with an exercise price of A$0.80 on the basis of 1 new option for every 2 new shares issued under the retail offer of the 2023 ANREO; and approximately 80.0 million institutional and placement options with an exercise price of A$0.80 to participants in the placement and institutional offer of the 2023 ANREO on the basis of 1 Institutional option for every 2 new shares issued under the Placement ("2023 Investor Options"). Pursuant to the 2023 ANREO, the company raised gross proceeds of A$90 million. Each Option entitles the holder to one ordinary share of the company.

Considering that the 2023 Investor Options are traded on the Australian Stock Exchange, we use the quoted price at the balance sheet date as the fair value of the options. The 2024 Investor Options have been fair valued based on the using a Black-Scholes model using relevant inputs including an expected volatility based on the implied volatility data from 2023 Investor Options, historical share price volatility, and other relevant factors.

Net Foreign Exchange Loss

Net foreign exchange differences were a loss of US$0.1 million for the fiscal year ended June 30, 2024, compared to a loss of US$0.5 million for the fiscal year ended June 30, 2023. The decrease was primarily the result of net variances of the exchange rate between the Australian dollar and U.S. dollar on Australian dollar-denominated cash and cash equivalents, financial assets, financial liabilities and foreign currency denominated transactions.

Net foreign exchange differences were a loss of US$0.5 million for the fiscal year ended June 30, 2023, compared to a loss of US$2.8 million for the fiscal year ended June 30, 2022. The decrease was primarily the result of net variances of the exchange rate between the Australian dollar and U.S. dollar on Australian dollar-denominated cash and cash equivalents, financial assets, financial liabilities and foreign currency denominated transactions.

Income Tax Benefit

Income tax benefit was US$9.4 million for the fiscal year ended June 30, 2024, compared to US$5.9 million for the fiscal year ended June 30, 2023. This increase was due to higher R&D tax incentive receivable recognized during the fiscal year ended June 30, 2024 based on eligible spend.

Income tax benefit was US$5.9 million for the fiscal year ended June 30, 2023, compared to US$6.3 million for the fiscal year ended June 30, 2022. This decrease was due to lower R&D tax incentive receivable recognized during the fiscal year ended June 30, 2023 based on eligible spend.

5B. Liquidity and Capital Resources

The liquidity and capital resources discussion that follows contains certain estimates as of the date of this annual report of our estimated future sources and uses of liquidity (including estimated future capital resources and capital expenditures) and future financial and operating results. These estimates reflect numerous assumptions made by us with respect to industry performance, general business, economic, regulatory, market and financial conditions and other future events, and matters specific to our businesses, all of which are difficult or impossible to predict and many of which are beyond our control.

Sources and Uses of Liquidity

Our operations relating to the development of sozinibercept have been financed primarily through the issuance and sale of new ordinary shares totaling US$377.3 million in the five years ended June 30, 2024. We have also received an aggregate of US$170.0 million in the five years ended June 30, 2024, under the Development Funding Agreement, pursuant to which Investor agreed to provide funding to support our development of sozinibercept for the treatment of wet AMD. We have also received an aggregate of US$36.1 million (A$44.4 million) in the five fiscal years ended June 30, 2024, under the R&D Tax Incentive Scheme for the funding of the development and clinical trials of sozinibercept.

In February 2022, we established an "at the market" program (the "ATM Program") with Jefferies LLC ("Jefferies"). Pursuant to the ATM Program, we may offer and sell up to US$75.0 million of our ordinary shares in the form of ADSs, with each ADS representing eight ordinary shares, through Jefferies.

Sales of ADSs under the ATM Program may be made from time to time, with the timing and amount of any sales to be determined by us based on a variety of factors. We may determine to sell some, all or none of the ADSs under the ATM Program and may terminate the ATM Program at our discretion. We, through Jefferies, may sell ADSs by any lawful method deemed to be an "at-the-market offering" defined by Rule 415(a)(4) under the Securities Act of 1933, as amended. Sales made through the ATM Program may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices. As a result, actual sales prices may vary.

To effectuate the establishment of the ATM Program, we have entered into a Sales Agreement with Jefferies, acting as sales agent, forward purchaser and forward seller (the "Sales Agreement"). The Sales Agreement provides that, in addition to the issuance and sale of ADSs through Jefferies as sales agent, we may, from time to time, enter into forward sale agreements (each, a "Forward Sale Agreement") with Jefferies, in its capacity as forward purchaser. To hedge each such Forward Sale Agreement, Jefferies or its affiliate will, at our request, attempt to borrow from third parties and then sell a number of ADSs equal to the number of ADSs underlying each such forward purchase agreement. We will not initially receive any proceeds from any sale of ADSs borrowed by Jefferies, or its affiliate, and sold through Jefferies. Instead, we expect to fully physically settle each Forward Sale Agreement, if any, with Jefferies on one or more dates specified by us on or prior to the maturity date of such Forward Sale Agreement. On physical settlement, we will receive aggregate net cash proceeds equal to the number of ADSs specified in such Forward Sale Agreement multiplied by the relevant forward price per ADS, as adjusted pursuant to the terms of such Forward Sale Agreement. However, subject to certain exceptions, we may also elect to cash settle or net share settle a particular Forward Sale Agreement, in which case we may not receive any proceeds from the issuance of ADSs, and we will instead receive or pay cash (in the case of cash settlement) or receive or deliver ADSs (in the case of net share settlement). As a result, the timing of any issuances of ADSs will depend on a variety of factors, including timing of sales under the ATM Program and the method of settlement of any Forward Sale Agreements. During the year ended June 30, 2024, no sales of our ordinary shares were made under the ATM Program

As of June 30, 2024, we had cash and cash equivalents of US$172.5 million, and we had an accumulated loss of US$579.7 million.

Funding Requirements

We believe that our existing cash and cash equivalents as of June 30, 2024, as well as the additional US$34.8 million net proceeds from the 2024 Equity Retail Offering, will enable us to fund our operating and research and development expenses into the third calendar quarter of 2025 and through the anticipated topline data readout dates for our Phase 3 clinical trials. We have based these estimates on assumptions and forecasts, including CRO, CDMO and labor costs, costs to retain and attract any required personnel and costs to engage additional consultants and advisors. We have in the past incurred significantly increased costs in connection with the activities conducted by third party CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials, and may continue to incur higher than expected costs for such activities in the future, including due to factors outside our control. If any additional factors cause the Phase 3 clinical trials to be further delayed or more costly, including higher than expected CRO, CDMO or labor costs, then we will need to obtain additional financing earlier than our forecast to report top-line data. Further, while we expect to have sufficient funds into the third calendar quarter of 2025 and through the anticipated topline data readout dates for our Phase 3 clinical trials, we will not have sufficient funds to fully fund all anticipated costs of the Phase 3 clinical trials and Opthea will require additional funding to reach commercialization of Sozinibercept in any indication, including wet AMD.

We will need to raise significant additional funds to complete both trials' two-year efficacy and safety phase, file a biologics license application with the FDA and EMA, potentially launch Sozinibercept, if approved, and meet the obligations under the Funding Agreement including the minimum cash condition and payment of development and commercialization costs in excess of funding received under the Funding Agreement. As a result of among other things certain obligations under the Funding Agreement and applicable law regarding liquidity, we expect to raise or obtain additional capital from external sources, in one or more transactions, earlier than the third calendar quarter of 2025 or anticipated topline data readout dates of our Phase 3 clinical trials.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, and seek marketing approval for, sozinibercept. In addition, if we obtain marketing approval for sozinibercept or any future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of any future collaborators. We have incurred and will continue to incur additional costs associated with operating as a public company in the United States. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, sozinibercept or any future product candidate, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of sozinibercept and any future product candidate that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. We may also require external funding to meet the minimum cash condition under the Funding Agreement and to pay development and commercialization costs in excess of funding received under the Funding Agreement, including prior to the readout of top-line results for our Phase 3 clinical trials for sozinibercept for the treatment of wet AMD. For more information as to the risks associated with our future funding needs, see "Item 3D—Risk Factors—Risks Related to Our Financial Position and Need for Capital."

Until we can generate a sufficient amount of revenue from the sale of approved products, if ever, we expect to finance our operating activities through our existing liquidity, including future financing activities, including a combination of equity offerings, including through our ATM program, exercise of the 2023 Investor Options and 2024 Investor Options, debt financings, collaborations, strategic alliances and licensing arrangements. However, the Funding Agreement limits the type of financings we may pursue in the future. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our equity holders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product

development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have in the past experienced delays in our Phase 3 clinical trials, including the establishment of trial sites and patient recruitment delays, and incurred significantly increased costs in connection with the activities conducted by third-parties that assist us with clinical development, including CROs, CDMOs and other service providers to prepare for and progress our Phase 3 clinical trials. We may also experience further delays in our clinical development of commercialization of sozinibercept for an indication, including due to factors and conditions set forth above or other factors that we cannot presently anticipate. Our present and future funding requirements, both short and long-term will depend on many factors, including, among other things:

- the initiation, progress, timing, costs and results of our clinical trials for sozinibercept, including our pivotal Phase 3 clinical trials of sozinibercept in combination with anti-VEGF-A therapies for the treatment of wet AMD, and any future product candidates we may develop;
- costs associated with expanding our organization, including our management infrastructure;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- the increasing costs incurred or might be incurred by CROs and CDMOs in connection with our ongoing Phase 3 clinical trials of sozinibercept;
- compliance with our contractual obligations, including under the Funding Agreement:
- selling and marketing activities undertaken in connection with the commercialization of sozinibercept, together with the costs involved in the creation of a sales and marketing organization; and
- the costs of operating as a public listed company in both Australia and the United States.

Commercial License Agreement with Selexis SA

In October 2013, we entered into a commercial license agreement, or the Selexis Agreement, with Selexis SA, or Selexis, under which Selexis granted us a non-exclusive, worldwide, sublicensable license under certain patents, know-how and other intellectual property controlled by Selexis to use certain cell lines, deliverables and materials provided by Selexis to manufacture sozinibercept and related products and to use, sell and otherwise exploit such products.

We paid Selexis a nominal upfront payment upon entering into the Selexis Agreement. We are also required to make certain payments under the Selexis Agreement totaling approximately US$1.3 million upon the achievement of certain development and commercial milestones. We are also obligated to pay a low single-digit running royalty on worldwide net sales of the licensed products. Our royalty obligations will continue, on a product-by-product and country-by-country basis, until the expiration of the relevant patents, but will not extend beyond October 2024 in any event. After the expiration of the royalty term, our license will continue and become full paid, perpetual and irrevocable.

The Selexis Agreement will expire on the date of expiration of the last-to-expire of the license patents. Either party may terminate the Selexis Agreement for the other party's uncured material breach or bankruptcy. We may also terminate the Selexis Agreement at any time upon prior notice to Selexis.

Development Funding Agreement

On August 12, 2022, we entered into a Development Funding Agreement (as amended and restated, the "Funding Agreement") with Ocelot SPV LP ("Ocelot"), an affiliate of Carlyle and Abingworth, in collaboration with Carlyle and Abingworth's recently formed development company Launch Therapeutics ("Launch Tx"),

pursuant to which Ocelot agreed to provide funding to support our development of sozinibercept for the treatment of wet AMD. On December 22, 2023, we entered into an Amended and Restated Development Funding Agreement with Ocelot as collateral agent, pursuant to which a new co-Investor (collectively with Ocelot, "Investors") provided an additional US$50.0 million in funding, bringing the total funding received under the Funding Agreement to US$170.0 million, the maximum amount under the terms of the Funding Agreement.

Pursuant to the Funding Agreement, we will be required to use commercially reasonable efforts to develop sozinibercept for the treatment of wet AMD in accordance with the Funding Agreement, including pursuant to certain development timelines set forth therein

In return, Opthea will pay to Investors (1) upon the first to occur of regulatory approval of sozinibercept for the treatment of wet AMD in the United States, United Kingdom or European Union ("Regulatory Approval"), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due within 90 days after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of sozinibercept for the treatment of wet AMD for each calendar quarter.

At the time that Investors receives an aggregate of four times the funding provided (US$680.0 million as Investors have funded the full US$170.0 million under the Funding Agreement) (the "Cap"), Opthea's payment obligations under the Funding Agreement will be fully satisfied.

We have the option to satisfy our payment obligations to Investor upon Regulatory Approval or a change of control of Opthea by paying an amount equal to the present value of the remaining payments payable to Investor subject to a mid-single-digit discount rate. We also have an option to buy out the remaining payments at any time by paying an amount equal to the remaining payments due subject to a proposed discount rate, which Investor may accept or reject. Upon a change of control of Opthea, an acceleration payment of a specified multiple of the funding provided is payable, net of payments already made to Investor and creditable against future payments to Investor.

We will grant Investor a security interest in all of our assets (other than intellectual property not related to sozinibercept). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Funding Agreement (the "Release Date"). The Funding Agreement also includes customary representations and warranties and covenants, including certain negative covenants regarding limitations on incurrence of indebtedness, liens, investments, restricted payments, sales of assets, and royalty sales. The negative covenants will terminate upon the Release Date.

The Funding Agreement terminates upon the payment of all payments owing to Investor, unless earlier terminated by Investor if:

- Opthea fails to comply with certain covenants and agreements set forth in the Funding Agreement, including failure to make required payments or develop sozinibercept as set forth in the Funding Agreement;
- Opthea suffers a material adverse event;
- there is a material adverse patent impact on Opthea's intellectual property covering sozinibercept;
- there are certain irresolvable disagreements within the joint steering committee overseeing Opthea's development of sozinibercept;
- the security interests of Opthea are invalidated or terminated other than as set forth in the Funding Agreement; or
- any Phase 3 clinical trial of sozinibercept is completed or terminated and (1) the primary endpoint is not met or (2) Investor reasonably determines that the results of any such trial do not support regulatory approval.

The Funding Agreement may also be earlier terminated by Opthea if Investor fails to fund as provided in the Funding Agreement. The Funding Agreement may be terminated by either party (i) if the other party materially breaches the Funding Agreement ("Material Breach"), (ii) if sozinibercept fails to receive regulatory approval in the United States or European Union, (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in an sozinibercept clinical trial or (v) upon a change of control of Opthea.

In certain instances, upon the termination of the Funding Agreement, we will be obligated to pay Investor a multiple, which may vary based on the termination event of the amounts paid to us under the Funding Agreement, including specifically,

- up to the Cap in the event that Investor terminates the agreement due to (w) failure by Opthea to comply with certain covenants and agreements set forth in the Funding Agreement, including failure to make required payments or develop sozinibercept as set forth in the Funding Agreement, (x) the bankruptcy of Opthea, (y) a safety concern resulting from gross negligence on the part of Opthea or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Investor, or in the diligence room made available to Investor or (z) the security interests of Investor being invalidated or terminated other than as set forth in the Funding Agreement;

- several multiples of such amounts in the event the Funding Agreement is terminated due to Material Breach by Opthea; and

- a small multiple of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing Opthea's development of sozinibercept.

In addition, if following certain events of termination of the Funding Agreement, Opthea continues to develop sozinibercept for the treatment of wet AMD and obtains Regulatory Approval, it will make the payments to Investor as if the Funding Agreement had not been terminated, less any payments made upon termination.

The Funding Agreement also includes a minimum cash requirement, and Opthea may need to obtain additional funding to meet this requirement in the future, including prior to the expected readout of top-line results for its Phase 3 clinical trials. To the extent that Opthea raises additional capital through the sale of equity or convertible debt securities to meet this requirement, Opthea's equity holders will be diluted.

The payments required under the Funding Agreement are significant. Failure to generate sufficient revenue to make such payments if and as they become due, or failure to otherwise finance such payments would have a material adverse effect on our business. In addition, if we are unable to comply with our obligations under the Funding Agreement and/or one of the termination events described above occurs, our payment obligations thereunder may be accelerated. The acceleration of payments under the Funding Agreement would have a material impact on our business and we may not be able to make such payments at such time. We may also require additional external funding to meet the minimum cash condition under our development funding agreement with Investor, including prior to the readout of top-line results for our Phase 3 clinical trials for Sozinibercept (OPT-302) for the treatment of wet AMD. If we unable to obtain such additional external funding and as such are unable to meet the minimum cash condition, we are required to provide notice to the Investors. Under the Funding Agreement, upon receipt of such notice, the Investors have the option, but not the obligation, to contribute additional funds under the terms of the Funding Agreement if we are unable to raise sufficient capital in a timely manner. If the Investors choose not to contribute additional funds and we are unable to raise additional capital, we may become insolvent or may otherwise be in material breach under the Funding Agreement for failing to fund development and commercialization costs in excess of the funding received, which will result in significant payments becoming due under the Funding Agreement. Based on our current cash flow estimates, and in the absence of any additional external funding, we expect to be unable to meet the minimum cash condition prior to the third calendar quarter of 2025 and may have to provide notice to the Investors at such time.

Furthermore, the obligations under the Funding Agreement are secured by a lien on all of our assets (other than intellectual property not related to Sozinibercept (OPT-302)). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Funding Agreement. A default under the Funding Agreement, including in the event of our insolvency or our inability to pay development and commercialization costs in excess of funding received under the Funding Agreement, may result in a foreclosure on our intellectual property and seizure of all of our assets and could result in us having to pay the Investors multiples of the amounts paid to us.

In addition, we may need to implement further internal controls and processes to ensure compliance with all obligations under the Funding Agreement, otherwise we could inadvertently default under it.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	2024	2023	2022
	US$	US$	US$
		(in thousands)	
Net cash used in operating activities	(161,015)	(120,608)	(71,335)
Net cash provided by investing activities	(33)	(22)	(17)
Net cash provided by financing activities	243,728	167,285	172
Net increase/(decrease) in cash and cash equivalents	82,680	46,655	(71,180)

Operating Activities

For the year ended June 30, 2024, net cash used in operating activities was US$161.0 million, attributable to a net loss of US$220.2 million adjusted for US$36.9 million in non-cash items as well as a net cash inflow from changes in operating assets and liabilities of US$17.3 million, and inflow of a R&D tax incentive of US$5.9 million received. Non-cash adjustments of US$36.9 million consisted of add back of US$9.4 million in income tax benefit recognized in profit and loss and the remeasurement gain on the DFA of US$0.4 million offset by positive US$0.1 million in net exchange differences, fair value loss add back on the investor options of US$11.2 million, US$5.1 million in share-based payments, US$30.3 million of non-cash interest expense on the DFA and US$103 thousand in depreciation expense.

For the year ended June 30, 2023, net cash used in operating activities was US$120.6 million, attributable to a net loss of US$142.5 million adjusted for US$1.7 million in non-cash items as well as a net cash inflow from changes in operating assets and liabilities of US$13.9 million, and inflow of a R&D tax incentive of US$6.3 million received. Non-cash adjustments of US$1.7 million consisted of US$5.9 million in income tax benefit recognized in profit or loss and the gain on remeasurement of the DFA of US$12.3 offset by US$0.5 million in net exchange differences, US$5.8 million in share-based payments, US$13.5 million of non-cash interest expense on the DFA and US$101 thousand in depreciation expense.

For the year ended June 30, 2022, net cash used in operating activities was US$71.3 million, attributable to a net loss of US$92.8 million adjusted for US$1.8 million in non-cash items as well as a net cash inflow from changes in operating assets and liabilities of US$14.7 million, and inflows of a R&D tax incentive of US$4.9 million received. Non-cash adjustments of US$1.8 million consisted of US$6.3 million in income tax benefit recognized in profit or loss offset by US$2.8 million in net exchange differences, US$5.2 million in share-based payments and US$78 thousand in depreciation expense.

Investing Activities

For the years ended June 30, 2022, 2023 and 2024, net cash provided by investing activities was cash outflow of US$17 thousand, US$22 thousand and US$33 thousand, respectively, attributable to cash payments for the purchase of computer equipment.

Financing Activities

For the year ended June 30, 2024, net cash provided by financing activities was US$243.7 million, attributable to $158.8 million from capital placement, US$85.0 million under the Development Funding agreement. Net cash provided by financing activities also included US$89 thousand in respect of the payment of lease liabilities.

For the year ended June 30, 2023, net cash provided by financing activities was US$167.3 million, attributable to $81.8 million from capital placement, US$1.0 million received on the exercise of options granted to employees and US$84.5 million under the Development Funding agreement. Net cash provided by financing activities also included US$71 thousand in respect of the payment of lease liabilities.

For the year ended June 30, 2022, net cash provided by financing activities was US$171 thousand, attributable to US$257 thousand received on the exercise of options granted to employees. Net cash provided by financing activities also included US$86 thousand in respect of the payment of lease liabilities

5C. Research and Development, Patents and Licenses

For a description of the amount spent during each of the last three fiscal years on company-sponsored research and development activities, as well as the components of research and development expenses, see "Item 5A—Operating Results – Results of Operations."

For a description of our research and development process, see "Item 4B—Business Overview."

5D. Trend Information

For a discussion of trends, see "Item 4B—Business Overview," "Item 5A—Operating Results" and "Item 5B—Liquidity and Capital Resources."

5E. Critical Accounting Estimates

Critical Accounting Estimates

We believe that the following accounting policies involve a high degree of estimation and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of our operations. See note 3 to our consolidated financial statements appearing elsewhere in this annual report for a description of our other significant accounting policies. The preparation of our consolidated financial statements in conformity with IFRS requires us to make estimates and judgments that affect the amounts reported in those financial statements and accompanying notes. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making those estimates, actual results reported in future periods could differ from those estimates.

Development Funding - Financial liability

The Group evaluated the Funding Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to DFA Investors was not considered substantive and genuine.

Accordingly, the Group has recorded payments received under the Funding Agreement as part of a development financing liability in its consolidated balance sheet. The Group measures the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. If the dates are delayed from those used at reporting date, it is expected that a remeasurement will result in a non-cash gain.

At each reporting date, the Group reassess the estimated timing of regulatory approval and attainment of sales milestones and the expected fixed and variable contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different from the estimates used on the initial recognition date, the Group will adjust the accretion of the development financing liability using the previously determined imputed interest rate.

At June 30, 2023 the Group performed a remeasurement of the carrying amount of the Financial Liability. The expected timeline for approval and commercial launch have been delayed by twelve months, thus extending date of expected repayments. As the Group has more time to repay the amounts owed, the carrying value of the Financial Liability at June 30, 2023 was adjusted downward to reflect this delay. The remeasurement resulted in a non-cash gain on revaluation of $12.3 million. This change is recorded on the Profit or Loss statement as a gain on remeasurement of financial liability.

If the timelines for approval and launch are accelerated, the Group would anticipate a remeasurement resulting in a non-cash charge to be recognized in the Consolidated Statement of Profit or Loss.

Derivative Financial Liability - Investor options

The Group accounts for investor options as a derivative financial liability. Such derivatives are measured at fair value with subsequent changes in fair value accounted for through profit and loss. For the investor options that are traded on the Australian Securities Exchange, we use the quoted price at the balance sheet date as the fair value of the options. For the investor options issued on June 14, 2024, fair values were determined internally using Binomial models as a quoted price was not available as at year end. Key inputs to the valuation include the share price at grant date, expected term, volatility, dividend yield, risk free rate and exercise price. Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting market conditions attached to the option), and behavioral considerations. Expected volatility is based on the historical share price volatility over the past two years. These investor options were listed for trading on the Australian Securities Exchange in July 2024. Should the quoted price differ from the internally determined fair value, this could have a material impact on the amounts recognized in derivative financial liabilities and in the profit and loss.

Share-based Payment Transactions

We provide benefits to our directors and employees (including key management personnel) in the form of share-based payments, whereby employees render services in exchange for ordinary shares or rights over ordinary shares (equity-settled transactions). The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. Binomial models are used to value the options issued, with key assumptions being the listed price per ordinary share on the grant date, the option exercise price, expected volatility of the underlying ordinary shares based on the historical share price volatility and the risk-free interest rate.

The cost of the equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date). The charge to profit or loss for the period is the cumulative amount less the amounts already charged in previous periods. There is a corresponding credit to equity.

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so. Should one or more of the assumptions and estimates used in estimating the fair value of share-based payments change, this could have a material impact on the amounts recognized in equity and employee-related expenses.

Recently Adopted Accounting Pronouncements relating to the Financial Statements

Amendments to Accounting Standards that are Mandatorily Effective for the Current Year

We have adopted all of the new and revised Standards and Interpretations issued by the IASB that are relevant to our operations and effective for the current year.

During the fiscal year ended June 30, 2024, we applied a number of amendments to IFRS and Interpretations issued by the IASB that are effective for an annual period that begins on or after January 1, 2023. Their adoption has not had any material impact on the disclosures or on the amounts reported in our consolidated financial statements.

New and Revised International Financial Reporting Standards and Interpretations on Issue But not Yet Effective

The new and revised International Financial Reporting Standards, Interpretations and amendments that have been issued but are not yet effective, are not expected to have a material impact on the amounts recognized or disclosures included in our consolidated financial statements.

Qualitative and Quantitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates and foreign currency exchange rate risk.

Interest Rate Risk

As of June 30, 2024, we had cash and cash equivalents of US$172.5 million, including US$80.7 million in short term deposit accounts. We have limited exposure to interest rate risk. Our exposure to market interest rates relates primarily to the short-term deposits. The deposits are held with two of Australia's largest banks. Our cash and cash equivalents are not locked into long-term deposits at fixed rates so as to mitigate the risk of earning interest below the current floating rate. We do not have any credit facilities bearing variable interest rates.

Foreign Currency Exchange Rate Risk

As a result of services provided by non-related entities in the United States, Canada, United Kingdom and Europe, part of our financial assets and liabilities and foreign currency denominated transactions are affected by movements in the applicable exchange rate. We do not enter into any hedging transactions. We enter into forward rate foreign exchange rate contracts in respect of the settlement of supplier invoices denominated in U.S. dollars to mitigate the risk of movements in the Australian dollar and U.S dollar exchange rates. As of June 30, 2024 and June 30, 2023, we had US$141.4 million and US$60.4 million, respectively, in net exposure to the Australian dollar and U.S. dollar, primarily in payables and cash. An increase or decrease of the Australian dollar to U.S. dollar exchange rate by 10% would increase our after-tax loss by US$9.0 million (2023: US$3.8 million) or decrease our after tax loss by US$11.0 million (2023: US$4.7 million), respectively. As we continue our clinical development activities, we expect to face continued exposure to exchange rate risk from the U.S. dollar. There was minimal or insignificant exposure to the British Pound, Euro and Canadian dollar during the years ended June 30, 2023 and 2024.

Emerging Growth Company Status

As a company with less than US$1.235 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and

- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information that we provide shareholders and holders of the ADSs may be different than you might obtain from other public companies. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than US$1.235 billion in annual revenue; (ii) the last day of the fiscal year in which we qualify as a "large accelerated filer"; (iii) the date on which we have, during the previous three-year period, issued more than US$1.0 billion in non-convertible debt securities; and (iv) June 30, 2026.

Foreign Private Issuer Status

We are also considered a "foreign private issuer" under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our senior management, the members of our board of directors and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as

promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that 50% or more of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of board of directors or our senior management are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this annual report. Accordingly, the information contained herein may be different from the information you receive from other public companies.

Item 6. Directors, Senior Management and Employees

6A. Directors and Senior Management

The following table sets forth information relating to our directors, senior management and key employees as of June 30, 2024.

Name	Age	Position
Senior Management and Key Employees		
Fred Guerard (1)	52	Chief Executive Officer
Megan Baldwin, Ph.D.	49	Chief Innovation Officer and Executive Director
Peter Lang (1)	52	Chief Financial Officer
Timothy E Morris (2)	62	Chief Financial Officer
Karen Adams	53	Vice President Finance and Company Secretary
Judith Robertson	64	Chief Commercial Officer
Kevin Bitter	32	Vice President, Strategy & Corporate Development
Joel Naor (3)	61	Chief Medical Officer
Mark O'Neill	58	Vice President Chemistry, Manufacturing and Controls
Fang Li	60	Senior Vice President Regulatory
Julie Clark	49	Senior Vice President Clinical Development
Bruno Gagnon	56	Senior Vice President Global Clinical Operations
Non-Employee Directors		
Julia Haller, M.D.	69	Director
Jeremy Levin, D.Phil, MB BChir	70	Chairperson
Lawrence Gozlan	45	Director
Sujal Shah	51	Director
Susan Orr	62	Director
Anshul Thakral	46	Director
Daniel Spiegelman (4)	66	Director
Quinton Oswald	73	Director

(1) Dr Guerard and Mr. Lang were appointed October 27, 2023.
(2) Mr. Morris's employment was terminated October 24, 2023.
(3) Dr. Naor resigned on July 15, 2023.
(4) Mr.Spiegelman resigned as a director in April 2024.

The business addresses for our senior management and board of directors is Opthea Limited, Suite 0403, Level 4, 650 Chapel Street, South Yarra, VIC 3141, Australia.

Senior Management and Key Employees

Frederic Guerard, PharmD, MS has served as our Chief Executive Officer since October 2023. Dr. Guerard's career in the pharmaceutical industry spans over 25 years and includes multiple leadership, strategic and commercial roles. Dr.Guerard served as the Chief Executive Officer of Graybug Vision, Inc., a clinical-stage pharmaceutical company developing potentially transformative therapies for ocular diseases. He led the clinical development of a late-stage wet AMD product candidate. Dr.Guerard led the merger of Graybug with CalciMedica, Inc. and remains a non-executive Board member of CalciMedica. Before Graybug, Dr.Guerard acted as the Worldwide Business Franchise Head of Ophthalmology at Novartis. In this role, he successfully led the integration of Novartis retina and Alcon Pharmaceuticals and accelerated the rejuvenation of the product pipeline through strategic acquisitions and licensing transactions in dry-eye, presbyopia, and inherited retinal diseases. Prior to this role, he served as Global Franchise Head of Pharmaceuticals at Alcon. He has also held multiple leadership positions at Novartis, including Head of United Kingdom and Ireland, Head and Country President of Australia and New Zealand, Head of Marketing and Sales for Emerging Growth Markets Region, Head and Country President Egypt, and Cluster Head North and West Africa. He has served on the Board of the Association of the British Pharmaceutical Industry (ABPI) and on the Board of Medicines Australia.

Megan Baldwin, Ph.D., has served as our Founder, Chief Executive Officer and Executive Director since October 2023. From October 2023. Previously, Dr. Baldwin has served as our Chief Executive Officer and Managing Director from February 2014 until October 2023 Dr. Baldwin has served as our Founder, Chief Innovation Officer and Executive Director. Since joining our company in 2008, Dr. Baldwin has held various positions, including Head of Preclinical R&D from February 2009 to November 2012 and Chief Executive Officer of Opthea Pty Ltd., previously a wholly-owned subsidiary, from November 2012 to December 2015. Dr. Baldwin has over 20 years of experience focusing on angiogenesis and therapeutic strategies for ophthalmic and cancer indications. Prior to joining our company, Dr. Baldwin was employed at Genentech, Inc. (now a subsidiary of the Roche Group), a leader in the field of angiogenesis-based therapies for cancer and other diseases. Dr. Baldwin earned a Bachelor of Science with Honours and a Ph.D. in Medicine from the University of Melbourne. We believe that Dr. Baldwin's business expertise and her daily insight into corporate matters as our Chief Innovation Officer qualify her to serve on our board of directors.

Peter Lang, has served as our Chief Financial Officer since October 2023. Mr. Lang comes to Opthea with over 25 years of experience delivering strategic, operational, and financial solutions, with deep expertise in the healthcare and biopharmaceutical sectors. He has held leadership roles at biopharmaceutical companies and well-recognized global and boutique investment banks. In addition, Mr. Lang has a long track record of working with management teams and boards to optimize companies' growth plans, capital structures, and return on capital. Prior to joining Opthea, Mr. Lang served as the Chief Financial Officer of Aerie Pharmaceuticals, Inc., a fully integrated pharmaceutical company focused on the discovery, development, and commercialization of first-in-class ophthalmic therapies for the treatment of patients with eye diseases. He co-led the successful strategic and financial repositioning of Aerie, including reinvigorating its commercial glaucoma franchise, refocusing the R&D pipeline, and improving the financial and operation results of the Company, ultimately resulting in a ~$950 million cash acquisition of Aerie by Alcon AG. Before Aerie, Peter was Managing Director and Partner at Ridge Advisory, LLC, a boutique advisory and banking firm. Prior to his work at Ridge Advisory, Mr. Lang served in various leadership roles in the healthcare investment banking divisions of well-respected firms, including HSBC, Bank of America Merrill Lynch, UBS Investment Bank, and Leerink Partners.

Timothy Morris, served as our Chief Financial Officer from October 2022 to October 2023. Mr. Morris is a veteran pharmaceutical executive with extensive professional finance and accounting background in both public and private companies, including over 25 years in public biotechnology companies as CFO. Prior to joining Opthea, he served as Chief Operating Officer/Chief Financial Officer at Humanigen, Inc. since August 2020. Previously, Mr. Morris was Chief Financial Officer of Iovance Biotherapeutics which raised over US$1 billion in four offerings to fund expansion of the clinical development program, build manufacturing capability and to prepare for commercialization. Prior to IOVA, Mr. Morris was Chief Financial Officer of AcelRx Pharmaceuticals, VIVUS Inc., and Questcor Pharmaceuticals Inc. He is currently on the Board of Directors of DBV Technologies S.A., Aquestive Therapeutics, Humanetics Corporation and Univercells S.A. Mr. Morris earned his Bachelor of Science in Business from California State University, Chico.

Karen Adams, has served as our Vice President Finance since May 2021 and as our Company Secretary since June 2021. Prior to joining Opthea, Ms Adams was the Chief Financial Officer of the Victor Smorgon Group, an investment management company, from December 2018 to May 2021. From February 2014 to August 2018, she served as the Director of Finance of Nexvet Biopharma Pty Ltd, a veterinary biologic therapeutics company. Karen holds a Graduate Degree in Business from Swinburne University and is a member of the Australian Society of Chartered Accountant, Graduate of Australian Institute of Company Directors and a Fellow of the Institute of Company Secretaries.

Judith Robertson has served as our Chief Commercial Officer since January 1, 2022. Ms. Robertson served as a member of our board of directors from June 2021 to January 1, 2022. Since 2019, Ms. Robertson has served as a member of the board of directors of Durect Corporation, a biotechnology company. From December 2020 to April 2021, Ms. Robertson served as the Chief Commercial Officer of Eleusis Ltd. From December 2016 she served as the Chief Commercial Officer of Aerie Pharmaceuticals Inc., a publicly held biotechnology company. Prior to Aerie, Ms. Robertson was Vice President Immunology and Ophthalmology Global Commercial Strategy Leader at Johnson and Johnson, Janssen Pharmaceuticals, and Vice President, Ophthalmology Global Business Franchise Head at Novartis (formerly Alcon). Ms. Robertson's prior experience also includes sales and marketing roles at Novartis, Bristol Myers Squibb and Searle USA. Ms. Robertson received Bachelor of Arts from Ryerson University and a Master of Business Administration from Kellogg School of Management at Northwestern University.

Julie Clark MD has served as our Senior Vice President of Clinical Development of Opthea since February 2024. Dr. Clark brings more than 15 years of experience in ophthalmology and clinical development, encompassing expertise in early and late-stage development programs, regulatory submissions, and approvals. Her impactful contributions contributed to the approval and successful launches of several pivotal retinal therapies, including Eylea, Jetrea, and Beovu. Previously, as the Chief Medical Officer at Adverum, Dr. Clark played a pivotal role in pioneering intravitreal gene therapy for retinal diseases. In her most recent role as Vice President Clinical Development at IvericBio, an Astellas Company, she led the clinical development program that culminated in the August 2023 FDA approval of Izervay – an innovative complement inhibitor indicated for the treatment of geographic atrophy secondary to age-related macular degeneration. Dr. Clark earned an M.D. from Wake Forest University School of Medicine and holds a B.S. in Biology from Wake Forest University. Additionally, she earned an M.S. in Biotechnology from the Center for Biotechnology Education and Advanced Biotechnology Studies at Johns Hopkins University. Her academic achievements underscore her commitment to excellence in ophthalmology, medical research, and patient care

Fang Li PhD has served as our Senior Vice President Regulatory Affairs of Opthea since February 2024. Dr. Li is an accomplished regulatory affairs professional with over three decades of experience in pharmaceutical development and regulatory affairs. She has held leadership positions at Novartis, Alcon, and Bausch & Lomb, where her contributions encompass health authority interactions, U.S. Food and Drug Administration advisory committee meetings, and guiding regulatory teams. Dr. Li's significant achievements include her pivotal role in securing FDA approvals for numerous ophthalmology products, including Jetrea, Lotemax Ointment, and Systane Complete. She also contributed to the development and registration of critical medicines, including Beovu, Pazeo, Lotemax Gel, Besivance, and Vyzulta. Dr. Li received a Regulatory Affairs certification in 2005. She possesses a comprehensive skill set that spans various pharmaceutical domains including expertise in Chemistry, Manufacturing, and Controls, clinical development, product labeling, advertising and promotion.

John Han PharmD has served as our Vice President, Medical Affairs of Opthea since April 2024. Dr. Han's career in biotechnology and pharmaceutical industry spans over 25 years, with 19 years in ophthalmology. He brings experience in early and late-stage drug development in both anterior and posterior ophthalmology. He has a proven track record of success in supporting several product launches, including launch of Eylea for multiple retinal indications. Recently, Dr. Han held the position as Vice President of Medical Affairs at Adverum. He has held various prominent leadership positions in the industry as well as in pharmacy practice. Industry experience spans various therapeutic areas in ophthalmology, oncology, cardiology, and metabolism, working with small molecules, biologics, and gene therapies. Prior experience includes work at Regeneron, Amgen, Chiron, and Bayer. He also served as a faculty member in academia. Dr. Han holds a PharmD from University of California San Francisco School of Pharmacy and a graduate from University of California Berkeley in Immunology and Microbiology.

Mark O Neill MSc. B Chem Eng, has served as our Vice President of Chemistry, Manufacturing and Controls since January 2022. Mr. O'Neill was most recently head of Process Development for Avexis Gene therapies where he orchestrated all product development and technical operations activities pertaining to the startup and licensure of Zolgensma drug substance manufacturing at the Colorado site. Prior to Avexis, he was Vice President and General Manager of the Thermo Fisher Groningen Single Use Biologics Manufacturing Facility in Groningen, The Netherlands, where he oversaw all operations including startup of commercial manufacturing and initial commercial licensure at the facility. Mr. O'Neill has over 30 years of experience in the manufacturing of biopharmaceuticals including 20 years with Amgen where he gained extensive experience in all aspects of lifecycle management including Quality, Engineering, Production, Development, Supply Chain and Business Development. Mark holds a Master of Science Degree from Colorado School of Mines in Environmental and Chemical Engineering and a Bachelor of Science Degree in Chemical Engineering from the University of Colorado

Bruno Gagnon, has served as our Senior Vice President, Global Clinical Operations since July 2022. Mr Gagnon is former Sr. Vice President of Development Operations at Eidos Therapeutics, a BridgeBio company in San Francisco, CA. Mr. Gagnon also served as Vice President of Clinical Operations at BioMarin Pharmaceutical. Previously, held positions of increasing responsibilities at Roche Diagnostics, Chiron and Hoechst Marion Roussel (now Sanofi). Over his 30-year career, functions under his leadership have included Global Clinical Trial Management, Patient Advocacy, Medical Writing, Outsourcing and Contracts, Supply Chain Management, Clinical Data Management, Clinical Systems, Document Management and Clinical Training. He has earned a Bachelor's Degree from the School of Pharmacy, Laval University and a Master's in Pharmaceutical Sciences from University of Montreal, both in Quebec, Canada.

Kevin Bitter has served as our Vice President & Corporate Strategy since November 22, 2023. Kevin brings broad experience in strategic planning and corporate development for life sciences companies, including two completed M&A transactions. Most recently, he led business development at Graybug Vision to in-license several development programs for retinal and corneal diseases. Prior to Graybug, he was responsible for strategic projects at Corium. Kevin holds a BS in Finance and Marketing from New York University.

Non-Employee Directors

Jeremy Levin, D.Phil., MB Bchir has served as the Chairperson of our board of directors since October 2020. Since March 2015, Dr. Levin has served as the Chief Executive Officer, and since April 2014, as the chairperson of the board of directors, of Ovid Therapeutics Inc., a biopharmaceutical company. From May 2012 to October 2013, Dr. Levin served as the President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd., a publicly held pharmaceutical company. From September 2007 to December 2012, Dr. Levin held several roles at Bristol-Myers Squibb Company, a publicly held pharmaceutical company, ultimately serving as the Senior Vice President of Strategy, Alliances and Transactions. Dr. Levin also served as a member of the executive committee at Bristol-Myers Squibb Company. Dr. Levin earned a Bachelor of Arts in Zoology, Master of Arts in Cell Biology and D.Phil. in Chromatin Structure, all from University of Oxford, and a Bachelor of Medicine, Bachelor of Surgery from the University of Cambridge. We believe Dr. Levin's extensive experience in the global biotechnology and pharmaceutical industry qualify him to serve on our board of directors.

Lawrence Gozlan has served as a member of our board of directors since July 2020. Since 2007, Mr. Gozlan has served as the Life Sciences Investment Manager of Jagen Pty Ltd., an international investment organization. Mr. Gozlan has also served as a member of the board of directors of Alterity Therapeutics Ltd., a drug development company, since 2011. Mr. Gozlan earned a Bachelor of Science in Microbiology and Immunology from the University of Melbourne. We believe Mr. Gozlan's extensive investment experience in biotechnology and life sciences companies qualify him to serve on our board of directors.

Julia Haller, M.D. has served as a member of our board of directors since June 2021. Since 2007, Dr. Haller has served as Ophthalmologist-in-Chief and William Tasman, ME Endowed Chair at Wills Eye Hospital in Philadelphia. Dr. Haller is Professor and Chair of the Department of Ophthalmology at the Sidney Kimmel Medical College at Thomas Jefferson University as well as a director of Bristol Myers Squibb, a biopharmaceutical company and Outlook Therapeutics, a biopharmaceutical company. She is also a member of the National Academy of Medicine, the Chair of the College of Physicians of Philadelphia, Chair of the Heed Ophthalmic Society, past president of the Women in Medicine Legacy Foundation, and serves on several prestigious boards including John Hopkins Medical and Surgical Association (immediate past president), the Association of University Professors of Ophthalmology, and the Society of Heed Fellows. Dr. Haller received a Bachelor of Arts from Princeton University and an M.D. from Harvard Medical School. We believe Dr. Haller's extensive experience as an internationally recognized ophthalmologist and vitreoretinal surgeon qualify her to serve on our board of directors.

Susan Orr, OD has served as a member of our board of directors since April 2022. Dr. Orr is an experienced medical and business leader with specialization in identifying, developing, and commercializing ophthalmic therapeutic product candidates. Since February 2020, Dr. Orr has served as the Chief Medical Officer at Claris Biotherapeutics, a biotechnology firm, and is a member of the Retina Global Board of Directors. From October 2018 to November 2019, Dr. Orr was the Chief Executive Officer at Notal Vision, an ophthalmic remote monitoring service provider. From July 2016 to September 2018, Dr. Orr served as Notal Vision's Chief Medical Officer and Vice President of Medical Affairs. Prior to joining Notal Vision, Dr. held leadership roles at Alcon and Janssen across Marketing, Strategy, Business Development, and multiple Development functions, following 10 years in private practice in Canada. Dr. Orr earned a Bachelor of Science and a Doctor of Optometry from the University of Waterloo. We believe Dr. Orr's extensive experience in ophthalmology and leadership qualifies her to serve on our board of directors.

Quinton Oswald has served as a member of our board of directors since April 2022. Mr. Oswald brings over 25 years of international general management experience, including onsite assignments in the U.S, Europe and South Africa. From April 2016 to December 2018, Mr. Oswald was the Chief Executive Officer of Notal Vision, a commercial stage ophthalmic home monitoring services provider with a focus on both wet and dry AMD. From April 2013 to April 2016, Mr. Oswald served as the President and Chief Executive Officer of Neurotech Pharmaceuticals, a biotechnology research company, and from September 2010 to April 2013, as the Chief Executive Officer of SARcode Bioscience, an ophthalmic biopharmaceutical company. We believe Mr. Oswalds extensive leadership experience in biotechnology companies qualifies him to serve on our board of directors.

Sujal Shah has served as a member of our board of directors since April 2024.Mr. Shah is an accomplished biopharmaceutical executive with extensive leadership and product development experience and a track record in capital formation that complements the deep expertise in retinal disease, especially wet AMD, of the Opthea Board. Most recently, Mr. Shah served as President and Chief Executive Officer of CymaBay Therapeutics which was acquired by Gilead Sciences for approximately $4.3 billion in total equity value in March 2024

Daniel Spiegelman has served as a member of our board of directors since September 2020 to his resignation in April 2024. From May 2012 to January 2020, Mr. Spiegelman served as Executive Vice President, Chief Financial Officer of BioMarin Pharmaceutical Inc., a biotechnology company. Mr. Spiegelman currently serves as Board Chairman for Tizona Therapeutics, and Audit Committee Chairman and for Myriad Genetics (NASDAQ: MYRD), Spruce Biosciences (NASDAQ: SPRB), Maze Therapeutics and Kyverna Therapeutics, and has previously served as board director for several other companies. Mr. Spiegelman has also served as a Venture Partner with Samsara BioCapital Since May 2023. From October 2008 to March 2018, Mr. Spiegelman served as a member of the board of directors of Cascadian Therapeutics, Inc., a publicly held biotechnology company that was acquired by Seattle Genetics, Inc. in 2018. From May 2009 to May 2012, Mr. Spiegelman served as a consultant to provide strategic financial management support to a portfolio of public and private life science companies. Mr. Spiegelman has also served as a member of the board of directors of Myriad Genetics, a molecular diagnostic company, since May 2020. Mr. Spiegelman earned a Bachelor of Arts from Stanford University and a Master of Business Administration from the Stanford Graduate School of Business. We believe Mr. Spiegelman's extensive leadership experience in biotechnology and pharmaceutical companies qualify him to serve on our board of directors.

Anshul Thakral has served as a member of our board of directors since June 2023. Mr. Thakral is Chief Executive Officer and Board Member of Launch Therapeutics, a clinical development company backed by funds managed by global investment firm Carlyle and its life sciences franchise, Abingworth. Mr. Thakral has worked for over 20 years in the pharmaceutical and biotechnology industry and is an experienced executive, management consultant and entrepreneur. Mr. Thakral was previously Chief Commercial Officer and Executive Vice President of Peri and Post-Approval Services at PPD, and prior to that was Global Head of PPD Biotech. Before PPD, Mr. Thakral ran the global life sciences business unit at Gerson Lehrman Group and worked at McKinsey & Company as an associate principal in the health care practice, where he provided strategic advice to global pharmaceutical and biotechnology companies on growth, research and development, business development and commercialization. He currently serves on the boards of TriNetX, Saama Technologies, Orsini Specialty Pharmacy, is an Operating Executive at Carlyle and is a Venture Partner at Abingworth. Mr. Thakral holds a Master's degree in Biomedical Engineering from Johns Hopkins University and a Masters Business Administration (MBA) from the Wharton School at the University of Pennsylvania. We believe Mr. Thakral's extensive experience in the global biotechnology and pharmaceutical industry qualifies him to serve on our board of directors.

Family Relationships

There are no family relationships among any of the members of our board of directors and our senior management.

Board Diversity Matrix

The following board diversity matrix sets forth the information concerning the gender, demographic background and certain other characteristics of our board of directors as of the date of this annual report, as self-identified by its members, in accordance with Rule 5606 of the Nasdaq Listing Rules.

Board Diversity Matrix (As of August 6, 2024)				
Country of Principal Executive Offices:	Australia			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	8			
	Female	**Male**	**Non- Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	3	5	-	-
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	-			
LGBTQ+	-			
Did Not Disclose Demographic Background	1			

6B. Compensation

Overview

Our remuneration policy is to align director and senior management objectives with shareholder and business objectives by providing a fixed remuneration component and typically offering long-term incentives based on key performance areas. Our board of directors believes the remuneration policy to be appropriate and effective in its ability to attract and retain the best executives and directors to run and manage the consolidated entity, as well as create goal congruence between directors, executives and shareholders. Our board of directors and the Remuneration Committee are responsible for determining the appropriate remuneration package for our senior management, including our Chief Executive Officer.

Australian executives and directors receive a superannuation guarantee contribution required under Australian law and do not receive any other retirement benefits.

Remuneration of Senior Management

For the fiscal year ended June 30, 2024, the aggregate cash remuneration paid to our senior management was US$2,805,182 (2023:US$2,420,219).

Our senior management receive fixed compensation and performance-linked remuneration. The level of fixed remuneration is set to provide a base level of compensation which is both appropriate to the applicable position and is competitive in the marketplace. The Remuneration Committee accesses external advice independent of senior management if required. Fixed compensation is comprised of base salary and superannuation contribution and is reviewed every 12 months by the Remuneration Committee.

Performance-linked remuneration consists of short-term and long-term incentives. The objective of short-term incentives is to link the achievement of our operational targets with the remuneration received by our senior management charged with meeting those targets. Total potential short-term incentives are set at a level that we believe provides sufficient incentive to our senior management to achieve the operational targets at a cost to us that is reasonable under the circumstances. Short-term incentives may include cash bonuses based on the extent to which specific targets set at the beginning of each fiscal year are met. The targets consist of a number of key performance indicators covering corporate objectives and individual measures of performance. Individual performance indicators are linked to our development plans. Our Remuneration Committee determines, on an annual basis and after consideration of performance against the key performance indicators, the amount, if any, of short-term incentives payable to our senior management. Payments of short-term incentive bonuses are made in the following reporting period.

We also provide long-term incentives through option grants under our Long-Term Incentive Plan. The objective of the Long-Term Incentive Plan is to reward our management and key employees in a manner that aligns this element of compensation with the creation of shareholder wealth. Long Term Incentive Plan grants are made to senior management and employees who are able to influence the generation of shareholder wealth and have a direct impact on our performance and development. Option vesting conditions are based on continued service to us.

In making remuneration determinations for our senior management, the Remuneration Committee considers operational contributions by our senior management as well as the following performance indicators: revenue, loss before tax, tax benefit, loss after tax, basic loss per ordinary share, net tangible assets per share and changes in prevailing trading prices of our ordinary shares on the ASX.

Remuneration of Non-Employee Directors

Our non-employee directors receive a fixed fee annually, which is reviewed by our board of directors on an annual basis. Dr. Orr and Mses. Haller, and Messrs. Oswald, Thakral and Gozlan are each entitled to an annual fixed fee of US$50,000/A$65,700,. Mr. Spiegelman was entitled to an annual fixed fee of US$75,000 (inclusive of fees for his service as chairperson of the audit and risk committee and nominations and governance committee member fee up until his resignation). Mr Shah is entitled to an annual fix fee of US$70,000 (inclusive of fees for his service as chairperson of the audit and risk committee) pro rata for the service period served. Dr. Levin is entitled to an annual fixed fee of US$75,000 (for his service as chairperson of the board of directors). Board members are entitled to an annual fixed fee of US$10,000/A$13,140 for service as Chair of any other committees and US$5,000/A$6,570 for service on any other committee in a non-Chair role. Unless otherwise noted, the fixed fees cover both service on the board of directors and committees of the board of directors. The remuneration of our non-employee directors is reviewed by our board of directors on an annual basis. Non-employee directors are not provided with retirement benefits apart from statutory superannuation, which is only applicable to Australian resident directors. Non-employee directors are reimbursed for costs directly related to conducting business related to their service on our board of directors.

We implemented a non-executive director share and option plan, or the NED Plan, in 2014. Under the NED Plan, present and future non-executive directors may:

- elect to receive ordinary shares or options to purchase ordinary shares in lieu of receiving some or all of their annual fixed fee;
- be awarded ordinary shares or options to purchase ordinary shares in lieu of additional cash remuneration in respect of services provided to the Company which in the opinion of the board of directors are outside the scope of the ordinary duties of the relevant director; and
- otherwise be awarded ordinary shares or options to purchase ordinary shares as part of the directors' remuneration in addition to any existing cash remuneration paid to directors (if any).

The NED Plan is designed to assist us in preserving our cash for use toward advancing the clinical development of our product candidate and provide our non-employee directors an opportunity to demonstrate their commitment and support for us through sacrificing some or all of their cash fees for ordinary shares or options. The NED Plan also provides us with further flexibility in the design of the directors' remuneration packages and in turn assists us with retaining existing directors and attracting new additional directors with the relevant experience and expertise.

For the fiscal year ended June 30, 2024, the aggregate cash remuneration paid to our non-employee directors was US$715,794 (2023:US$615,492), including Nil in cash reimbursements.

Employment Agreements with Senior Management

The key provisions of the employment agreements are set out below for each member of our senior management. None of these employment agreements have termination dates. The base salary under the employment agreements may be increased by the board of directors from time to time.

Officer	Date of Agreement	Base Salary	Termination without Cause	Benefits upon Termination without Cause
Fred Guerard *Chief Executive Officer (from October 27, 2023)*	October 27, 2023	US$550,000 per year	Not less than twelve months' notice or payment in lieu of notice period (if by us)	Upon notice of termination by us any options that have vested or will vest during the notice period will be released, all other options will lapse at the discretion of our board of directors
Megan Baldwin, Ph.D. *Chief Innovation Officer and Executive Director*	April 23, 2014	A$609,500 per year	Not less than three months' notice (if by employee) Not less than twelve months' notice or payment in lieu of notice period (if by us)	Upon notice of termination by us, any options that have vested or will vest during the notice period will be released; all other options will lapse at the discretion of our board of directors.
Karen Adams *Vice President Finance and Company Secretary*	June 15, 2021	A$353,510 per year	Not less than three months' notice (if by employee) Not less than three months' notice or payment in lieu of notice period (if by us	Not applicable.
Peter Lang *Chief Financial Officer (from October 27, 2023)*	October 27, 2023	US$500,000 per year	Not less than twelve months' notice or payment in lieu of notice period (if by us)	Upon notice of termination by us any options that have vested or will best during the notice period will be released, all other options will lapse at the discretion of our board of directors
Timothy Morris *Chief Financial Officer (until October 24, 2023)*	October 24, 2022	US$475,000 per year	Not less than twelve months' notice or payment in lieu of notice period (if by us)	Upon notice of termination by us, any options that have vested or will vest during the notice period will be released; all other options will lapse at the discretion of our board of directors
Judith Robertson *Chief Commercial Officer*	January 1, 2022	US$413,400 per year	Not less than twelve months' notice or payment in lieu of notice period (if by us	Upon notice of termination by us, any options that have vested or will vest during the notice period will be released; all other options will lapse at the discretion of our board of directors

Upon termination of employment, our senior management are entitled to receive their statutory entitlements of accrued annual and long service leave, together with any superannuation benefits.

Remuneration of Our Non-Employee Directors and Senior Management During the Fiscal Year Ended June 30, 2024

Details of the remuneration of our non-employee directors and senior management for the fiscal year ended June 30, 2024 are set forth below in US$.

		Short-Term Incentive		Post-Employment			
	Salary/ Fees[1]	Cash Bonus[2]	Benefits	Superannuation/ 401k plan	Termination	Share-Based Payment	Total
Non-Employee Directors							
Anshul Thakral (3)	$ 60,852	$ —	$ —	$ —	$ —	$ 42,866	$ 103,718
Daniel Spiegelman (8)	56,327	—	—	—	—	390,830	447,157
Jeremy Levin	76,950	—	—	—	—	232,475	309,425
Julia Haller	58,049	—	—	—	—	112,202	170,251
Lawrence Gozlan[4]	310,247	—	—	—	—	480,268	790,515
Quinton Oswald	71,098	—	—	—	—	64,708	135,806
Sujal Shah (5)	16,722	—	—	—	—	—	16,722
Susan Orr	65,549	—	—	—	—	64,708	130,257
Senior Management					—		
Fred Guerard (6)	373,012	187,030	31,701	5,526	—	720,870	1,318,139
Megan Baldwin, Ph.D.	399,470	144,446	—	58,257	—	757,529	1,359,702
Peter Lang (6)	339,102	127,520	36,072	5,026	—	653,558	1,161,278
Timothy Morris (7)	160,340	—	1,319	—	475,000	(109,703)	526,956
Karen Adams	231,693	42,447	—	30,230	—	161,798	466,168
Judith Robertson	413,400	148,824	37,264	4,252	—	111,355	715,095
Joel Naor	26,534	—	—	1,714	—	(468,848)	(440,600)

(1) For our non-employee directors, amounts set forth in this column include our reimbursement of expenses incurred in connection with performance of services relating to board service.

(2) Bonuses are paid in the fiscal year following the year in which they were earned.

(3) Mr Anshul Thakral was appointed as a non-executive director on June 7, 2023.

(4) Mr.Gozlan received a payment of $125,00 under consultancy agreement for assisting in the 2023 capital raise.and received a bonus for assisting with the DFA funding of A$150,000 Mr. Gozlan's annual director fee is A$65,700.

(5) Mr Sujal Shah was appointed as a non-executive director on April 4, 20243.

(6) Dr. Guerard and Mr Lang were appointed as CEO and CFO, respectively on October 27, 2023.

(7) Mr. Timothy Morris was appointed as CFO on October 24, 2022 and was terminated on October 24, 2023.

(8) Mr. Spiegelman resigned as a director in April 2024.

Details of options held by our non-employee directors and senior management as of June 30, 2024 are set forth below.

	Number of Options/rights/ADS Options	Grant Date	Exercise Price	Percentage Vested[1]	Last Vesting Date	Expiration Date
Non-Employee Directors[2]						
Lawrence Gozlan	2,000,000	10/12/2020	$ 3.24	100%	10/11/2023	10/11/2024
Lawrence Gozlan	500,000	11/16/2022	Nil	100%	11/15/2032	11/16/2032
Lawrence Gozlan	2,000,000	11/16/2022	0.658	21%	11/15/2032	11/16/2032
Lawrence Gozlan	500,000	11/30/2023	0.382	19%	11/30/2026	11/30/2033
Julia Haller	2,000,000	10/19/2021	0.948	50%	10/19/2024	10/18/2025
Jeremy Levin	3,000,000	01/19/2021	1.56	75%	01/19/2024	01/18/2025
Jeremy Levin	3,000,000	11/30/2023	0.38	19%	11/30/2026	11/30/2033
Michael Sistenich	1,500,000	11/16/2022	0.658	21%	11/29/2019	11/29/2022
Daniel Spiegelman	2,000,000	10/12/2020	2.16	75%	10/11/2023	10/11/2024
Daniel Spiegelman	2,000,000	11/16/2022	0.672	21%	11/15/2032	11/16/2032
Daniel Spiegelman	150,000	11/16/2022	Nil	100%	11/15/2032	11/16/2032
Susan Orr	1,000,000	04/21/2022	0.948	75%	04/21/2025	04/20/2026
Quinton Oswald	1,000,000	04/21/2022	0.948	75%	04/21/2025	04/20/2026
Anshul Thakral	1,000,000	11/30/2023	0.382	19%	11/30/2026	11/30/2033
Senior Management						
Fred Guerard (3)	1,400,000	10/27/2024	1.66	0%	10/27/2028	11/27/2033
Fred Guerard(3)	600,000	10/27/2024	1.66	0%		11/27/2033
Megan Baldwin, Ph.D. (4)	3,000,000	11/16/2022	0.658	21%	11/29/2019	11/29/2022
Megan Baldwin, Ph.D. (4)	1,600,000	10/19/2021	Nil	11%	09/30/2024	10/18/2031
Megan Baldwin, Ph.D. (4)	500,000	11/16/2022	Nil	100%	11/15/2032	11/16/2032
Megan Baldwin, Ph.D. (4)	3,000,000	11/30/2023	0.261	19%	11/30/2026	11/30/2033
Peter Lang (3)	1,300,000	27/10/2024	1.660	0%	10/27/2028	11/27/2033
Peter Lang (3)	300,000	27/10/2024	1.660	0%		11/27/2033
Tim Morris (3)	300,000	10/24/2022	4.850	0%	10/23/2032	10/24/2032
Karen Adams (4)	800,000	06/06/2022	1.460	75%	06/06/2025	06/05/2032
Karen Adams (4)	150,000	11/16/2022	Nil	100%	11/15/2032	11/16/2032
Karen Adams (4)	800,000	10/10/2023	0.205	0%	10/10/2027	10/10/2033
Judith Robertson (4)	2,000,000	10/19/2021	0.948	50%	10/19/2024	10/18/2025
Joel Noar (3)	300,000	03/01/2022	6.090	25%	02/28/2026	03/01/2032

(1) No options lapsed or were forfeited during the fiscal year ended June 30, 2024 or 2023.

(2) Non-employee director options are in ordinary shares.

(3) ADS options (one ADS option equals 8 ordinary shares).

(4) Options in ordinary shares.

6C. Board Practices

Board of Directors

Our board of directors currently consists of eight members, including Dr. Baldwin, our Chief Innovation Officer and Executive Director. Directors are elected at our annual general meeting of shareholders. Under our Constitution, at the close of each annual general meeting one-third of the directors, other than the Managing Director, or if their number is not a multiple of three, then the number nearest to but not more than one-third of the directors must retire. In addition, a director, other than the managing director, must retire from office at the conclusion of the third annual general meeting of shareholders after the director was last elected, even if his or her retirement results in more than one-third of all directors retiring from office. A retiring director remains in office until the end of such shareholder meeting and will be eligible for re-election at that meeting.

The membership of our board of directors is directed by the following requirements as set forth in our Constitution and our Board Charter, as applicable:

- there will be a minimum of three directors and a maximum of 10, and our board of directors may determine the number of directors within those limits;
- the majority of our board of directors should be independent;
- our board of directors has the power to appoint any person to be a director, either to fill a vacancy or as an additional director (provided that the total number of directors does not exceed the maximum number of directors permitted), and any director so appointed will hold office until the end of the next annual general meeting when he or she may be re-elected; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience and time commitment to properly fulfill its responsibilities.

Our board of directors has delegated responsibility for the management of our businesses to the Chief Executive Officer but remains responsible for overseeing the performance of management. The principal roles and responsibilities of our board of directors include the following:

- review, evaluate, provide input into and approve our business plan;
- monitor senior management's performance and implementation of strategy, and ensure appropriate resources are available;
- review, evaluate and approve and monitor major resource allocations and capital investments, and acquisitions and divestitures;
- review, evaluate, approve and monitor major resource allocations and capital investments, and acquisitions and divestitures;
- review and monitor our financial and operating results;
- review, evaluate and approve the overall corporate organizational structure, the assignment of senior management responsibilities and plans for senior management development and succession;
- review, evaluate and approve compensation strategy as it relates to our senior management; and
- review and ratify systems of risk management and internal compliance and control, codes of conduct and legal compliance.

Our board of directors has established delegated limits of authority, which define the matters that are delegated to management and those that require board of director approval. Under the Corporations Act, at least two of our directors must be resident Australians. None of our non-employee directors have any service contracts with us that provide for benefits upon termination of employment. Under our Board Charter, the board of directors is required to meet at least six times per year.

Board Committees

To assist with the effective discharge of its duties, the board of directors has established an Audit and Risk Committee, a Remuneration Committee, Research and Development Committee and a Nomination and Governance Committee. Each committee operates under a charter approved by our board of directors, which sets forth the purposes and responsibilities of the committees as well as qualifications for committee membership, committee structure and operations and committee reporting to the board of directors.

Audit and Risk Committee

The members of our Audit and Risk Committee are Messrs. Shah, Oswald and Dr Orr. Our board of directors has determined that each of Messrs. Shah and Oswald and Dr Orr satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) under the Exchange Act. The chairperson of our Audit and Risk Committee is Mr. Shah. Our board of directors has determined that Mr. Shah is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our Audit and Risk Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each member's scope of experience and the nature of his or her employment.

The charter for our Audit and Risk Committee requires the committee to consist of at least three directors, each of whom must be non-employee directors and a majority of which must be independent directors. The chairperson of our Audit and Risk Committee must be an independent director and cannot be the chairperson of our board of directors. The Audit and Risk Committee is required to hold at least one regular meeting per fiscal quarter and must review its charter at least annually.

The role of the Audit and Risk Committee is to advise our board of directors in discharging responsibilities of our board of directors with respect to our financial reporting including accounting standards, internal control integrity and compliance, external audit activities including auditor appointment, independence, terms of engagement and fees and business risk management. Specific responsibilities of our Audit and Risk Committee include:

- reviewing accounting standards and quarterly and annual financial statements prior to referral to the board of directors;
- monitor developments likely to affect financial reporting including legislative pronouncements or disclosure requirements, as they affect both current and future years;
- review any unusual transactions, pending litigation, outstanding claims or contingencies which the management, auditors or legal counsel believe may have a material effect on the financial position or operations and the manner in which these matters are disclosed in financial statements;
- evaluating internal control policies and procedures;
- making recommendations to the board of directors on the appointment, reappointment or replacement of external auditors;
- evaluating the independence and effectiveness of external auditors and preapprove all audit and material non-audit services provided by external auditors;
- reviewing the results of the external audit and assess remedial action taken or proposed in audit reports;
- reviewing all representation letters signed by management to ensure that the information presented is complete and appropriate;
- monitoring risks and establish risk management policies;
- making recommendations to the board of directors regarding proposed changes to our risk management framework; and
- reviewing the schedule of insurance annually.

Remuneration Committee

The members of our Remuneration Committee are Messrs. Gozlan Thakral and Oswald. The chairperson of our Remuneration Committee is Mr. Gozlan. The objectives of the Remuneration Committee are to link remuneration to the creation of shareholder value, to offer competitive and appropriate remuneration for the business performance delivered and to put into place a remuneration framework that reflects the responsibilities of senior management while being sufficiently competitive to attract and retain high caliber performers. The charter of our Remuneration Committee requires the committee to consist of at least three directors, a majority of whom must be independent. The chairperson of our Remuneration Committee must be an independent director. The Remuneration Committee is required to hold at least one regular meeting each year. Specific responsibilities of our Remuneration Committee include:

- overseeing our remuneration strategy;
- ensuring remuneration policies and practices enable us to attract, motivate and retain a diverse mix of directors and senior management;
- fairly and responsibly remunerating directors and senior management;
- at least annually, reviewing and reporting on diversity of our employee base; and
- seeking information it considers necessary to fulfill its duties, including external advice.

Nomination and Governance Committee

The members of our Nomination and Governance Committee are Messrs. Thakral, Gozlan, and Levin. The chairperson of our Nomination and Governance Committee is Mr. Thakral. The role of the Nomination and Governance Committee is to assist our board of directors by identifying, reviewing and evaluating individuals qualified to become members of our board of directors, reviewing and recommending the nomination of directors and assisting the board of directors with other related tasks. The charter of our Nomination and Governance Committee requires the committee to consist of at least three directors, the majority of whom must meet the independence recommendations of the ASX Corporate Governance Council (as well as all applicable laws and regulations) and each of whom must be free of any relationship that, in the opinion of the board of directors, would interfere with his or her exercise of independent judgment. The members of the Nomination and Governance Committee will be appointed annually by the board of directors. The Nomination and Governance Committee is required to hold at least one regular meeting each year. Specific responsibilities of our Nomination and Governance Committee include:

- assisting in identifying, interviewing and recruiting candidates for the board of directors;
- reviewing potential director qualifications;
- preparing a description of the role and capabilities required for a particular role;
- at least annually, presenting to the board of directors a list of individuals recommended for nomination for election to the board of directors at the annual meeting of shareholders;
- planning succession of our directors;
- inducting and coordinating professional development programs for our directors;
- developing and implementing a process for evaluating the performance of the board of directors and its committees;
- managing the succession of our senior management;
- reviewing and making recommendations about changes to the charter of the Nomination Committee as required in the Committee's opinion; and

- annually review its own performance.

Research and Development Committee

The members of our Research and Development Committee are Messrs. Thakral, Oswald, and Dr Haller and Dr Orr. The chairperson of our Research and Development Committee is Dr Orr. The role of the Research and Development Committee is to guide and oversee and implement Opthea's Research and Development strategy of and recommend or make such changes to the strategy as the Committee may deem to be appropriate, including by not limited to the clinical development strategy, including the planning and design of clinical studies, Opthea's interactions with regulatory authorities and over all regulatory strategy and processes for products and the manufacture and supply of Opthea's product candidates. The charter of our Research and Development committee requires the committee to consist of at least three directors, the majority of whom must meet the independence recommendations of the ASX Corporate Governance Council (as well as all applicable laws and regulations) and each of whom must be free of any relationship that, in the opinion of the board of directors, would interfere with his or her exercise of independent judgment. The members of the Research and Development Committee will be appointed annually by the board of directors. The Research and Development Committee is required to hold at least one regular meeting each year. Specific responsibilities of our Research and Development Committee include:

- assisting the Board in overseeing Opthea scientific, technical, research and development strategy and the implementation thereof;
- review and provide input on the Intellectual Property portfolio;
- review and provide input on Regulatory Affairs strategy;
- review and provide input on CMC;
- review and provide input on Clinical Trial design and strategies; and
- provide assistance as requested, to the Remuneration Committee in setting performance goals under Opthea's incentive compensation program and reviewing the performance results in respect of Research & Development goals and objectives.

Code of Conduct

We have adopted a Code of Conduct applicable to all of our directors, officers and employees. Our Code of Conduct is available on our website at www.opthea.com. We post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the Code of Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of, this annual report.

6D. Employees

As of June 30, 2024, we had thirty-four full-time employees, fifteen of whom had an M.D. or Ph.D. degree. None of our employees are represented by collective bargaining agreements. We believe that our management maintains good relations with our employees. As of June 30, 2024, our employees were based in Australia (8) and the United States (26), with seventeen (27) employees in our research and development and commercialization department and seven employees in our general and administrative department.

6E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “Item 6B—Compensation” and “Item 7A—Major Shareholders.”

6F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable. The Company adopted a clawback policy in compliance with the Dodd-Frank Wall Street Reform and Consumer Protection Act, Exchange Act Rule 10D-1 and Nasdaq Listing Rule 5608, effective October 2, 2023. The clawback policy is attached as Exhibit 97.1 to this annual report.

Item 7. Major Shareholders and Related Party Transactions

7A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of August 20, 2024, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our ordinary shares;
- each member of our senior management;
- each of our directors; and
- all of our directors and senior management as a group.

To our knowledge, as of the date of this annual report, 92,468,272 of our ordinary shares (11,558,534 ADRs) were held by one record holder in the United States, representing approximately 7.0% of our total outstanding shares. The record holder is The Bank of New York Mellon, the depositary of our ADS program. The number of beneficial owners of our ADSs in the United States is likely to be much larger than the number of record holders of our ordinary shares in the United States.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we have included ordinary shares that the person has the right to acquire within 60 days of August 20, 2024, including through the exercise of any option, warrant or other right or the conversion of any other security. These ordinary shares, however, are not included in the computation of the percentage ownership of any other person.

The calculations of the percentage of beneficial ownership are based on 1,231,094,617 ordinary shares (including ordinary shares in the form of ADSs) issued and outstanding as of August 20, 2024.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Opthea Limited, Suite 0403, Level 4, 650 Chapel Street, South Yarra, VIC 3141, Australia.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent**
Principal Shareholders		
Funds affiliated with Regal Funds Management Pty Ltd.[1]	312,995,827	25.4%
Funds affiliated with Baker Bros. Advisors L.P.[2]	28,100,345	2.3
Directors and Senior Management		
Megan Baldwin, Ph.D.[3]	3,531,354	*
Fred Guerard	—	—
Peter Lang	—	—
Karen Adams[4]	750,000	*
Julia Haller[5]	2,000,000	*
Lawrence Gozlan[6]	5,326,215	*
Jeremy Levin, DPhil, MB BChir[7]	3,615,057	*
Susan Orr [8]	750,000	*
Quinton Oswald [9]	750,000	*
Judith Robertson[10]	2,000,000	*
Daniel Spiegelman[11]	3,914,234	*
Anshul Thakral[12]	194,521	*
Sujal Shah	—	—
All directors and senior management as a group (eleven persons)	22,831,381	1.9%

* Represents beneficial ownership of less than 1%.

- Represents unexercised options

Mr. Sujal Shah is expected to receive options upon shareholder approval at the 2024 AGM and Dr Guerard and Mr Lang has no exercisable options until post one full year of employment.

(1) Consists of (i) 289,736,603 ordinary shares and (ii) 2,907,403 ADSs held by funds affiliated with Regal Funds Management Pty Ltd., referred to together as the Regal Funds. This information is based on the public filings with the SEC or ASX as of August, 20 2024. As disclosed in the Company's Form 6-K dated June 12, 2024 funds affiliated with Regal Funds Management Pty Ltd. had a pro rata entitlement under the 2024 ANREO to take up 108,936,750 ordinary shares and also entered into a sub-underwriting arrangement with the Australian underwriter of the 2024 ANREO under which such funds affiliated with Regal Funds Management Pty Ltd. sub-underwrote the subscription of up to 212,607,736 ordinary shares in the 2024 ANREO. Regal Funds Management Pty Ltd. is the investment manager for each of such funds holding our ordinary shares. Philip King and Craig Collie are the Chief Investment Officer and portfolio manager, respectively, of Regal Funds Management Pty Ltd. and, as such, they may be deemed to have voting and dispositive power with respect to the ordinary shares held by the affiliated funds. Philip King and Craig Collie disclaim beneficial ownership of the ordinary shares held by the Regal Funds except to the extent of their pecuniary interest. The address for Regal Funds Management Pty Ltd. is Level 47, Gateway, 1 Macquarie Place, Sydney, NSW 2000, Australia.

(2) Consists of (i) 28,100,345 ordinary shares held by Baker Brothers Life Sciences L.P. and 2,253,850 ordinary shares held by 667, L.P., including 20,709,160 Ordinary Shares of the Issuer that are represented by 2,588,645 ADS. This information is based on the public filings with the SEC or ASX as of August 20, 2024. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker and, as such, they may be deemed to have voting and dispositive power with respect to the ordinary shares held by the Baker Brothers Life Sciences, L.P. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the ordinary shares held by the Baker Brothers Life Sciences, L.P. except to the extent of their pecuniary interest therein. The address for Baker Bros. Advisors LP, Baker Bros. Advisors (GP) LLC, Julian C. Baker, Felix J. Baker and the Baker Brothers Life Sciences, L.P. is 860 Washington Street, 3rd Floor, New York, New York 10014.

(3) Consists of (i) 195,2991 ordinary shares beneficially owned and (ii) 3,659,343 ordinary shares issuable upon the exercise of options that are exercisable within 60 days of August 20, 2024.

(4) Ms. Adams joined as Company Secretary in June 2021.Consists of 750,000 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which option were granted on June 6, 2022 and October 13, 2023.

(5) Dr Julia Haller joined our board of directors in June 2021 Consists of 1,500,000 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which options was granted on October 19, 2021.

(6) Consist of (i) 1,877,357 ordinary shares beneficially owned and (ii) 3,448,858 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 202 2024, which option were granted on October 12, 2020, November 16, 2022 and November 30, 2023.

(7) Consists of (i) 31,496 ordinary shares beneficially owned and (ii) 3,583,561 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which options were granted on January 19, 2021.

(8) Dr. Orr joined our board of directors in April 2022. Consists of 750,000 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which option was granted on April 21, 2022.

(9) Mr. Oswald joined our board of directors in April 2022. Consists of 750,000 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which option was granted on April 21, 2022.

(10) Ms. Robertson joined our board of directors in June 2021 and resigned on January 1, 2022. Ms. Robertson was appointed as Chief Commercial Officer in January 2022.Consists of 1.500,000 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which option was granted on October 19, 2021.

(11) Mr. Spiegelman joined our board of directors in September 2020 and resigned in April 2024. Consists of 3,162,374 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which options were granted on October 12, 2020, November 16, 2022 and November 30, 2023.

(12) Mr. Thakral joined our board of director in June 2023. Consists of 194,521 ordinary shares that will vest and become issuable upon the exercise of an option within 60 days of August 20, 2024, which option was granted on November 30, 2023.

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7B. Related Party Transactions

Following the appointment of Anshul Thakral (who is the CEO of Launch Tx, Operation Executive of Carlyle and on the board of Saama Technologies) as a Director of Opthea on June 7, 2023, Launch, Ocelot (an affiliate of Carlyle and Abingworth), Carlyle and Saama Technologies became related parties of Opthea..

Trading transactions

During the year, the Company entered into the following transactions with related parties:

	Consolidated		
	Purchase of Service (US$)		
	2024	2023	2022
Ocelot	—	—	—
Launch Tx	2,700,000	900,000	—
Mr Lawrence Gozlan	—	—	—
Saama Technologies	342,762	—	—

Transactions with Launch TX relate to the purchase of services assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx.

Transactions with Saama Technologies relate to the purchase of services assisting Opthea with analytical work on clinical trials.

	Consolidated		
	Amounts owed to related parties (US$)		
	2024	2023	2022
Ocelot	141,554,653	85,660,000	—
Launch Tx	—	900,000	—
Lawrence Gozlan	—	—	—
Saama Technologies	—	—	—

Amounts owed to Ocelot and Co Investor relate to the Development Funding Agreement and carry an effective rate of 23%.

	Consolidated		
	Amounts owed to related parties* (US$)		
	2024	2023	2022
Ocelot	—	—	—
Launch Tx	3,150,000	—	—
Mr. Lawrence Gozlan	—	—	—
Saama Technologies	24,238	—	—

*The above amounts represent prepayments.

Amounts due to related parties relates to the services assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx which was entered into in March 2023. Amounts due to Saama Technologies relate to subscription fees for the use of analytical platform, which were in a prepayment position at June 30, 2024.

On August 28,2023 Mr. Lawrence Gozlan, a director of the Company, and the Company have entered into a Consultancy Agreement of up to US$300,000 in respect of the provision of services associated with managing, overseeing and coordinating the conduct and implementation of the 2023 Equity Offering. The consultancy agreement was effective for the financial year June 30, 2024 and ended at the completion of the 2023 Equity Offering in September 2023. In the opinion of the Directors, these duties are outside the scope of the ordinary duties of a Non-Executive Director. Included in equity are transaction costs paid under this consulting agreement of US$125,000 for the year ended June 30, 2024.

Other than compensation arrangements which are described under "Item 6B—Compensation" or as disclosed below, from July 1, 2023 through the date of this annual report, we did not enter into any transactions or loans with any: (i) enterprises that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with us; (ii) associates; (iii) individuals owning, directly or indirectly, an interest in our voting power that gives them significant influence over us, and close members of any such individual's family; (iv) key management personnel and close members of such individuals' families; or (v) enterprises in which a substantial interest in our voting power is owned, directly or indirectly, by any person described in (iii) or (iv) or over which such person is able to exercise significant influence.

Director and Senior Management Compensation

See "Item 6B—Compensation" for information regarding compensation of our senior management and directors.

Indemnification Agreements

Our Constitution provides that, except to the extent prohibited by law including under the Corporations Act and, to the extent that an officer is not otherwise indemnified by us pursuant to an indemnity, we will indemnify every person who is or has been an officer of the company against any liability (other than legal costs that are unreasonable) incurred by that person as an officer. This includes any liability incurred by that person in their capacity as an officer of our subsidiaries where we requested that person to accept that appointment.

We have entered into Deeds of Indemnity, Insurance and Access, or Indemnity Deeds, with Megan Baldwin, Ph.D., Timothy Morris, Karen Adams, Lawrence Gozlan, Julia Haller, Jeremy Levin, Susan Orr, Quinton Oswald, Anshul Thakral, Sujal Shah and Daniel Spiegelman, each a non-employee director (or former non-employee director for Mr. Spiegelman), or executive officer (or former executive officer for Mr. Morris). Under the Indemnity Deeds, we have agreed to indemnify (to the maximum extent permitted under Australian law and our Constitution, subject to certain specified exceptions) each director and executive officer against all liabilities incurred in their capacity as our or our subsidiaries' director or officer and any and all costs and expenses relating to such a claim or to any notified event incurred by such director or executive officer, including costs and expenses reasonably and necessarily incurred to mitigate any liability for such a claim or any claim which may arise from such a notified event. The Indemnity Deeds provide that the indemnities are unlimited as to amount, continuous and irrevocable.

Separately, we have obtained insurance for our directors and executive officers, as required by the Indemnity Deeds.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related Person Transaction Policy

We comply with Australian law and the rules and regulations of the ASX regarding approval of transactions with related parties. We have also adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which became effective in connection with the listing of our ADSs on Nasdaq. For purposes of our policy, a related person transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and the amount involved in the transaction exceeds US$120,000, with the exception of usual transactions concluded under normal conditions. A related person is any member of our board of directors, our senior management or any beneficial owner of more than 5% of any class of our ordinary shares, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our senior management must present information regarding the related person transaction to the board of directors for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our board of directors and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

All of the transactions described above were entered into prior to the adoption of the written policy, but our board of directors evaluated and approved all transactions that were considered to be related party transactions under Australian law and the rules and regulations of the ASX at the time at which they were consummated.

7C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

8A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See "Item 18—Financial Statements."

Legal Proceedings

See "Item 4B—Business Overview—Legal Proceedings."

Dividend Policy

We have not declared or paid any dividends on our ordinary shares since February 2005. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our ordinary shares. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to Australian law.

Any dividend we declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of the ADSs, subject to the terms of the deposit agreement.

8B. Significant Changes

No significant change, other than as otherwise described in this annual report, has occurred in our operations since the date of our financial statements included in this annual report.

Item 9. The Offer and Listing

9A. Offer and Listing Details

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "OPT" since October 16, 2020. Our ordinary shares are listed on the ASX under the symbol "OPT."

9B. Plan of Distribution

Not applicable.

9C. Markets

See "—Offer and Listing Details."

9D. Selling Shareholders

Not applicable.

9E. Dilution

Not applicable.

9F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

10A. Share Capital

Not applicable.

10B. Constitution

See Exhibit 2.3 “Description of Securities,” which is incorporated herein by reference.

10C. Material Contracts

For information on our material contracts, see “Item 4B—Business Overview—Our Commercial License Arrangement with Selexis SA,” “Item 5B—Liquidity and Capital Resources—Sources and Uses of Liquidity,” and “Item 5B–Liquidity and Capital Resources–Development Funding Agreement .”

10D. Exchange Controls

The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Transaction Reports and Analysis Centre (or "AUSTRAC”), which monitors such transaction, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

10E. Taxation

The following summary of the material Australian and U.S. federal income tax considerations relating to an investment in the ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this annual report, all of which are subject to change, possibly with retroactive effect. This summary does not deal with all possible tax consequences relating to an investment in the ADSs or ordinary shares, such as the tax consequences under U.S. state, local and other tax laws other than U.S. federal income tax laws and certain Australian tax laws.

Material United States Federal Income Tax Considerations

The following discussion is a summary of U.S. federal income tax considerations generally applicable to the ownership and disposition of the ADSs or ordinary shares by a U.S. holder (as defined below). This summary applies only to U.S. holders that hold such ADSs or ordinary shares as capital assets (generally, property held for investment) for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax considerations that may be relevant to a particular U.S. holder and does not represent a detailed discussion of all of the U.S. federal income tax considerations applicable to a holder of our ordinary shares or ADSs that may be subject to special tax rules including, without limitation:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold ADSs or ordinary shares as part of a “hedging,” “integrated,” “wash sale” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- S corporations, partnerships, or other entities or arrangements classified as passthrough entities for U.S. federal income tax purposes, or U.S. holders who hold the ADSs or ordinary shares through such an entity;

- certain former citizens or long-term residents of the United States;
- persons that received ADSs or ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation for the performance of services;
- holders that own or have owned directly, indirectly, or through attribution 10% or more of the voting power or value of our ordinary shares or ADSs; and
- holders that have a "functional currency" other than the U.S. dollar.

Holders of the ADSs or ordinary shares who fall within one of the categories above are advised to consult their tax advisor regarding the specific tax consequences which may apply to their particular situation.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds the ADSs or ordinary shares, the tax consequences relating to an investment in the ADSs or ordinary shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of the ADSs or ordinary shares in its particular circumstances.

The discussion in this section is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof, and the Convention between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on August 6, 1982, as amended and currently in force, or the Treaty, in each case as in effect and available on the date hereof. Such authorities are subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a position concerning the tax consequences of the ownership and disposition of ADSs or ordinary shares or that such a position would not be sustained by a court. U.S. holders should consult their own tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADSs or ordinary shares in their particular circumstances.

This summary does not address the estate tax considerations, alternative minimum tax considerations, the potential application of the Medicare contribution tax on net investment income, the special tax accounting rules under Section 451(b) of the Code, or any U.S. state, local, or non-U.S. tax considerations applicable to the acquisition, ownership and disposition of ordinary shares or ADSs or ordinary shares.

For the purposes of this description, a "U.S. holder" is a beneficial owner of the ADSs or ordinary shares that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust, or if such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

The discussion in this section is based in part upon the representations of the depositary and the assumption that each obligation in the amended and restated deposit agreement and any related agreement will be performed in accordance with its terms.

In general, and taking into account the earlier assumptions, for U.S. federal income tax purposes, a U.S. holder holding ADSs will be treated as the owner of the ordinary shares represented by the ADSs. Exchanges of ordinary shares for ADSs, and ADSs for ordinary shares, generally will not be subject to U.S. federal income tax.

ALL HOLDERS AND POTENTIAL HOLDERS OF THE ADSs SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ADSs OR ORDINARY SHARES, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE AND LOCAL TAX LAWS, AUSTRALIAN TAX LAWS AND OTHER NON-U.S. TAX LAWS.

Passive Foreign Investment Company Considerations.

If we are classified as a PFIC in any taxable year, during which a U.S. holder holds the ADSs or ordinary shares, such U.S. holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

We will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of our subsidiaries, either: (1) at least 75% of the gross income is "passive income" or (2) at least 50% of the average quarterly value of our total gross assets (which would generally be measured by fair market value of our assets, and for which purpose the total value of our assets may be determined in part by the market value of the ADSs and our ordinary shares, which are subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income."

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our securities. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation or the partnership interests in a partnership, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation or partnership and as receiving directly its proportionate share of the other corporation's or partnership's income.

We believe we were a PFIC for our taxable year ended June 30, 2024, and based on the nature and composition of our income, assets, activities and market capitalization, we may be a PFIC in future taxable years. However, our PFIC status is based on an annual determination and may change from year to year. Our status as a PFIC will depend on the composition of our income and the composition and value of our assets, which may be determined in large part by reference to the market value of the ADSs and our ordinary shares, which may be volatile, from time to time. Our status may also depend, in part, on how quickly we utilize the cash we raise in any offering of our securities. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

If we are classified as a PFIC in any year with respect to which a U.S. holder owns the ADSs or ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ADSs or ordinary shares, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. holder has made a "deemed sale" election under the PFIC rules. If the "deemed sale" election is made, a U.S. holder will be deemed to have sold the securities the U.S. holder holds at their fair market value as of the date of such deemed sale and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. holder's securities with respect to which such election was made will not be treated as shares in a PFIC and the U.S. holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. holder receives from us or any gain from an actual sale or other disposition of the securities. U.S. holders should consult their tax advisors as to the possibility and consequences of making a deemed sale or other "purging" election if such election becomes available.

If we are a PFIC, and you are a U.S. holder that does not make one of the elections described herein, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year, other than the taxable year in which your holding period in the shares or ADSs begins, which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or the portion of your holding period for the ADSs or ordinary shares that preceded the year of

the distribution) and (b) any gain realized on the sale or other disposition of the ADSs or ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below) and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to qualified dividends discussed above under "Distributions."

Certain elections may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of our ordinary shares or ADSs.

If a U.S. holder makes a mark-to-market election, with respect to our ordinary shares or ADSs, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of our ordinary shares or ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of our ordinary shares or ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in our ordinary shares or ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of our ordinary shares or ADSs in a year in which we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and our ordinary shares or ADSs are "regularly traded" on a "qualified exchange." Our ordinary shares or ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ordinary shares or ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement are disregarded). Nasdaq is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to a U.S. holder. It should be noted that only the ADSs and not our ordinary shares are listed on Nasdaq. Consequently, our ordinary shares may not be marketable if the ASX (where our ordinary shares are currently listed) does not meet the applicable requirements. U.S. holders should consult their tax advisors regarding the availability of the mark-to-market election for ordinary shares that are not represented by ADSs.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." As a result, even if a U.S. holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

We do not currently intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we were treated as a PFIC for any taxable year. U.S. holders should consult their tax advisors to determine whether any of the other elections described above would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

For years in which we are determined to be a PFIC, the general tax treatment for U.S. holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. holders in respect of any of our subsidiaries that also may be determined to be PFICs. U.S. holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a U.S. holder owns ordinary shares or ADSs during any taxable year in which we are a PFIC, the U.S. holder may be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. holder's federal income tax return for that year. You should consult your tax advisor concerning any filing requirements arising from the PFIC rules.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisors with respect to the acquisition, ownership and disposition of our ordinary shares or ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to ordinary shares and ADSs and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of ordinary shares and ADSs.

Distributions

We do not expect to make any distributions in respect of the ADSs or ordinary shares. Subject to the discussion under "—Passive Foreign Investment Company Considerations" above, the gross amount of any distribution (including any amounts withheld in respect of foreign tax) actually or constructively received by a U.S. holder with respect to the ADSs or ordinary shares will generally be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will generally be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce (but not below zero), the U.S. holder's adjusted tax basis in the ADSs or ordinary shares. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs or ordinary shares for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on the ADSs or ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) and "qualified dividend income" (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-U.S. corporation generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ADSs or ordinary shares which are readily tradable on an established securities market in the United States. The ADSs are listed on Nasdaq, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on Nasdaq. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. The Company, which is incorporated under the laws of Australia, believes that it qualifies as a resident of Australia for purposes of, and is eligible for the benefits of, the Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. However, the preferential tax rates available for qualified dividend income do not apply if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year. [As discussed above under "—Passive Foreign Investment Company Considerations", we believe that we were a PFIC for our taxable year ended June 30, 2024 and we may be a PFIC in future taxable years.] In addition, the dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any Australian withholding tax as either a deduction from gross income or a credit against its U.S. federal income tax liability. The foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. In addition, the creditability of foreign taxes could be affected by actions taken by intermediaries in the chain of ownership between the holders of the ADSs and our company if, as a result of such actions, the holders of the ADSs are not properly treated as beneficial owners of the underlying ordinary shares. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the U.S. dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the depositary receives the distribution, in the case of the ADSs, or on the day the distribution is received by the U.S. holder, in the case of ordinary shares, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

Sale, Exchange or Other Taxable Disposition

A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of the ADSs or ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder's adjusted tax basis in those securities, determined in U.S. dollars. Subject to the discussion under "—Passive Foreign Investment Company Considerations" above, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in the ADSs or ordinary shares generally will be equal to the cost of such ADSs or ordinary shares. Capital gain from the sale, exchange or other taxable disposition of the ADSs or ordinary shares by a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such securities exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source gain or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale.

An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of our ordinary shares or ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

Backup Withholding and Information Reporting.

U.S. holders generally will be subject to information reporting requirements with respect to distributions on the ordinary shares or ADSs and on the proceeds from the sale, exchange, or disposition of the ordinary shares or ADSs that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting.

Certain individual U.S. holders are required to report information relating to an interest in the ordinary shares or ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ordinary shares or ADSs.

THE DISCUSSION ABOVE IS A SUMMARY OF THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN THE ORDINARY SHARES OR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN THE ORDINARY SHARES OR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Material Australian Tax Considerations

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ADSs or ordinary shares represented by ADSs. It is based upon existing Australian tax law as of the date of this registration statement, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any non-Australian or state tax considerations, other than stamp duty and goods and services tax.

Prospective investors are urged to consult their tax advisors regarding the Australian and non-Australian income and other tax considerations of the acquisition, ownership and disposition of the ADSs or shares. This summary is based upon the premise that the holder of an ADS is not an Australian tax resident for Australian income tax purposes and is not carrying on business in Australia through a permanent establishment (referred to as a "Non-Australian Holder" in this summary). This summary is also based on the assumption that a Non-Australian Holder is "absolutely entitled" to the ordinary shares represented by an ADS (see "—Nature of ADSs for Australian Taxation Purposes" below).

Nature of ADSs for Australian Taxation Purposes

Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding their rights and obligations under the deposit agreement with the depositary, including whether the deposit arrangement constitutes a "bare trust" which results in the holders of an ADS being "absolutely entitled" to the underlying shares represented by the ADS for Australian taxation purposes. Apart from certain aspects of the Australian tax legislation (for example, the Australian capital gains tax and withholding tax provisions, which are discussed below), there is no express legislative basis for disregarding "bare trusts" for Australian tax purposes generally.

This summary proceeds on the assumption that the deposit arrangement results in holders of ADSs being "absolutely entitled" to the underlying shares. On this basis, holders of ADSs can be treated as the owners of the underlying ordinary shares for Australian capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends derived by the holders of ADSs as the persons presently entitled to those dividends.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent they are paid out of company profits that have been subject to income tax. Fully franked dividends are not subject to dividend withholding tax. To the extent that they are unfranked, dividends payable to Non-Australian Holders will be subject to dividend withholding tax except to the extent they are declared to be "conduit foreign income", or CFI. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation treaty and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to which a resident of the United States is beneficially entitled is limited to 15%.

Under the Double Taxation Convention between Australia and the United States, if a U.S. resident company that is a Non-Australian Holder directly owns 10% or more of the voting interests in us, the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to which the company is beneficially entitled is limited to 5%.

Character of ADSs or Shares for Australian Taxation Purposes

The Australian tax treatment of a sale or disposal of the ADSs or underlying shares will depend on whether they are held on revenue or capital account. ADSs may be held on revenue rather than capital account, for example, where they are held by share traders or any profit arises from a profit-making undertaking or scheme entered into by the holder. Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding the characterization of any gain or loss on a sale or disposal of the ADSs or underlying shares as revenue or capital in nature.

Tax on Sales or other Dispositions of Shares or ADSs—Capital Gains Tax

Non-Australian Holders who are treated as the owners of the underlying shares on the basis that they are absolutely entitled to those shares will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of ordinary shares, provided the shares are not "taxable Australian property." Taxable Australian property includes "indirect Australian real property interests," which are interests in a company where:

- the Non-Australian Holders, together with associates, hold 10% or more of our issued shares, at the time of disposal or for a 12-month period during the two years prior to disposal; and

- more than 50% of our assets held directly or indirectly, determined by reference to market value, consists of Australian real property (which includes Australian land and leasehold interests) or Australian mining, quarrying or prospecting rights at the time of disposal (referred to as the Principal Asset Test).

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rates. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

If a Non-Australian Holder of ADSs was not absolutely entitled to the underlying shares, and the ADSs were held on capital account, the same principles would apply in determining whether a gain on the sale or disposal of the ADSs would be subject to Australian capital gains tax. That is, a Non-Australian Holder should not be subject to Australian capital gains tax provided the ADSs are not taxable Australian property.

The 50% capital gains tax discount is not available to Non-Australian Holders on gains from assets acquired after May 8, 2012 where they were non-Australian residents during the entire holding period. Companies are not entitled to a capital gains tax discount.

In the 2024-2025 Federal Budget, the Federal Government of Australia announced that it will be strengthening the foreign resident capital gains tax rules in respect of disposal of assets occurring on or after July 1, 2025. There is limited detail on the proposed changes and they will be subject to consultation. Non-Australian Holders should monitor any developments in relation to these proposed changes and obtain specialist Australian tax advice regarding the Australian tax implications made on a sale or other disposal of the ADSs or underlying shares if and when the changes to the foreign resident capital gains tax rules become effective.

Tax on Sales or other Dispositions of ADSs—Revenue Account

Non-Australian Holders who hold their ADSs on revenue account may have the gains made on the sale or other disposal of the ADSs included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia. In the case of gains which are ordinary income, there are no express provisions which treat holders of ADSs as the owners of the underlying shares where they are absolutely entitled to those shares under a bare trust.

Non-Australian Holders assessable under these ordinary income provisions in respect of gains made on ADSs held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which currently start at a marginal rate of 32.5% for individuals and would be required to file an Australian tax return. Some relief from Australian income tax may be available to a Non-Australian Holder who is resident of a country with which Australia has a double taxation treaty, qualifies for the benefits of the treaty and does not, for example, derive the gain in carrying on business through a permanent establishment in Australia.

To the extent an amount would be included in a Non-Australian Holder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount may be reduced, so that the holder may not be subject to double Australian tax on any part of the gain.

Dual Residency

If a holder of ADSs is a resident of both Australia and the United States under those countries' domestic taxation laws, that holder may be subject to tax as an Australian resident. If, however, the holder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia and qualifies for the benefit of that treaty, the Australian tax may be subject to limitation by the Double Taxation Convention. Holders should obtain specialist taxation advice in these circumstances.

Stamp Duty

No Australian stamp duty is payable by Australian residents or non-Australian residents on the issue, transfer and/or surrender of the ADSs or ordinary shares, provided that the securities issued, transferred and/or surrendered do not represent 90% or more of our issued shares.

Australian Death Duty

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax.

Goods and Services Tax

No Australian goods and services tax will be payable on the supply of the ADSs or ordinary shares.

THE DISCUSSION ABOVE IS A SUMMARY OF THE AUSTRALIAN TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

10F. Dividends and Paying Agents

Not applicable.

10G. Statement by Experts

Not applicable.

10H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC. With respect to references made in this annual report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

We maintain a corporate website at www.opthea.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report and our website address is included herein as an inactive textual reference only.

10I. Subsidiary Information

Not required.

10J. Annual Report to Security Holders

Pursuant to Item 10J of Form 20-F, exhibit 15.2 to this annual report on Form 20-F includes our annual report to security holders. None of such annual report is incorporated by reference into this annual report on Form 20-F. Such annual report is not deemed to be filed as part of this annual report on Form 20-F.

Item 11. Quantitative and Qualitative Disclosures about Market Risk

For information about our exposure to market risk and how we manage this risk, see "Item 5E—Critical Accounting Estimates— Qualitative and Quantitative Disclosures about Market Risk."

Item 12. Description of Securities Other than Equity Securities

12A. Debt Securities

Not applicable.

12B. Warrants and Rights

Not applicable.

12C. Other Securities

Not applicable.

12D. American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, or ADSs. Each ADS represents eight ordinary shares (or a right to receive eight ordinary shares) deposited with HSBC Bank Australia Limited, as custodian for the depositary in Australia. Each Ads also represents any other securities, cash or other property that may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs are administered, and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs receive statements from the depositary confirming their holdings.

As an ADS holder, you are not treated as one of our shareholders and you do not have shareholder rights. Australian law governs shareholder rights. The depositary is the holder of the shares underlying your ADSs. As a registered holder of ADSs, you have ADS holder rights. The amended and restated deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

Fees and Expenses

The following table shows the fees and charges that a holder of our ADSs may have to pay, either directly or indirectly. The majority of these costs are set by the depositary bank and are subject to change:

Persons depositing or withdrawing shares or ADS holders must pay:	For:
US$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
US$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
US$0.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which

that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from the United States in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of Taxes

ADS holders are responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes. Your obligation to pay taxes and indemnify us and the depository against any tax claims will survive the transfer or surrender of your ADSs, the withdrawal of the deposited ordinary shares as well as the termination of the deposit agreement.

See Exhibit 2.3 -Description of Securities" for additional information on the ADSs.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

E. Use of Proceeds

Not applicable

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of June 30, 2024. Based on such evaluation, our Principal Executive Officer and Principal Financial Officer have concluded that, as of June 30, 2024, our disclosure controls and procedures were not effective because of the material weakness in our internal control over financial reporting as described below.

B. Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Under the supervision and with the participation of our Principal Executive Officer and our Principal Financial Officer, management assessed our internal control over financial reporting based upon the framework in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting was not effective as of June 30, 2024 because we did not design and maintain effective controls in relation to accounting for non-routine transactions and its related note disclosures which resulted in our failure to prevent and detect material errors which were corrected in our consolidated financial statements as of and for the year ended June 30, 2024 related to the (1) remeasurement of the financial liabilities in connection with our Funding Agreement and (2) the accounting application and related disclosures of investor options issued during the year.

We will continue to take certain measures to remediate the material weakness described above including implementing key mitigating controls to address the risk associated with accurately accounting for and disclosing non-routing transactions, such as the Funding Agreement and investor options. The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We are working to remediate the material weakness as efficiently and effectively as possible.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

C. Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the company's registered public accounting firm due to a transition period established by the SEC's rules for emerging growth companies.

D. Changes in Internal Control Over Financial Reporting

Other than as discussed above in Management's Annual Report on Internal Control Over Financial Reporting, there have been no changes to our internal control over financial reporting during the fiscal year ended June 30, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

The members of our Audit and Risk Committee are Messrs. Quinton Oswald, Daniel Spiegelman (till his resignation in April 2024), Mr Sujal Shah (appointed April 2024) and Dr Susan Orr Our board of directors has determined that each of Messrs. Oswald, Spiegelman, Shah and Dr Orr satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairperson of our Audit and Risk Committee is Mr Shah as of April 2024 with Mr. Spiegelman until his resignation in April 2024. Our board of directors has determined that Mr. Shah is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our Audit and Risk Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each member's scope of experience and the nature of his or her employment.

Item 16B. Code of Ethics

We have adopted a Code of Conduct applicable to all of our directors, officers and employees. Our Code of Conduct is available on our website at www.opthea.com. We post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the Code of Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of, this annual report.

Item 16C. Principal Accountant Fees and Services

Fees Paid to Independent Public Accountants

The following table sets forth, for each of the years indicated, the fees billed by Deloitte Touche Tohmatsu.

	2024	2023	2022
		(in thousands A$)	
Audit Fees	A$563	A$357	A$295
Audit-Related Fees	—	—	—
Tax Fees	—	—	—
Other Fees	—	—	171
Total	A$563	A$357	A$499

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that Deloitte Touche Tohmatsu provides, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit, including fees related to our public offering, and are not reported under Audit Fees.

"Tax Fees" are the aggregate fees billed for professional services rendered by Deloitte Touche Tohmatsu for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by Deloitte Touche Tohmatsu.

There were no "Audit-Related Fees," or "Tax Fees" billed or paid during the fiscal years ended June 30, 2024, 2023 or 2022.

Pre-Approval of Audit and Non-Audit Services

The Audit and Risk Management Committee's pre-approval is required for all services provided by Deloitte Touche Tohmatsu. These services may include audit services, audit-related services, tax services and permissible non-audit services, and are subject to a specific budget. The Audit and Risk Management Committee uses a combination of two approaches – general pre-approval and specific pre-approval – in considering whether particular services or categories of services are consistent with the SEC's rules on auditor independence. Under general pre-approval proposed services may be pre-approved without consideration of specific case-by-case services.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

Under Nasdaq Stock Market Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the Nasdaq Stock Market Rules. In order to rely on this exception, we are required to disclose each Nasdaq Stock Market Rule that we do not follow and describe the home country practice we do follow in lieu thereof. In accordance with this exception, we intend to follow Australian corporate governance practices in lieu of the following Nasdaq corporate governance standards:

- We follow Australian law and corporate governance practices in lieu of the requirement under the Nasdaq Stock Market Rules that a quorum for a meeting of shareholders may not be less than 33 1/3% of the outstanding shares of an issuer's voting ordinary shares. In compliance with Australian law, our Constitution provides that a quorum is three or more shareholders present at the meeting of shareholders and entitled to vote on a resolution at the meeting and, accordingly, we claim the exemption for foreign private issuers with respect to the Nasdaq quorum requirement.

- We follow Australian law and corporate governance practices in lieu of the requirements under the Nasdaq Stock Market Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with a change of control, certain acquisitions, private placements of securities, or the establishment or amendment of certain stock option, purchase or other equity compensation plans or arrangements. Applicable Australian law prohibits the acquisition of a relevant interest in voting shares of a public company such us, if, because of that transaction, a person's voting power in the company increases from under 20% to over 20% or increases from a starting point that is above 20% and below 90%. This prohibition is subject to a number of exceptions including where the acquisition is approved by a resolution of shareholders of the company in which the acquisition is made. Due to differences between Australian law and corporate governance practices and the Nasdaq Stock Market Rules, we claim the exemption for foreign private issuers with respect to the Nasdaq shareholder approval requirements.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J. Insider Trading Policies

Our board of directors has adopted an insider trading policy, which outlines when directors, senior management and other employees may deal in our securities and procedures to reduce the risk of insider trading .A copy of the insider trading policy is attached as Exhibit 11.1 to this annual report.

Item 16K. Cybersecurity

Risk Management and Strategy

- We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature such as data about our research and clinical trials ("Information Systems and Data").

- Our information security function helps identify, assess and manage the Company's cybersecurity threats and risks. We identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including: manual and automated tools; subscribing to and analyzing reports and services that identify cybersecurity threats; and evaluating threats reported to us; conducting vulnerability assessments.

- Depending on the environment, systems, and data, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response process; disaster recovery/business continuity plans; encrypting certain data; using network security controls; maintaining access controls; managing assets; and maintaining cybersecurity insurance.

- Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management program; (2) we prioritize our risk management processes to include mitigation of risks from cybersecurity threats that are more likely to lead to a material impact to our business; (3) management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the board of directors, which evaluates our overall enterprise risk.

- We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats.

- We use third-party service providers to perform a variety of functions throughout our business, such as distributors and supply chain resources and contract research organizations ("CRO") and contract manufacturing organizations ("CMO"). We have certain vendor management processes to manage cybersecurity risks associated with our use of certain providers, depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider. These processes may include information security questionnaires, audits, and imposition of contractual obligations relating to cybersecurity.

- For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors in this Annual Report on Form 20-F, including "*If our information technology systems or data, or those of the third-parties with whom we work, are or were compromised,*

we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations' reputational harm' loss of revenue or profits; loss of customers or sales; and other adverse consequences ."

Governance

- Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

- Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management and service provider, including Exigence, our external IT service provider. Management is responsible for budgeting, hiring appropriate cybersecurity personnel, and helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy.

- Our cybersecurity incident response process is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including Chief Executive and Chief Financial Officer who help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response process includes reporting to the board of directors for certain cybersecurity incidents.

- The board receives periodic reports from company management, including Exigence and our external IT service provider and Chief Financial Officer concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The board also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

PART III

Item 17. Financial Statements

See "Item 18—Financial Statements."

Item 18. Financial Statements

The consolidated financial statements and the related notes required by this Item are included in this annual report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	Certificate of Registration of Opthea Limited.	F-1	333-249020	3.1	9/24/20	
1.2	Constitution of Opthea Limited.	F-1	333-249020	3.2	9/24/20	
2.1	Form of Amended and Restated Deposit Agreement.	F-1/A	333-249020	4.1	10/9/20	
2.2	Form of American Depositary Receipt evidencing American Depositary Shares.	F-1/A	333-249020	4.1	10/9/20	
2.3	Description of Securities.	20-F	001-39621	2.3	10/28/21	
4.1*	Amended and Restated Long Term Incentive Plan Rules.	6-K	001-39621	99.3	9/13/21	
4.2*	Non-Executive Directors Share and Option Plan Rules.	F-1	333-249020	10.6	9/24/20	
4.3*	Executive Employment Contract, dated April 23, 2014, between the Registrant and Megan Baldwin, Ph.D.	F-1	333-249020	10.7	9/24/20	
4.4*	Executive Employment Contract, dated May 3, 2021, between the Registrant and Karen Adams.	20-F	001-39621	4.4	10/28/21	
4.5*	Executive Employment Contract, dated October 24, 2022, between the Opthea US Inc and Timothy Morris	20-F	001-39621	4.5	09/30/23	
4.6*	Form of Non-Executive Director Agreement.	F-1/A	333-249020	10.9	10/9/20	
4.7#	Commercial License Agreement, dated as of October 28, 2013, between the Registrant and Selexis SA.	F-1	333-249020	10.1	9/24/20	
4.8#	Biopharmaceutical Manufacturing Agreement, dated as of October 28, 2013, between the Registrant, Patheon Biologics Company Australia Pty Ltd. and Patheon Biologics Company B.V.	F-1	333-249020	10.2	9/24/20	
4.9	Form of Deed of Indemnity, Insurance and Access.	F-1	333-249020	10.3	9/24/20	
4.10	Lease Agreement, dated November 12, 2019, between the Registrant and The Trust Company (Australia) Limited, as custodian for the Newmark Como Property Trust.	F-1	333-249020	10.4	9/24/20	

4.11	Deed of Variation of Lease dated July 18, 2022, between the Registrant and the Trust Company (Australia) Limited as custodian for the Newmark Como Property Trust	20-F	001-39621	4.10	9/29/22	
4.12 *	Executive Employment Contract, dated December 31, 2021, between Opthea US Inc and Judith Robertson.	20-F	001-39621	4.11	9/29/22	
4.14	Sales Agreement by and between the Registrant and Jefferies LLC, dated February 1, 2022.	F-3	333-262444	1.2	2/1/22	
4.15 #	Development Funding Agreement by and between Opthea Limited and Ocelot SPV LP dated August 12, 2022	20-F	001-39621	4.14	9/29/22	
4.16	Consultancy Agreement by and between Opthea Limited and Lawrence Gozlan, dated as of August 28, 2023	20-F	001-39621	4.16	9/30/23	
4.17	Executive Employment Contract dated October 27, 2023 between Opthea US Inc and Fred Guerard					X
4.18	Executive Employment Contract dated October 27, 2023 between Opthea US, Inc. and Peter Lang.					X
4.19	Amended and Restated Development Funding Agreement by and between Opthea Limited, Ocelot SPV LP, as Collateral Agent, and the Investors from Time to Time Party Thereto, dated December 22, 2023					X
8.1	List of subsidiaries.	20-F	001-39621	8.1	10/28/21	
11.1	Securities Trading policy					X
12.1	Certification of the Principal Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.					X
12.2	Certification of the Principal Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.					X
13.1†	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.					X
15.1	Consent of Deloitte Touche Tohmatsu, independent registered public accounting firm.					X
15.2	Annual Report 2023 - 2024	6-K	001-39621	99.1	08/30/24	
97.1	Opthea Limited Incentive Compensation Recoupment Policy.					X

101.INS	Inline XBRL Instance Document—this instance document does not appear in the Interactive Data File because its XBRL tags embedded within the Inline XBRL document	X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

* Indicates management contract or compensatory plan or arrangement.
# Certain confidential portions of this exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions are not material and are of the type that the Company treats as private or confidential. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.
† The certifications attached as Exhibits 13.1 accompanying this Annual Report on Form 20-F is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Opthea Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 20-F, irrespective of any general incorporation language contained in such filing.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Opthea Limited

By:	/s/ Fred Guerard
Name:	Fred Guerard.
Title:	Chief Executive Officer

Dated: August 30, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Opthea Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Opthea Limited and subsidiaries (the "Company") as of June 30, 2024 and 2023, the related consolidated statements of profit or loss and other comprehensive income, changes in equity, and cash flows, for each of the three years in the period ended June 30, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2024, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board (IASB).

Substantial Doubt related to Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Group incurred a net loss of $220.2 million, had a net cash outflow from operating activities of $161.0 million during the year and, as of June 30, 2024, the Group had an equity deficit of $75.8 million that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Melbourne, Australia
August 30, 2024

We have served as the Company's auditor since 2012.

OPTHEA LIMITED
Consolidated Statements of Profit or Loss and Other Comprehensive Income
For the Years ended June 30, 2024, and 2023, and 2022

	Years ended June 30,		
	2024	**2023**	**2022**
	US$	**US$**	**US$**
Revenue	124,666	108,406	90,683
Other income	137,193	276,869	108,322
Operating expenses:			
Research and development (includes amounts owed by related parties $3,042,762 2023:$900,000)1	(176,326,321)	(128,828,888)	(81,445,843)
Administration expenses 1	(15,778,271)	(21,582,181)	(15,291,294)
Total operating expenses	(192,104,592)	(150,411,069)	(96,737,137)
Operating Loss	**(191,842,733)**	**(150,025,794)**	**(96,538,132)**
Finance income	3,394,726	3,227,496	235,468
Interest expense on DFA* (includes amounts owed to related party $24,698,653 (2023: $13,462,160))	(30,263,042)	(13,462,160)	—
Gain on remeasurement of financial liability - DFA2	387,284	12,302,160	—
Fair value loss on derivative - investor options	(11,223,535)	—	—
Net foreign exchange (loss)/gain	(107,001)	(489,137)	(2,813,993)
Loss before income tax	**(229,654,301)**	**(148,447,435)**	**(99,116,657)**
Income tax benefit	9,412,196	5,926,350	6,299,286
Loss for the year	**(220,242,105)**	**(142,521,085)**	**(92,817,371)**
Other comprehensive income			
Other comprehensive income for the period, net of tax	—	—	—
Total comprehensive loss for the year	**(220,242,105)**	**(142,521,085)**	**(92,817,371)**
Loss for the year is attributable to:			
Owners of the Company	(220,242,105)	(142,521,085)	(92,817,371)
Net loss	**(220,242,105)**	**(142,521,085)**	**(92,817,371)**
Total comprehensive loss for the year is attributable to:			
Owners of the Company	(220,242,105)	(142,521,085)	(92,817,371)
Comprehensive loss	**(220,242,105)**	**(142,521,085)**	**(92,817,371)**
Loss per share attributable to the owners of the Company:			
- Basic and diluted loss per share (cents)	**(34.51)**	**(32.20)**	**(26.40)**

* Development Funding Agreement ("DFA")

The above consolidated statements of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.
1. Figures have been presented as described in Note 3
2. In the current year, the description of this amount has been changed as described in Note 13.

OPTHEA LIMITED
Consolidated Statements of Financial Position
as of June 30, 2024, and 2023

	June 30, 2024	June 30, 2023
	US$	US$
Assets		
Current assets:		
Cash and cash equivalents	172,471,346	89,188,713
Current tax receivable	10,398,039	5,926,350
Receivables	1,426,400	636,564
Prepayments (includes amounts owed by related parties $2,724,238 (2023: $nil))	3,896,779	2,634,671
Total current assets	188,192,564	98,386,298
Non-current assets:		
Property and equipment, net	47,725	33,035
Right-of-use assets	84,226	168,451
Prepayments (includes amounts owed by related party $450,000 (2023: $nil))	466,701	53,535
Total non-current assets	598,652	255,021
Total assets	188,791,216	98,641,319
Liabilities		
Current liabilities:		
Payables	38,104,421	17,891,854
Lease liabilities	93,033	97,485
Derivative financial liabilities - investor options	24,840,456	—
Provisions	1,017,748	753,300
Total current liabilities	64,055,658	18,742,639
Non-current liabilities:		
Lease liabilities	—	84,226
Financial liabilities - DFA (includes amounts due to a related party $141,554,653 (2023: $85,660,000))	200,535,758	85,660,000
Provisions	9,877	7,631
Total non-current liabilities	200,545,635	85,751,857
Total liabilities	264,601,293	104,494,497
Net Assets	(75,810,077)	(5,853,178)
Equity		
Contributed equity	466,084,145	320,883,552
Accumulated Loss	(579,704,543)	(359,462,438)
Reserves	37,810,321	32,725,708
Total Equity	(75,810,077)	(5,853,178)

The above consolidated statements of financial position should be read in conjunction with the accompanying notes.

OPTHEA LIMITED
Consolidated Statements of Changes in Equity
for the Years ended June 30, 2024, and 2023, and 2022

	Contributed equity	Share-based payment reserve	Fair value of Investment reserve	FX translation Reserve	Accumulated Deficit	Total Equity
	US$	US$	US$	US$	US$	US$
Balance at June 30, 2021	**234,147,526**	**4,087,650**	**1,085,411**	**20,089,163**	**(124,123,982)**	**135,285,768**
Net loss for the year	—	—	—	—	(92,817,371)	(92,817,371)
Total Comprehensive income and expense for the period	—	—	—	—	(92,817,371)	(92,817,371)
Exercise of options granted under LTIP and NED plan	1,129,691	(872,516)	—	—	—	257,175
Recognition of share-based payment	—	5,251,572	—	—	—	5,251,572
Balance at June 30, 2022	**235,277,217**	**8,466,706**	**1,085,411**	**20,089,163**	**(216,941,353)**	**47,977,144**
Net loss for the year	—	—	—	—	(142,521,085)	(142,521,085)
Total Comprehensive income and expense for the period	—	—	—	—	(142,521,085)	(142,521,085)
Issuance of ordinary shares net of issuance costs $4,531,040	81,815,357	—	—	—	—	81,815,357
Exercise of options granted under LTIP and NED plan	3,790,978	(2,750,258)	—	—	—	1,040,720
Recognition of share-based payment	—	5,834,686	—	—	—	5,834,686
Balance at June 30, 2023	**320,883,552**	**11,551,134**	**1,085,411**	**20,089,163**	**(359,462,438)**	**(5,853,178)**
Net loss for the year	—	—	—	—	(220,242,105)	(220,242,105)
Total Comprehensive income and expense for the period	—	—	—	—	(220,242,105)	(220,242,105)
Issuance of ordinary shares in September 2023 net of issuance costs $4,764,890 (includes issuance costs paid to related party of $125,000)	50,273,023	—	—	—	—	50,273,023
Issuance of ordinary shares in June 2024 net of issuance cost of $8,903,734	94,926,676	—	—	—	—	94,926,676
Exercise of options investor options	894	—	—	—	—	894
Recognition of share-based payment	-—	5,084,613	—	—	—	5,084,613
Balance at June 30, 2024	**466,084,145**	**16,635,747**	**1,085,411**	**20,089,163**	**(579,704,543)**	**(75,810,077)**

The above consolidated statements of change in equity should be read in conjunction with the accompanying notes.

OPTHEA LIMITED
Consolidated Statements of Cash Flows
for the Years ended June 30, 2024, and 2023, and 2022

	Year ended June 30, 2024	2023	2022
	US$	US$	US$
Cashflow from operating activities			
Interest received	3,276,909	3,121,594	216,422
Royalty and license income received	209,487	3,826	90,683
Grant and other income	137,193	276,869	455,807
Payment of lease interest	(5,660)	(17,148)	(5,920)
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)	(170,559,633)	(130,292,806)	(77,064,842)
Research and development tax incentive scheme credit received	5,926,350	6,299,286	4,972,898
Net cash flows used in operating activities	(161,015,354)	(120,608,379)	(71,334,952)
Cash flow from investing activities:			
Purchase of plant and equipment	(33,489)	(21,954)	(16,910)
Net cash used in investing activities	(33,489)	(21,954)	(16,910)
Cash flows from financing activities:			
Payment of lease liabilities	(88,679)	(70,966)	(85,578)
Proceeds on issue of shares, net of issuance costs	158,817,514	81,815,358	—
Net proceeds from DFA	85,000,000	84,500,000	—
Cash received for ordinary shares issued on exercise of options	—	1,040,718	257,175
Net cash provided by financing activities	243,728,835	167,285,110	171,597
Increase in cash and cash equivalents	82,679,992	46,654,777	(71,180,265)
Effects of exchange rate changes on the balance of cash held in foreign currencies	602,641	(2,097,357)	(2,381,619)
Cash and cash equivalents at beginning of period	89,188,713	44,631,293	118,193,177
Cash and cash equivalents at end of period	172,471,346	89,188,713	44,631,293

The above consolidated statements of cash flows should be read in conjunction with the accompanying notes.

OPTHEA LIMITED
Notes to Consolidated Financial Statements

Note 1 Reporting Entity

Opthea Limited (the Company) is a listed public company incorporated in Australia. The address of its registered office and principal place of business is: Suite 0403, Level 4, 650 Chapel Street, South Yarra, VIC 3141, Australia. These consolidated financial statements comprise the Company and its subsidiaries (together referred to as the Group). The Group's principal activity is the development of new drugs for the treatment of eye diseases.

Note 2. Basis of Accounting

These financial statements are general purpose financial statements which have been prepared in accordance with International Financial Reporting Standards ("or IFRS Accounting Standards") as issued by the International Accounting Standards Board (the "IASB").

The financial statements comprise the consolidated financial statements of the Group. For the purposes of preparing the consolidated financial statements, the Company is a for-profit entity.

The financial statements were authorized for issue by the directors on August 30, 2024.

Going Concern

The consolidated financial statements have been prepared on the going concern basis, which contemplates continuity of normal activities and realization of assets and settlement of liabilities in the normal course of business.

For the full year ended June 30, 2024, the Group incurred a loss after income tax of $220,242,105 (2023: $142,521,085), and had net cash outflows from operating activities of $161,015,354 (2023: $120,608,379). As of June 30, 2024, the Group had cash and cash equivalents of $172,471,346 (June 2023: $89,188,713), net current assets of $124,136,906 (June 2023: $79,643,659), and was in a net liability position of $75,810,077 (June 2023: net liability $5,853,178).

The Group expects that the cash on hand at June 30, 2024 of $172.5 million, along with net proceeds from the Retail Entitlement Offer which closed in July 2024, will be able to fund its operations into the third calendar quarter of 2025 and that such proceeds will also be sufficient to fully fund all anticipated costs of the Phase 3 clinical trials to 52-week top-line data, expected in early second quarter calendar year 2025 for COAST and in mid-calendar year 2025 for ShORe trial. While sufficient funds are available into the third calendar quarter of 2025, the Group will need to raise significant additional funds to complete both trials' two-year efficacy and safety phase, file a biologics license application with the FDA and EMA, potentially launch sozinibercept, if approved, and meet the obligations under the Amended and Restated Development Funding Agreement ("DFA"). As the Group is still in the research and development phase, the ability of the Group to continue its development activities as a going concern is dependent on it deriving sufficient cash from debt and equity investors.

The Group does not have any committed external source of funds and expects to finance future cash needs through the exercise of outstanding registered investor options, public or private equity financings, or potential collaborations within select regions such as the U.S., E.U., Australia, or rest of world markets, to leverage greater market exposure and to commercialize sozinibercept for wet AMD.

As part of both equity financings in August/September 2023 and June/July 2024, investors in these equity capital raises received investor options ("Investor Options"). These Investor Options are registered and trade on the Australian Securities Exchange ("ASX"). Currently on issue are approximately 97.8 million 2023 Investor Options with an exercise price of A$0.80 and an expiry of August 31, 2025, and approximately 189.4 million 2024 Investor Options with an exercise price of A$1.00 and an expiry of June 30, 2026. Option holders can exercise their options and pay the cash proceeds to Opthea to secure their ordinary shares at any time before expiry. Assuming the holders exercise all their options, Opthea will receive approximately $50.9 million and $123.1 million in gross cash proceeds from the 2023 and 2024 Investor Options, applying current foreign exchange rates between the period 30 August 2024 to 30 June 2026.These options are considered uncommitted

funding at the date of the approval of these financial statements. Refer to Note 14 and 25 for details of how Investor Options are accounted for.

Opthea has a US$350.0 million shelf of American Depositary Shares ("ADS") on file with the Securities and Exchange Commission ("SEC") which it can draw upon in the U.S. market until its expiry in February 2025. Under this shelf, Opthea may offer and sell up to US$75.0 million of its ordinary shares in the form of ADSs through Jefferies, with each ADS representing eight ordinary shares (the "At the Market Program" or "ATM Program"). Opthea has not sold any ordinary shares under the ATM Program and the ability to raise capital under this program is subject to market conditions and is not guaranteed.

The DFA contains terms that require compliance by the Company to maintain a minimum cash balance and to provide a notice to the DFA Investors in the event it anticipates that it may not meet the requirement. Under such a notification, the DFA investors have the option, but not the obligation, to contribute additional funds under the existing DFA terms if the Group cannot sufficiently raise capital in a timely manner. Based on the cash flow forecast and in the absence of any capital raises or other sources of funding, the Group is expected to be below this requirement prior to the third calendar quarter 2025 and would therefore trigger a notification to the DFA Investors.

In certain instances which may result upon the termination of the DFA, the Group will be obligated to pay the DFA investors several multiples of the amounts paid to the Group under the DFA. At 30 June 2024, the Group remains in compliance with the DFA and no such instances have occurred or are expected to occur.

The Directors and management have considered the cash flow forecasts including the funding requirements of the business. They have also considered the Group's key risks and uncertainties affecting the likely development of the business, as well as the progress of the clinical trials. On February 14, 2024, the Group announced that it had completed enrollment of the COAST Phase 3 trial, and completion of enrollment of the ShORe Phase 3 trial was announced on May 28, 2024. The completion of the enrollments of these trials was a critical milestone in the Company's plans to commercialize sozinibercept for wet AMD.

While the Group can manage the timing of expected future cash outflows, any material changes to the Group's forecasts may impact the progress of the clinical trials and the timing of regulatory approval. The Group has a history of successfully raising capital to fund its ongoing operations, including a US$58.2 million private placement and rights equity offering in August/ September of 2023, securing the additional US$50.0 million option under the Amended DFA in December 2023, and a US$151.9 million private placement and rights equity offering in June/July of 2024 (of which US$114.3 million was received prior to 30 June 2024).

Based on this assessment, the Directors and management believe that the Group has adequate funding between its existing funds and the funds it is reasonably likely able to raise to continue normal activities, realize its assets, and settle its liabilities in the normal course of business. Accordingly, the directors have prepared the consolidated financial statements on the going concern basis.

There is no guarantee that sufficient funds will be able to be raised to finance operations for twelve months from the issuance of these consolidated financial statements. Therefore, a material uncertainty exists that may cast significant doubt as to whether the Group will continue as a going concern and, therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business.

The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the Group not continue as a going concern.

Note 3. Summary of Accounting Policies

The consolidated financial statements have been prepared using the material accounting policies and measurement bases summarized below.

Basis of measurement

The consolidated financial statements have been prepared on a historical cost basis, except for certain financial liabilities, which have been measured at fair value. All amounts are presented in United States dollars unless otherwise stated.

Change in Presentation

i. *Research and Development and Administrative expenses*

In the current financial year the Group changed its presentation in the consolidated statement of profit or loss and other comprehensive income to reflect expenses by business function. As part of this change, it was identified that certain insurance and employee costs should be reclassified from Administration expenses to Research and Development expenses to better reflect the full nature of the Research and Development expenses. These adjustments represent reclassifications within operating expenses and had no effect on the operating loss and total loss for the year. Prior year comparative amounts have been reclassified which resulted in $8 million of expenses being reclassified from Administration expenses to Research and Development expenses.

ii. Adjustment of 31 December 2023 derivative financial liability

Subsequent to the issuance of the Company's 31 December 2023 condensed consolidated interim financial statements furnished through a 6-K on February 29, 2024, the Company determined that a $3.2 million adjustment to contributed equity, $5.6 million Fair value loss on derivatives – investor options and a corresponding financial liability of $8.7 million relating to Investor options issued in September 2023 were improperly excluded from the condensed consolidated interim financial statements as of and for the six-month period ended 31 December 2023. The below table reflects the impact of the adjustment on key statement of profit and loss and other comprehensive income and statement of financial position line items. We will reflect these adjustments in the comparatives included in the 31 December 2024 condensed consolidated interim financial statements at the time such financial statements are issued.

	As previously reported - December 31, 2023	Adjustment	As adjusted
Fair value loss on derivatives - investor options	-	5,499,738	5,499,738
Loss before tax	101,223,489	5,499,738	106,723,227
Derivative financial liabilities – investor options	-	(8,662,603)	(8,662,603)
Contributed equity	374,320,334	(3,162,865)	371,157,469
Accumulated losses	(455,647,868)	(5,499,738)	(461,147,606)
Total equity	(46,913,724)	(8,662,603)	(55,576,327)
Basic and diluted loss per share (cents)	(16.23)	(0.95)	(17.18)

Basis of Consolidation

The consolidated financial statements incorporate the financial statements of the Company and its subsidiaries. Control is achieved when the Company:

- Has power over the investee;
- Is exposed, or has rights, to variable returns from its involvement with the investee; and
- Has the ability to use its power to affect its returns.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Foreign currency translation

i. Functional and presentation currency

The functional and presentation currency of the Group is the United States dollars (US$).

ii. Transactions and balances

Transactions in foreign currencies are initially recorded in the functional currency by applying the exchange rates ruling in place at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling in place at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as of the date of the initial transaction. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

Financial assets and liabilities

Recognition and derecognition of financial assets

Purchases and sales of financial assets that require delivery of assets within the time frame generally established by regulation or convention in the marketplace are recognized on the trade date, i.e., the date that the Group commits to purchase the asset. Financial assets are derecognized when the right to receive cash flows from the financial assets has expired or when the entity transfers substantially all the risks and rewards of the financial assets. If the entity neither retains nor transfers substantially all of the risks and rewards, it derecognizes the asset if it has transferred control of the assets.

When financial assets are recognized initially, they are measured at fair value, plus directly attributable transaction costs.

Cash and cash equivalents

Cash and cash equivalents in the statement of financial position comprise cash at bank and in hand and short-term deposits with an original maturity of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purposes of the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Other receivables

Other receivables generally comprise bank interest receivable, other receivables from external parties and Goods and Services Tax (GST) credits receivable and are recognized and carried at original invoice amount less an allowance for any uncollectible amounts. The amounts are usually received within 30 to 60 days of recognition.

The Group measures the loss allowance for receivables at an amount equal to lifetime expected credit losses (ECL). The ECL on receivables are estimated under the simplified approach as permitted under IFRS 9 “Financial Instruments.” This uses a provision matrix by reference to past experience of the debtor and an analysis of the debtor’s current financial position, adjusted for factors that are specific to the debtors and general economic conditions of the industry in which the debtors operate.

The Group writes off a receivable when there is information indicating that the debtor is in severe financial difficulty and there is no realistic prospect of recovery.

Finance income

Almost all of the Group’s finance income is earned on short-term bank deposits, and as such, finance income is recognized when the Group’s right to receive the payment is established.

Payables

Payables are carried at amortized cost and due to their short-term nature, they are not discounted. They represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services.

The amounts are unsecured and are usually paid within 30 days of recognition.

Financial liabilities - DFA

Financial liabilities are recognized in the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. Financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisitions or issue of financial liabilities (other than financial liabilities at fair value through profit or loss) are deducted from the fair value of the financial liabilities, as appropriate, on initial recognition. Subsequent measurement of the liability will be at its amortized cost, subject to any re-measurement of the obligation for changes in assumptions, which would be recognized through the consolidated statement of profit or loss and other comprehensive income.

Amortized cost and effective interest method

The effective interest method is a method of calculating the amortized cost of an instrument and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or (where appropriate) a shorter period, to the amortized cost of the financial liability.

Interest expense is recognized in profit and loss and is included in the "Interest expense on DFA" line item.

Derivative financial liabilities -investor options

Derivative financial liabilities relate to investor options and are recognized in the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. These options are considered a derivative as these are options with an exercise price denominated in a currency that differs from an entity's functional currency and where certain existing equity investors were not offered to participate in the equity raise on a pro rata basis. Such derivatives are measured at fair value with subsequent changes in fair value accounted for through profit and loss Transaction costs that are directly attributable to the issue of derivative financial liabilities at fair value through profit or loss are recognized immediately in profit or loss. Transaction costs are allocated between the instruments issued based on the proportionate fair value.

At every reporting period, the Company reviews the fair value of the investor options which can be measured against the current trading value of the options on ASX., It is expected that a revaluation will result in a non-cash gain or loss depending on the closing trading price of the options. Revaluation gains or losses are recognized on the Profit and Loss statement with a corresponding adjustment recorded to the liability. The gains or losses are unrealized.

Equipment

Equipment is stated at historical cost less accumulated depreciation and any accumulated impairment losses. Depreciation is calculated on a straight-line basis over their useful economic lives as follows:

- Equipment and furniture – 3 to 10 years; and
- Leasehold improvements – 8 years or the term of the lease if shorter.

The assets' residual values, useful lives and amortization methods are reviewed, and adjusted if appropriate, at each financial year end.

An item of equipment is derecognized upon disposal or when no further economic benefits are expected from its use or disposal.

Research and development costs

Research costs are expensed as incurred. An intangible asset arising from the development expenditure on an internal project will only be recognized when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the

development and the ability to measure reliably the expenditure attributable to the intangible asset during its development. The Company considers that the capitalization may only be considered after regulatory approval.

As of June 30, 2024, 2023 and 2022, the Group is in the research phase and has not capitalized any development costs to date.

Provisions and employee benefits

i. Wages, salaries, annual leave and sick leave

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the reporting date are recognized in current provisions in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled. Expenses for non-accumulating sick leave are recognized when the leave is taken and are measured at the rate paid or payable.

ii. Long service leave

The liability for long service leave is recognized in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date. Consideration is given to expected future wage and salary levels, experience of employee departures, and periods of service. Expected future payments are discounted using market yields at the reporting date on bonds with terms to maturity that match, as closely as possible, the estimated future cash outflows.

Share-based payment transactions

The Group provides benefits to directors and employees (including key management personnel) of the Group in the form of share-based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions).

The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. Binomial models are used to value the options issued.

The cost of the equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

The charge to profit or loss for the period is the cumulative amount less the amounts already charged in previous periods. There is a corresponding credit to equity.

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so.

Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds. Transaction costs are allocated between the instruments issued based on the proportionate fair value.

Revenue recognition

License revenue in connection with licensing of the Group's intellectual property (including patents) to customers is recognized as a right to use the Group's intellectual property as it exists at the point in time in which the license is granted. This is because the contracts for the license of intellectual property are distinct and do not require, nor does the customer reasonably expect, that the Group will undertake further activities that significantly affect the intellectual property to which the customer has the rights. Although the Group is entitled to sales-based royalties from the eventual sales of goods and services to third parties using the intellectual property licensed, these royalty arrangements do not in themselves indicate that the customer would reasonably expect the Group to undertake such activities, and no such activities are undertaken or contracted in practice. Accordingly, the promise

to provide rights to the Group's intellectual property is accounted for as a performance obligation satisfied at a point in time.

The following consideration is received in exchange for licenses of intellectual property:

- Up-front license fees – these are fixed amounts and are recognized at the point in time when the Group transfers the intellectual property to the customer.

- Sales-based royalties – these are variable consideration amounts promised in exchange for the license of intellectual property and are recognized when the sales to third parties occur given the performance obligation to transfer the intellectual property to the customer is already satisfied.

During the years ended June 30, 2024, 2023 and 2022, the Group's only revenue related to sales-based royalties.

Income tax

Current tax

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities based on the current period's taxable income.

The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date.

Research and development tax incentive

The Research and Development (R&D) Tax Incentive Scheme is an Australian Federal Government program under which eligible companies with annual aggregated revenue of less than A$20 million can receive cash amounts equal to 43.5% of eligible research and development expenditures from the Australian Taxation Office (ATO). The R&D Tax Incentive Scheme incentive relates to eligible expenditure incurred in Australia and, under certain circumstances, overseas on the development of the Group's lead candidate, sozinibercept. The R&D tax incentive is applied annually to eligible expenditure incurred during the Group's financial year following annual application to AusIndustry, an Australian governmental agency, and subsequent filing of its Income Tax Return with the ATO after the financial year end.

The Group estimates the amount of R&D tax incentive after the completion of the financial year based on eligible Australia and overseas expenditures incurred during that year.

The Group has presented incentives in respect of the R&D Tax Incentive Scheme within income tax benefit in the Statements of Profit or Loss and Other Comprehensive Income by analogizing with IAS 12 *"Income Taxes"*.

Deferred tax

Deferred income tax is provided on all temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognized for all taxable temporary differences except when the deferred income tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, does not give rise to equal taxable and deductible temporary differences.

Deferred income tax assets are recognized for all deductible temporary differences, carry forward of unused tax assets (or credits) and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized, except when the deferred income tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit or taxable profit or loss.

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilized.

Unrecognized deferred income tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at balance date.

Income taxes relating to items recognized directly in equity are recognized directly in equity and not in profit or loss.

Tax consolidation legislation

Tax consolidation is a system adopted by the ATO that treats a group of entities as a single entity for tax purposes. Opthea Limited and its 100% owned Australian domiciled subsidiary formed a tax consolidated group effective July 1, 2003. The head entity, Opthea Limited, and its controlled entity, Vegenics Pty Ltd, are current members of the tax consolidated group and account for their own current and deferred tax amounts. Members of the tax consolidated group have adopted the "separate taxpayer within group" method to allocate the current and deferred tax amounts to each entity within the Group. This method requires adjustments for transactions and events occurring within the tax consolidated group that do not give rise to a tax consequence for the Group or that have a different tax consequence at the level of the Group.

This method requires adjustments for transactions and events occurring within the tax consolidated group that do not give rise to a tax consequence for the Group or that have a different tax consequence at the level of the Group.

The head entity which is the parent entity, in assuming the net unused tax losses and unused relevant tax credits, has recognized reductions to investments in subsidiaries and where the amount of tax losses assumed is in excess of the carrying value of the investment, the parent has recognized the difference as a distribution from subsidiaries in profit or loss.

Other taxes

Revenues, expenses, assets and liabilities are recognized net of the amount of GST except:

- When the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognized as part of the cost of acquisition of the asset or as part of the expense item as applicable; and

- Receivables and payables are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to the taxation authority is included as part of receivables or payables in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority is classified as part of operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

Note 4. Critical Accounting Judgments and Key Sources of Estimation Uncertainty

In applying the Group's accounting policies, management continually evaluates judgments, estimates and assumptions based on experience and other factors, including expectations of future events that may have an impact on the Group. All judgments, estimates and assumptions made are believed to be reasonable based on the most current set of circumstances available to management. Actual results may differ from the judgments, estimates and assumptions.

Significant judgments, estimates and assumptions made by management in the preparation of these financial statements are outlined below:

4.1 Critical judgments in applying accounting policies

Research and development costs

The majority of Opthea's expenditure is incurred as a result of clinical trials for sozinibercept. During the years ended June 30, 2020 2021 and 2022, Opthea completed its Phase 2b wet age-related macular degeneration (wet AMD) and Phase 1b/2a diabetic macular edema (DME) trials and Phase 3 clinical trials for sozinibercept was initiated during 2021. A key measure of Opthea's performance is the level of expenditure incurred on the research of sozinibercept**.**

Judgment is required in relation to:

- The classification of expenses in the income statement between research and development costs and operating expenses; and
- Whether costs relate to R&D, and consequently if they meet the capitalization criteria under IAS 38 "*Intangible Assets*."

The directors have determined that the Group is still in a research phase and accordingly, no development costs have been capitalized as of June 30, 2024, 2023 and 2022. The development costs may be considered for capitalization post receiving regulatory approval.

DFA

The Group's accounting policy for DFA requires judgment around the determination of it having the characteristics of a debt instrument. The payments received under the DFA have been recorded as a financial liability in the Group's consolidated statement of financial position. The Company exercised significant judgement in accounting for the amended DFA, including consideration of whether the amended DFA resulted in a modification of the original loan. The Company concluded that the amended DFA agreement forms part of the existing agreement as the US$50 million is contemplated in the existing agreement on the same return and repayment profile, there have been no substantive changes in the original terms and conditions of the loan and the co-investor was introduced by Ocelot SPV LP ("Ocelot"). Judgment is also required in assessing the timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due as discounted using an imputed interest rate. If the timing and/or amount of such expected payments is materially different from the estimates used on the initial recognition date, the Group will adjust the accretion of the development financing liability using the previously determined imputed interest rate. Refer to Note 13 and 24 for further information.

Derivative financial liabilities – investor options

The Group's accounting for investor options requires judgment as these are options with an exercise price denominated in a currency that differs from an entity's functional currency and are treated as a derivative where certain existing equity investors were not offered to participate in the equity raise on a pro rata basis. Judgement is required in determining whether the offer was made on a pro rata basis, which impacts the accounting of the options. Such derivatives measured at fair value with subsequent changes in fair value accounted for through profit and loss. Refer to Note14 and 25 for further information.

Taxation

Research and development tax incentive

The Research and Development (R&D) Tax Incentive Scheme is an Australian Federal Government program under which eligible companies can receive cash refunds of 43.5% of eligible R&D expenditure. Judgments are required as to the R&D tax incentive refundable offset eligibility in respect of:

- The Group's ability to make claims and its continued compliance under the scheme;
- R&D and other supporting costs previously approved by Australian tax authorities;
- Estimated amounts, timing and geographical location of future costs related to the projects for which applications have been approved to date; and
- Assessment of whether expenditure on projects for which approval has been given by Australian tax authorities relate to Australian or overseas expenditure.

For the years ended June 30, 2024, and 2023, the Group has recognized an R&D tax incentive receivable of US$10.4 million and US$5.9 million respectively within the consolidated statements of financial position, with a corresponding amount recognized within income tax benefit within the consolidated statements of profit or loss and other comprehensive income.

The R&D tax incentive receivable as of June 30, 2024 and 2023 is based on the legislation as currently enacted as of June 30, 2024 and 2023, respectively. Any proposed changes to the legislation, such as rate changes and eligibility requirements, may have a retrospective impact if the legislation is passed. During the years ended June 30, 2024 and 2023, no such legislative changes have occurred.

Investment tax credits such as the R&D tax incentive are outside of the scope of IAS 12 "*Income Taxes*" and IAS 20 "*Accounting for Government Grants and Disclosure of Government Assistance*." Based on the guidance in IAS 8 "Accounting Policies, Changes in Accounting Estimates and Errors," companies need to make an accounting policy choice on how to present these incentives, which in practice is done by either analogizing with IAS 12 or with IAS 20. In the Group's opinion, the R&D tax incentive should be presented by analogizing to IAS 12 because the nature of the incentive is considered to be more closely aligned to income taxes, based on the following considerations:

- The R&D tax incentive is considered an income tax offset which will be offset against the Group's tax obligation if and when the Group returns to a net tax payable position. In addition, whilst the Group is currently eligible to receive cash payments under the scheme since its consolidated revenue is currently below A$20 million, if and when the Group generates revenue in excess of A$20 million the R&D tax incentive will become non-refundable and can only be offset against any future income tax payable by the Group.
- The ATO, which is the tax authority in Australia, manages the annual claims process as the R&D tax incentive is included in the Group's annual income tax return.
- The ATO is also responsible for making the R&D tax incentive cash payment if a company is eligible for a cash refund under the program, oversees compliance with the requirements of the R&D tax incentive scheme and performs pre-issuance reviews. Refer to Note 16 for further information.

Income tax

The Group's accounting policy for taxation requires judgments as to the differences between tax and accounting treatments of income and costs recognized in the consolidated statements of profit or loss and other comprehensive income. Judgment is also required in assessing whether deferred tax assets and liabilities are recognized in the statements of financial position and if accumulated income tax losses can be used to offset potential future tax profits.

Functional currency

Significant judgment is required in determining the currency of the primary economic environment in which the Group operates, which requires an evaluation of various indicators related to the Group's underlying transactions, events and conditions as they relate to generating and expending cash.

4.2 Key sources of estimation uncertainty

Development funding - financial liability

The Group evaluated the Funding Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to DFA investors was not considered substantive and genuine. Accordingly, the Group has recorded payments received under the Funding Agreement as part of a development financing liability in its consolidated balance sheet. The Group measures the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. If the dates are delayed from those used at reporting date, it is expected that a remeasurement will result in a non-cash gain. If the timelines for approval and launch are accelerated, the Group would anticipate a remeasurement resulting in a non-cash charge to be recognized in the Consolidated Statements of Profit or Loss. Refer to Note 13 and 27 for further information.

Derivative financial liabilities - investor options

The Group accounts for investor options as a derivative financial liability. Such derivatives are measured at fair value with subsequent changes in fair value accounted for through profit and loss. For the investor options that are traded on the Australian Securities Exchange, the Group uses the quoted price at the balance sheet date as the fair value of the options. For the investor options issued on June 14, 2024, fair values were determined internally using Binomial models as a quoted price was not available as at year end. Key inputs to the valuation include the share price at grant date, expected term, volatility, dividend yield, risk free rate and exercise price. Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting market conditions attached to the option), and behavioral considerations. Expected volatility is based on the historical share price volatility over the past 2 years. These investor options were listed for trading on the Australian Securities Exchange in July 2024. Should the quoted price differ from the internally determined fair value, this could have a material impact on the amounts recognized in derivative financial liabilities and in the profit and loss. Refer to Note 14 and 25 for further information.

Share-based payment transactions

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Fair values are determined internally using Binomial models. The related assumptions are detailed in note 34. The accounting estimates and assumptions relating to equity-settled share-based payments have no impact on the carrying amounts of assets and liabilities in future reporting periods but may impact expenses and equity. Should one or more of the assumptions and estimates used in estimating the fair value of share-based payments change, this could have a material impact on the amounts recognized in equity and employee-related expenses. Refer to Note 39 for further information.

Note 5. Application of New and Revised Accounting Standards

New and amended Accounting Standards that are effective for the current year

The Group has adopted all of the new and revised Standards and Interpretations issued by the International Accounting Standards Board (the IASB) that are relevant to its operations and effective for the current year.

In the current year, the Group has applied a number of amendments to International Financial Reporting Standards and Interpretations issued by the International Accounting Standards Board (IASB) that are effective for an annual period that begins on or after July 1, 2023. Their adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.

New and revised International Accounting Standards and Interpretations on issue but not yet effective

At the date of authorization of the financial statements, certain new accounting standard and interpretations have been published that are not mandatory for June 30, 2024 reporting periods and have not been early adopted by the Company.

- IFRS 18 *Presentation and Disclosure in Financial Statements*

The Directors have not yet evaluated the impact that the new and revised Accounting Standards, Interpretations and amendments will have on the Group's financial statements.

The Group has not applied the new and revised International Accounting Standards, Interpretations and amendments that have been issued but are not yet effective.

The new and revised Accounting Standards, Interpretations and amendments are not expected to have a material impact on the amounts recognized or disclosures included in the Group's financial statements

Note 6. Segment Information

The Group operates in one industry and two geographical areas, those being the biotechnology and healthcare industry and Australia and United States, respectively.

The Group is focused primarily on developing a novel therapy for the treatment of highly prevalent and progressive retinal diseases.

The chief executive officer regularly reviews entity wide information that is compliant with International Financial Reporting Standards. There is only one segment for segment reporting purposes, and the information reviewed by the chief executive officer for the purpose of resources allocation and performance assessment is the same as the information presented in the consolidated financial statements.

The Group's only revenue stream in the current and previous financial year is royalty income generated from licenses granted in respect of the Group's intellectual property that are unrelated to the Group's core business and the development of sozinibercept and that are not under development. These licenses are primarily used by third-party licensees for research purposes. All of the royalty income of US$124,666 (2023: US$108,406 2022:US$90,683) was generated from customers based outside of Australia. The Group does not have any major customers. All equipment is located in Australia and United States.

Note 7. Revenue

	2024	2023	2022
	US$	US$	US$
Sales-based royalties	124,666	108,406	90,683
Total Revenue	**124,666**	**108,406**	**90,683**

Note 8. Other Income

	2024	2023	2022
	US$	US$	US$
Grant and other income	137,193	276,869	108,322
Total other income	**137,193**	**276,869**	**108,322**

Note 9. Research and Development Expenses

	2024	2023	2022
	US$	US$	US$
Employee benefits expenses:			
Salaries and fees	4,809,177	3,756,109	1,407,205
Cash bonuses	1,424,817	445,097	190,198
Superannuation	182,223	120,311	71,055
Share-based payments expense	1,299,456	1,909,173	829,598
Total employee benefits expense	7,715,673	6,230,690	2,498,056
Payroll tax	295,069	207,562	81,281
Research Insurance	322,306	262,322	212,289
Research project costs	167,993,273	122,128,314	78,654,217
Total research and development expenses	**176,326,321**	**128,828,888**	**81,445,843**

The research project costs relate to the research programs in respect to the treatment of eye diseases by sozinibercept .

Note 10. Expenses

	2024	2023	2022
	US$	US$	US$
Administrative expenses			
Employee benefits expenses:			
Salaries and fees	3,946,256	2,518,450	1,524,038
Cash bonuses	707,384	820,848	186,451
Superannuation	120,197	167,086	100,844
Share-based payments expense	3,785,157	3,925,513	4,421,974
Total employee benefits expense	8,558,994	7,431,897	6,233,307
Other expenses:			
Insurance	1,669,307	2,289,446	3,992,816
Investor relations costs	383,092	451,378	328,026
Audit and accounting	526,002	337,038	496,652
Travel expenses	743,878	580,644	13,616
Payroll tax	186,627	132,441	91,604
Legal fees	1,303,884	1,330,054	1,252,014
Advisory fees[1]	8,239	6,084,005	156,978
Consultancy costs	708,955	1,389,048	1,619,824
Other expenses	1,586,268	1,455,004	1,027,906
Total other expenses	7,116,252	14,049,058	8,979,436
Depreciation of:			
Equipment and furniture	18,800	17,000	11,917
Right-of-use assets	84,225	84,226	66,465
Total depreciation expense	103,025	101,226	78,382
Loss on disposal of non-current assets	—	—	169
Total administrative expenses	**15,778,271**	**21,582,181**	**15,291,294**

1. Advisory fees relates to a market assessment of potential financing alternatives and solutions.

Note 11. Finance Income

	2024	2023	2022
	US$	US$	US$
Interest income	3,394,726	3,227,496	235,468
Total finance income	**3,394,726**	**3,227,496**	**235,468**

Note 12. Interest expense on DFA

	2024	2023	2022
	US$	US$	US$
Interest expense on DFA	30,263,042	13,462,160	—
Total interest expense on DFA	**30,263,042**	**13,462,160**	**—**

The interest expense on DFA is non-cash interest at the imputed rate of 23%.

Note 13. Gain on remeasurement of financial liability -DFA

	2024	2023	2022
	US$	US$	US$
Gain on remeasurement of financial liability - DFA	387,284	12,302,160	—
Total gain on remeasurement of financial liability - DFA	**387,284**	**12,302,160**	**—**

At each reporting date, the Group reassess the estimated timing of regulatory approval and attainment of sales milestones and the expected fixed and variable contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different from the estimates used on the initial recognition date, the Group will adjust the accretion of the development financing liability using the previously determined imputed interest rate.

At June 30, 2023 the Group performed a remeasurement of the carrying amount of the Financial Liability. The expected timeline for approval and commercial launch have been delayed by twelve months, thus extending date of expected repayments. As the Group has more time to repay the amounts owed, the carrying value of the Financial Liability at June 30, 2023 was adjusted downward to reflect this delay. The remeasurement resulted in a non-cash gain on revaluation of $12.3 million. This change is recorded on the Profit or Loss statement as a gain on remeasurement of financial liability.

At June 30, 2024, the Group performed a remeasurement of the carrying amount of the Financial Liability recognized under the Development Funding Agreement. The remeasurement resulted in a non-cash gain on remeasurement of $0.4 million. This change is recorded on the consolidated statement of profit or loss and other comprehensive income as an unrealized adjustment gain on the DFA. The Group will continue to accrete non-cash interest at the imputed rate of approximately 23%. Refer to Note 27.

The DFA financial liability is initially recognized at fair value, and subsequently measured at amortized cost, using the effective interest rate method. In the prior period, changes in the financial liability arising from changes in the expected timeline for approval and commercial launch were presented in the consolidated statement of profit or loss and other comprehensive income as a “Fair value adjustment gain on DFA.” In the current year, the description of this amount has been updated to “Gain on remeasurement of financial liability – DFA” to better reflect the underlying nature of the instrument and the subsequent measurement at amortized cost. This change had no effect on the statement of financial position and the reported results of operations in any of the financial periods presented.

Note 14. Fair value loss on derivative - investor options

	2024	2023	2022
	US$	US$	US$
Fair value loss on derivative - investor options in September 2023 (2023 Investor options)	11,192,991	—	—
Fair value loss on derivative - investor options in June 2024 (2024 Investor options)	30,544	—	—
Total fair value loss on derivative - investor options	**11,223,535**	**—**	**—**

Refer to Note 25 and Note 30.

Note 15. Net Foreign Exchange loss

	2024	2023	2022
	US$	US$	US$
Net foreign exchange loss	107,001	489,137	2,813,993
Total net foreign exchange loss	**107,001**	**489,137**	**2,813,993**

Exchange differences arising on the translation of monetary items are recognized in the consolidated statements of profit and loss and other comprehensive income.

Note 16. Income Taxes

	2024	2023	2022
	US$	US$	US$
(a) Income tax benefit			
The major components of income tax benefit are:			
Statement of Profit or Loss and Other Comprehensive Income			
Current tax	(985,843)	—	0
Current income tax credit	10,398,039	5,926,350	6,299,286
	9,412,196	5,926,350	6,299,286
Deferred tax			
In respect of the current year	—	—	—
Total income tax benefit recognized in the Statement of Comprehensive Income	9,412,196	5,926,350	6,299,286
(b) Current tax receivable			
	US$	**US$**	**US$**
Research and Development Tax Incentive Credit receivable	10,398,039	5,926,350	6,299,286

(c) Numerical reconciliation between aggregate income tax benefit recognized in the Statement of Profit of Loss and Other Comprehensive Income and benefit calculated per the statutory income tax rate

A reconciliation between income tax benefit and the product of accounting loss before income tax multiplied by the Group's applicable income tax rate is as follows:

	2024	2023	2022
	US$	US$	US$
Accounting loss before tax	(229,654,301)	(148,447,435)	(99,116,657)
At the Company's statutory income tax rate of 30%	68,896,290	44,534,230	29,734,997
R&D tax incentive on eligible expenses	10,398,039	5,926,350	6,299,286
Non-deductible R&D expenditure	(7,175,011)	(4,087,138)	(4,344,335)
Other non-deductible expenses - share-based payment expense	(1,525,384)	(1,750,406)	(1,575,472)
Amount of temporary differences and carried forward tax losses not recognized	(61,181,738)	(38,696,687)	(23,815,190)
	9,412,196	5,926,350	6,299,286

(d) Recognized deferred tax assets and liabilities in statement of financial position	**June 30, 2024**	**June 30, 2023**	**June 30, 2022**
Deferred income tax at June 30 relates to the following:			
Deferred tax liabilities:			
Interest and royalty income receivable (future assessable income)	(77,184)	(44,785)	(17,085)
	(77,184)	(44,785)	**(17,085)**
Deferred tax assets related to temporary differences:			
Recognition of tax losses		—	—
Accrued expenses and other liabilities	201,437	200,536	198,607
Employee provisions	189,897	161,006	161,159
Other miscellaneous items	3,340,215	270,721	306,531
	3,731,549	632,263	666,297
Net deferred tax assets	3,654,365	587,478	649,212
Less: temporary differences not recognized	(3,654,365)	(587,478)	(649,212)
Net deferred tax recognized in the statement of financial position	—	—	—

(d) Carry forward unrecognized tax losses

The Group had income tax losses of US$124,807,138 and capital losses of US$412,122 at year end (2023: income tax losses of US$67,878,759 and capital losses of US$412,122) for which no deferred tax asset is recognized on the consolidated statement of financial position as they are currently not considered probable of realization. These tax losses are available indefinitely for offset against future assessable income subject to continuing to meet relevant statutory tests.

(e) Franking credit balance

Franking credits are a type of tax credit in Australia that is available to the Group's shareholder to reduce double taxation on any dividends paid by the Group. The franking account balance at the end of the financial year at 30% (2023: 30%) is A$227,371 (2023: A$227,371), which represents the amount of franking credits available for the subsequent financial year. Franking credits are not recognized in the consolidated statement of financial position.

Note 17. Earnings per Share

	2024	2023	2022
	US$	US$	US$
The following reflects the income used in the basic and diluted earnings per share computations:			
(a) Earnings used in calculating earnings per share			
Net loss attributable to ordinary equity holders of the parent	(220,242,105)	(142,521,085)	(92,817,371)
(b) Weighted average number of shares			
Weighted average number of ordinary shares on issue for basic earnings per share	638,202,922	442,637,406	351,560,198
Effect of dilution:			
Share options	—	—	—
Weighted average number of ordinary shares adjusted for the effect of dilution	**638,202,922**	**442,637,406**	**351,560,198**
Loss per share (basic and diluted in cents)	**(34.51)**	**(32.20)**	**(26.40)**

On August 24 and 28, 2023 the company announced a capital raising which has involved 195,647,457 ordinary shares and investor options that represent potential ordinary shares of 97,823,728.

On June 14, 2024 the company announced a capital raising which involved an additional 139,627,846 ordinary shares and options that represent potential ordinary shares of 189,428,654.

Diluted earnings per share is calculated as net loss divided by the weighted average number of ordinary shares and dilutive potential ordinary shares. Options granted under the Long Term Incentive (LTIP) and Non-Executive Director Share and Option (NED Plan) plans would generally be included in the calculation due to the conditions of the issuance being satisfied.

As the Group is in a loss position, the options are anti-dilutive and, accordingly, the basic loss per share is the same as the diluted loss per share.

At June 30, 2024, a total number of 35,300,000 options/rights (2023: 25,450,000), 6,550,000 ADS options that represent 8 ordinary shares for each ADS held (2023:1,505,000) and 240,708,149 (2023: nil) investor options were anti-dilutive and were therefore excluded from the weighted average number of ordinary shares for the purpose of diluted earnings per share. These options related to the option plans listed below.

Fully paid ordinary shares have no par value, carry one vote per share and carry the right to dividends. No cash dividends have been paid, declared or recommended during or since the end of the financial year by the Company.

Ordinary Options	**2024**	**2023**	**2022**
NED Plan	21,000,000	16,500,000	14,000,000
LTIP	11,400,000	6,050,000	7,388,000
	32,400,000	**22,550,000**	**21,388,000**

	2024	**2023**	**2022**
Performance Rights			
NED Plan	650,000	650,000	—
LTIP	2,250,000	2,250,000	1,600,000
	2,900,000	**2,900,000**	**1,600,000**

	2024	**2023**	**2022**
ADS Options			
NED Plan	—	—	—
LTIP - Extended terms	277,000	—	—
LTIP	6,273,000	1,505,000	925,000
	6,550,000	**1,505,000**	**925,000**

Investor Options	**2024**	**2023**	**2022**
2023 investor options - listed	97,822,109	—	—
2024 investor options- granted and not listed	142,886,040	—	—
	240,708,149	**—**	**—**

As of June 30, 2024, 20,024,203 outstanding options and rights were exercisable as of that date (2023: 10,842,234 2022: 12,857,589). As at June 30, 2024 537,914 outstanding ADS options were exercisable as of that date (2023: 250,000, 2021: nil).

Note 18. Current Assets – Cash and Cash Equivalents

	June 30, 2024	**June 30, 2023**
	US$	**US$**
Cash at bank and in hand	91,728,846	12,067,158
Short-term deposits	80,742,500	77,121,555
Total cash and cash equivalents	**172,471,346**	**89,188,713**

Cash at bank earns interest at floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value.

Short term-deposits are with two major Australian banks and are made for varying periods of between 30 and 92 days, depending on the immediate cash requirements of the Group, and earn interest at a fixed rate for the respective short-term deposit periods. At year end, the average rate was 4.71% (2023: 4.67%, 2022: 0.43%).

Note 19. Current Assets - Receivables

	June 30, 2024	June 30, 2023
	US$	US$
Interest receivable	280,669	162,853
GST receivable[1]	1,071,001	325,474
Other receivable[1]	74,730	148,237
Total current receivables	**1,426,400**	**636,564**

1 The GST and other receivables are non-interest bearing. There were no receivables with a material expected credit loss recorded during the financial year (2023: nil, 2022: nil).

Note 20. Current Assets - Prepayments

	June 30, 2024	June 30, 2023
	US$	US$
Launch Service Agreement	2,700,000	900,000
R&D Contract Research Organization	223,239	793,964
Insurance	608,467	717,064
Other prepayments	365,073	223,643
Total current prepayments	**3,896,779**	**2,634,671**

The Launch Service Agreement prepayment is for the management and oversight of trials The R&D Contract Research Organization prepayment consists of prepayments on the Phase 3 clinical trial for sozinibercept in order to secure services across the world. These prepayments cover key milestones and are expected to be consumed within the next 12 months. The insurance amount relates to specific Phase 3 Clinical trial insurance in place for various sites around the world covering periods to end of 2024. The non-current portion of the prepayments are recorded as non-current assets. Refer to Note 22.

Note 21. Non-Current Assets - Right of Use Assets

The Group has a three- year lease contract for its head office premises in Melbourne, Australia, which commenced on 15 July 2022. The agreement does not contain any extension options. The carrying amount of the lease at June 30, 2024 is as follows:

	June 30, 2024	June 30, 2023
	US$	US$
Right-of-Use Asset Cost		
Opening balance as at July 1	534,231	281,554
Additions	—	252,677
Exchange on translations	—	—
	534,231	534,231
Right-of-Use-Asset Depreciation		
Opening balance as at July 1	(365,780)	(281,554)
Charge to the period	(84,225)	(84,226)
Exchange on translation	—	—
	(450,005)	(365,780)
Net carrying amount at June 30	**84,226**	**168,451**

Note 22. Non-Current Assets - Prepayments

	June 30, 2024	June 30, 2023
	US$	US$
Prepayments	466,701	53,535
Total non-current prepayments	**466,701**	**53,535**

The non-current prepayment amount relates to the Launch Service Agreement and specific Phase 3 Clinical trial insurance in place for various sites around the world covering periods to 2026.

Note 23. Current Liabilities – Payables

	June 30, 2024	June 30, 2023
	US$	US$
Accounts Payable (unsecured)[1]	38,059,829	17,842,981
Payroll related tax liability	44,592	48,873
Total current payables	**38,104,421**	**17,891,854**

1 Accounts Payable are non-interest bearing and are normally settled on 30 day terms.

Note 24. Current Liabilities - Provisions

	June 30, 2024	June 30, 2023
	US$	US$
Annual leave	761,559	500,361
Long service leave	256,189	252,939
Total current provisions	**1,017,748**	**753,300**

Note 25. Current Liabilities - Derivative Financial Liabilities Investor Options

	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
	Number outstanding	Number outstanding	US$	US$
Carrying amount at July 1	—	—	—	—
Fair valuation upon listing in September -2023	97,823,852	—	3,162,954	—
Fair valuation upon issuance in June -2024	142,886,040		10,454,056	
Fair value on conversions of options to shares	(1,743)	—	(89)	—
Fair value loss on investor options at reporting date-2023 Investor options	—	—	11,192,991	—
Fair value loss on investor options at reporting date-2024 Investor options	-	—	30,544	—
Total financial liabilities investor options	**240,708,149**	**—**	**24,840,456**	**—**

Equity and Investor options -2023

On August 28, 2023, the Company offered 160,213,060 new shares in an fully underwritten ANREO at the offer price of A$0.46 per new share and approximately 80.0 million Institutional and placement options with an exercise price of A$0.80 to participants in the Placement and Institutional Entitlement Offer on the basis of 1 Institutional option for every 2 new shares issued under the Placement. As part of this 2023 Equity Offering, the Company offered 35,434,397 new shares at the offer price of A$0.46 per new share in the fully underwritten Retail Entitlement Offer and approximately 18.0 million new options to eligible shareholders with an exercise price of A$0.80 on the basis of 1 new option for every 2 new shares issued under the Retail Entitlement Offer. Pursuant to the Retail Entitlement Offer and Institutional Entitlement Offer, the Company raised gross proceeds of A$90.0 million (US$58.2 million). Each Option entitles the holder to one ordinary share of the Company. These Investor options were first listed September 21, 2023 at $0.05 per option and trading price closed year end at $0.22 (ASX: OPT-OA).

Equity and Investor options - 2024

On June 14, 2024, the Company offered approximately 543,285,766 new shares in an partially underwritten ANREO at the offer price of A$0.40 per new share and approximately 142.9 million Institutional and placement options with an exercise price of A$1.00 to participants in the Placement and Institutional Entitlement Offer on the basis of 1 Institutional option for every 3 new shares issued under the Placement. As part of this 2024 Equity Offering, the Company offered 139,627,846 new shares at the offer price of A$0.40 per new share in the fully underwritten Retail Entitlement Offer and approximately 46.5 million new options to eligible shareholders with an exercise price of A$1.00 on the basis of 1 new option for every 3 new shares issued under the Retail Entitlement Offer. Pursuant to the Retail Entitlement Offer and Institutional Entitlement Offer, the company raised gross proceeds of A$227.3 million (US$151.9 million), of which A$55.9 million (US$37.6 million) was received after year end. Each Option entitles the holder to one ordinary share of the company. These Investor options were unlisted on issue and year end, a fair value was determined by management at year end of $0.11 (ASX: OPT-OB).

Under IFRS 9 Financial Instruments and IAS 32 Financial Instruments: Presentation, options with an exercise price denominated in a currency that differs from an entity's functional currency are treated as a derivative where not all existing equity investors are offered to participate in the equity raise on a pro rata basis. Such derivatives are measured at fair value with subsequent changes in fair value accounted for through profit and loss. Options with an exercise price of A$0.80 and A$1.00 meet this requirement as not all investors were offered to participate in the equity raise on a pro rata basis and the Company has presented the fair value of these options as a current liability on the consolidated statement of financial position. As these options are exercised, the fair value at the date of exercise and the associated non-cash liability will be included in our share capital along with the proceeds from the exercise. If these options expire, the non-cash option liability is reversed through the consolidated statement of profit and loss. There is no cash flow impact as a result of the accounting treatment for changes in the fair value of the option derivative or when options expire unexercised.

Considering that the options are traded on the Australian Securities Exchange, the Company used the quoted price at the balance sheet date as the fair value of the options. The 2024 options have been fair valued using a Black Scholes model and are level 2 inputs. Key inputs to the valuation include the share price at grant date, expected term, volatility, dividend yield, risk free rate and exercise price. Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting market conditions attached to the option), and behavioral considerations. Expected volatility is based on the historical share

price volatility over the past 2 years and the implied volatility of the traded options.

Note 26. Current Liabilities - Lease Liabilities

Lease liabilities are as indicated below.

At the commencement date of the lease of its office premises, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term ending on July 14, 2025 using an incremental borrowing rate of 3%.

	June 30, 2024	June 30, 2023
	US$	US$
Carrying amount at July 1	181,711	
New lease	—	252,677
Payments	(88,678)	(70,966)
Carrying amount at June 30	**93,033**	**181,711**
Maturity analysis:		
Year 1	98,693	102,806
Year 2	—	84,226
	98,693	187,032
Less: unearned interest	(5,660)	(5,321)
	93,033	**181,711**
Analyzed into:		
Current portion	93,033	97,485
Non-current portion	—	84,226
	93,033	**181,711**

	2024	2023	2022
	US$	US$	US$
Amounts recognized in profit or loss:			
Depreciation expense on right-of-use asset	84,225	84,226	66,465
Lease finance costs	5,660	5,321	5,920
Expense relating to leases of low value assets	—	2,101	7,376
	89,885	**91,648**	**79,761**

Note 27. Non-Current Liabilities - Financial Liabilities - DFA

	June 30, 2024	June 30, 2023
	US$	US$
Carrying amount at July 1	85,660,000	—
Funding at fair value	85,000,000	84,500,000
Interest expense on DFA* (includes amounts owed to related party $24,698,653 (2023: $13,462,160))	30,263,042	13,462,160
Gain on remeasurement of financial liability - DFA2	(387,284)	(12,302,160)
Total financial liabilities	**200,535,758**	**85,660,000**

In August 2022, Ocelot an affiliate of Carlyle and Abingworth, in collaboration with Carlyle's and Abingworth's development company Launch Therapeutics, have committed to provide Opthea no less than US$120.0 million and up to a maximum of US$170.0 million (the additional US$50 million being at the option of the Investor). In December 2023, Opthea entered into an Amended and Restated DFA which resulted in a co-investor contributing funding of US$50.0 million directly to the Company on the same terms and conditions as the existing agreement. The Company exercised significant judgment in accounting for the amended DFA, including consideration of whether the amended DFA resulted in a modification of the original loan. The Company concluded that the amended DFA agreement forms part of the existing agreement as the US$50.0 million is contemplated in the existing agreement on the same return and repayment profile, there have been no substantive changes in the original terms and conditions of the loan and the co-investor was introduced by Ocelot.

In return, Opthea will pay to the DFA Investors (1) upon the first to occur of regulatory approval of sozinibercept for the treatment of wet AMD in the United States, United Kingdom or European Union ("Regulatory Approval"), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six annual payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of sozinibercept for the treatment of wet AMD for each calendar quarter. The fixed and variable payment obligation discharge once the DFA Investors have received a total of four times their investment.

The Group evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to the DFA Investors was not considered substantive and genuine. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in its consolidated balance sheet. The Group accounts for the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. Certain legal and financial advisory fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and will also be amortized to interest expense using the effective interest method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Group's control. Therefore, at each reporting date, the Group reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Group will prospectively adjust the accretion of the development financing liability . Refer to Note 12 and 13.

As of June 30, 2024, the development financing liability was classified as a long-term liability, as the Group expects the related repayments of US$680.0 million (four multiples of the funding received), plus $51.0 million relating to withholding tax obligations to take place between 2027 and 2032 for purposes of the model used to calculate its carrying value. The Group is liable for the withholding tax obligations and as a result, this obligation forms part of the financial liability. The imputed interest rate on the unamortized portion of the development financing liability was approximately 23%.

Pursuant to the DFA, Opthea is required to use commercially reasonable efforts to develop sozinibercept for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein.

In certain instances which may result upon the termination of the DFA, the Group will be obligated to pay the Investors up to four multiples of the amounts paid to us under the DFA. Termination can be triggered by a range of events including if Opthea fails to use commercially reasonable efforts to develop and commercialize sozinibercept, if positive trial results are not achieved or if regulatory approval is not obtained. The agreement also includes termination clauses relating to change of control, disagreement with DFA Investors, inability to fund development costs, safety, bankruptcy and other material breaches, as defined in the Financing Agreement. Each termination trigger has a corresponding percentage to be paid, with possible outcomes requiring the Group to repay an amount equal to 0%, 135%, 150%, 275% or 400% of the initial amounts paid to the Group under the DFA. This is equivalent to potential repayments of $nil, $229.5 million, $255.0 million, $467.5 million or $680.0 million if a termination event is to occur. At June 30, 2024, the Group remains in compliance with the DFA and no such instances have occurred or are expected to occur.

The DFA contains terms that require compliance by the Company to maintain a minimum cash balance and to provide a notice to Ocelot in the event it anticipates that it does not have sufficient cash to fund its operations for the next six months. At June 30, 2024 the Group remains in compliance with the minimum cash balance requirements of the DFA.

Pursuant to the Financing Agreement, Opthea granted the DFA Investors a security interest in all its assets (other than intellectual property not related to sozinibercept), provided that the Group is permitted to incur certain indebtedness. The security interest will terminate when the Group has paid the DFA Investors of the funding provided or upon certain terminations of the Financing Agreement.

Note 28. Non-Current Liabilities - Provisions

	June 30, 2024	June 30, 2023
	US$	US$
Long service leave	9,877	7,631
Total non-current provisions	**9,877**	**7,631**

Note 29. Non-Current Liabilities - lease liabilities

	June 30, 2024	June 30, 2023
	US$	US$
Lease liabilities	—	84,226
Total non-current provisions	**—**	**84,226**

Note 30. Contributed Equity

	June 30, 2024 US$	June 30, 2023 US$	June 30, 2022 US$
(a) Ordinary shares			
Issued and fully paid at June 30	466,084,145	320,883,552	235,277,217
Movement in ordinary shares:			
Opening balance	320,883,552	235,277,217	234,147,526
Issue of shares on exercise of options granted under the LTIP	—	3,790,978	1,129,691
Issue of shares on exercise of options granted from Placement and Institutional Offer	894	—	—
Issue of shares net of issuance costs from 2023 Placement and Institutional Offer $4,764,890	50,273,023	—	—
Issue of shares net of issuance costs from 2024 Placement and Entitlement Offer $8,903,734	94,926,676	81,815,357	—
	466,084,145	**320,883,552**	**235,277,217**
Ordinary shares on issue:	**No:**	**No:**	**No:**
Opening balance	467,159,434	352,152,542	351,003,541
Issue of shares on exercise of options granted under the LTIP	—	2,387,826	1,149,001
Issue of share on exercise of options from Placement and Institutional Offer	1,743	—	—
Issue of shares on ASX from 2023 Placement and Entitlement Offer	195,647,457	—	—
Issue of shares on ASX from 2024 Placement and Entitlement Offer	428,658,137	112,619,066	—
	1,091,466,771	**467,159,434**	**352,152,542**

Fully paid ordinary shares have no par value, carry one vote per share and carry the right to dividends. No cash dividends have been paid, declared or recommended during or since the end of the financial year by the Company. We have not declared or paid any dividends on our ordinary shares. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our ordinary shares. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to Australian law.

Equity and Investor options - 2023

On August 28, 2023, the Company offered approximately 160,213,060 new shares at the offer price of A$0.46 per new share and approximately 80.0 million Institutional and placement options with an exercise price of A$0.80 to participants in the Placement and Institutional Entitlement Offer on the basis of 1 Institutional option for every 2 new shares issued under the Placement and 35,434,397 new shares at the offer price of A$0.46 per new share and approximately 18.0 million new options to eligible shareholders with an exercise price of A$0.80 on the basis of 1 new option for every 2 new shares issued under the Retail Entitlement Offer. Pursuant to the Retail Entitlement Offer and Institutional Entitlement Offer, the company raised gross proceeds of A$90.0 million (US$58.2 million). Each Option entitles the holder to one

ordinary share of the company. These Investor options were listed September 21, 2023 at A$0.05 and year end A$0.22 (ASX: OPT-OA).

Equity and Investor options – 2024

On June 14, 2024, the Company offered approximately 543,285,766 new shares at the offer price of A$0.40 per new share and approximately 142.9 million Institutional and placement options with an exercise price of A$1.00 to participants in the Placement and Institutional Entitlement Offer on the basis of 1 Institutional option for every 3 new shares issued under the Placement and approximately 139,627,846 new shares at the offer price of A$0.40 per new share and approximately 46.5 million new options to eligible shareholders with an exercise price of A$1.00 on the basis of 1 new option for every 3 new shares issued under the Retail Entitlement Offer. Pursuant to the Retail Entitlement Offer and Institutional Entitlement Offer, the company raised gross proceeds of A$227.3 million (US$151.9 million) of which A$55.9 million (US$37.6 million) was received after year end. Each Option entitles the holder to one ordinary share of the company. These Investor options were unlisted on issue and year end, a fair value was determined was determined by management at issuance and at year end of $0.11 (ASX: OPT-OB).

Issued capital at June 30, 2024 amounted to US$466,084,145 (1,091,446,771 fully paid ordinary shares) net of share issue costs and tax

During the year ended June 30, 2024 the Company issued 624,305,594 ordinary shares on ASX listing for net proceeds of US$145,199,699.

Issued capital at June 30, 2023 amounted to US$320,883,552 (467,159,434 fully paid ordinary shares) net of share issue costs and tax.

During the year ended June 30, 2023 the Company issued 112,619,066 ordinary shares on ASX listing for net proceeds of US$81,815,3571.

Options granted to directors and employees.

The company has two share-based payment schemes, the Long-Term Incentive Plan (LTIP) and Non-Executive Director Share and Option Plan. Options to subscribe for the Company's shares have been granted under these plans to certain employees and directors.

The Company granted 9,850,000 options/rights over ordinary shares and 5,045,000 ADS options under these plans during the year ended June 30, 2024 (Note 38). These options/rights had a weighted average fair value at grant date of $1.18 per option and $1.97 per ADS option. During the year ended June 30, 2024, no options granted under the LTIP and NED Plan were exercised.

The company granted 10,050,000 options/rights and 755,000 American Depository Shares (ADS) options over ordinary shares under these plans during the year ended June 30, 2023 (Note 38). These options/rights had a weighted average fair value at grant date of $1.62 per options and the ADS options had a weighted average fair value at grant date of $6.75. During the year ended June 30, 2023, 6,613,000 options granted under the LTIP and NED Plan were exercised for $3,790,977 ($1,040,718 for cash and $2,750,258 via cashless conversion)

The company granted 8,400,000 options/rights and 925,000 American Depository Shares (ADS) options over ordinary shares under these plans during the year ended June 30, 2022 (Note 38). These options/rights had a weighted average fair value at grant date of $0.781 per options and the ADS options had a weighted average fair value at grant date of $6.75. During the year ended June 30, 2022, 2,056,000 options granted under the LTIP and NED Plan were exercised for $1,129,691 ($257,175 for cash and $872,516 via cashless conversion).

The company granted 7,000,000 options over ordinary shares under these plans during the year ended June 30, 2021 (note 38). These options had a weighted average fair value at their grant date of US$1.03 per option. During June 30, 2021 8,400,000 options granted under the LTIP and NED Plan were exercised for US$3,271,542. No options were granted under the Plans during the year ended June 30, 2020.

At June 30, 2024, the Company had 13,848,860 Non-Executive Director options that remain unexercised with expiry of November 2026 for 875,342 options and November 2025 for 2,973,518, options, October 2024 for 4,000,000 options, January 2025 for 3,000,000 options, October 2025 for 1,500,000 options and April 2026 for 1,500,000 options..

At June 30, 2023, the company had 7,250,000 Non-Executive Director options that remain unexercised with expiry of October 2024 for 3,000,000 options, January 2025 for 2,250,000 options, October 2025 for 1,000,000 options and April 2026 for 1,000,000 options.

At June 30, 2022, the company had 7,500,000 Non-Executive Director options that remain unexercised with expiry of November 2022 for 3,000,000 options, October 2024 for 2,000,000 options, January 2025 for 1,500,000 options, October 2025 for 500,000 options and April 2026 for 500,000 options.

Capital management

The Group is not subject to any externally imposed capital requirements. When managing share capital, management's objective is to ensure the entity continues as a going concern as well as to provide benefits to shareholders and for other stakeholders. In order to maintain or achieve an appropriate capital structure, the Company may issue new shares or reduce its share capital, subject to the provisions of the Company's constitution. The Group only commits to significant R&D expenditure when this is fully funded either by existing funds, the DFA or further equity raises.

Note 31. Accumulated Losses and Reserves

	2024 US$	2023 US$
(a) Movements in accumulated losses were as follows:		
Balance at July 1	(359,462,438)	(216,941,353)
Net loss for the period	(220,242,105)	(142,521,085)
Balance at June 30	**(579,704,543)**	**(359,462,438)**
(b) Reserves		
Fair value of Investments reserve (i)	1,085,411	1,085,411
Share-based payments reserve (ii)	16,635,747	11,551,134
Foreign translation reserve (iii)	20,089,163	20,089,163
Total reserves	**37,810,321**	**32,725,708**
(i) Movement in fair value of investments reserve:		
Opening balance	1,085,411	1,085,411
Fair value on gains on investments in financial assets	—	—
Exchange on translation	—	—
Closing balance	**1,085,411**	**1,085,411**
(ii) Movement in share-based payments reserve:		
Opening balance	11,551,134	8,466,706
Share-based payments expense	5,084,613	5,834,686
Exercise of options	—	(2,750,258)
Exchange on translation	—	—
Closing balance	**16,635,747**	**11,551,134**
(iii) Movement in foreign translation reserve:		
Opening balance	20,089,163	20,089,163
(Gains)/loss on translation	—	—
Closing balance	**20,089,163**	**20,089,163**

Nature and purpose of reserves

Fair value of investments reserve

This reserve records fair value changes on listed investments. As at June 30, 2024 and 2023, no remaining investments are held by the Group. Management's accounting policy is to not reclassify the realized fair value to accumulated loss upon disposal.

Share-based payment reserve

This reserve is used to record the value of equity benefits provided to executives and employees as part of their remuneration.

Foreign currency translation reserve

The reserve records the value of foreign currency movements on the initial translation of financial statements from A$ to US$ that was completed in 2021.

Note 32. Financial Risk Management Objectives and Policies

The Group's principal financial assets comprise cash, receivables and short-term deposits.

The Group manages its exposure to key financial risks, including interest rate and currency risk in accordance with the Group's financial risk management practices. The objective is to support the delivery of the Group's financial targets whilst protecting future financial security.

The Group's other various financial assets and liabilities, such as receivables and payables, arise directly from its operations. The main risks arising from the Group's financial assets and liabilities are interest rate risk, foreign currency risk, equity securities price risk and liquidity risk.

The Group uses different methods to measure and manage different types of risks to which it is exposed. These include monitoring levels of exposure to interest rate and foreign exchange risk and assessments of market forecasts for interest rates and foreign exchange rates. Liquidity risk is monitored through future rolling cash flow forecasts.

The board reviews and agrees policies for managing each of these risks as summarized below.

Risk exposures and responses

The Group has investigated the main financial risk areas which could impact on its financial assets and determined the impact on post tax (losses) or profits for a range of sensitivities. These can be seen in the post-tax (loss)/profit impact for each risk area.

For each risk area, the equity impact relates solely to reserve movements and excludes movements in accumulated losses as the impact of these can be seen within the post-tax (loss)/profit impact.

(i) Interest rate risk

The Group's exposure to market interest rates relates primarily to the short-term deposits. The deposits are held with two of Australia's largest banks.

The objective of managing interest rate risk is to minimize the Group's exposure to fluctuations in interest rates that might impact its interest income and cash flow. To manage interest rate risk, the Group invests the majority of its cash in short-term deposits for varying periods of between 30 days and 92 days, depending on the short and long-term cash requirements of the Group which is determined based on the Group's cash flow forecast. This consideration also takes into account the costs associated with recalling a term deposit should early access to cash and cash equivalents be required. Cash is not locked into long-term deposits at fixed rates so as to mitigate the risk of earning interest below the current floating rate.

The Group currently has borrowings under the DFA with the DFA Investors. Due to the structure of the DFA Agreement, the Group has determined that there is no interest rate risk. Refer to Note 27.

The following sensitivity analysis (an annual effect) is based on the interest rate risk exposures at June 30, 2024 and 2023.

At June 30, 2024, 2023 and 2022, if interest rates moved, with all variables held constant, post tax (loss)/profit and equity would have been affected as illustrated in the following table:

	Post tax (loss)/profit impact		
	2024	2023	2022
	US$	US$	US$
Judgments of reasonably possible movements			
+0.50% (50 basis points) (2023:+0.50%)	282,599	270,059	114,859
-0.50% (50 basis points) (2023:-0.50%)	(282,599)	(270,059)	(114,859)

The post-tax figures include an offset for tax losses (bringing the tax effect to nil) for the year ended June 30, 2024 (2023: nil ,2022: nil).

Significant assumptions used in the interest rate sensitivity analysis include:

- The reasonably possible movement of 0.5% was calculated by taking the interest rates as of balance date, moving these by plus and minus 0.5% and then re-calculating the interest on term deposits with the 'new-interest-rate'.
- The net exposure at balance date is representative of what the Group was and is expecting to be exposed to in the next twelve months from balance date.

(ii) Foreign currency risk

As a result of services provided by non-related entities in Australia, Canada, United Kingdom and Europe, part of the Group's monetary assets and liabilities are affected by movements in the exchange rate.

The Group does not enter into any hedging transactions.

At the reporting date, the Group has the following exposure to foreign currencies. :

	Consolidated			
2024	**AUD**	**EURO**	**GBP**	**CAD**
Financial assets				
Cash	131,913,902	—	—	—
Receivables	485,840	—	—	—
Financial liabilities				
Payables	(2,350,157)	(488,341)	(3,161)	(13,182)
Other financial liabilities	—	—	—	—
Net exposure	130,049,585	(488,341)	(3,161)	(13,182)

	Consolidated			
2023	**AUD**	**EURO**	**GBP**	**CAD**
Financial assets				
Cash	55,307,319	—	—	—
Receivables	38,263	—	—	—
Financial liabilities				
Payables	(1,138,778)	(53,332)	(3,166)	(136,689)
Other financial liabilities	—	—	—	—
Net exposure	54,206,804	(53,332)	(3,166)	(136,689)

The following sensitivity is based on the foreign currency risk exposures in existence at June 30, 2024, 2023 and 2022.

At June 30, 2024, 2023 and 2022, had the United States dollar moved with all other variables held constant, post-tax (loss) profit and equity would have been affected as illustrated in the table below:

	Post tax (loss)/profit impact		
	2024	2023	2022
	US$	US$	US$
Judgments of reasonably possible movements			
Consolidated			
AUD/USD +10% (2023:+10%)	(9,005,731)	(3,847,285)	(2,119,834)
AUD/USD -10% (2023:-10%)	11,007,004	4,702,237	2,590,908

The reasonably possible movements at June 30, 2024 are higher than at June 30, 2023 and higher than June 30, 2022 due mainly to net exposure to the Australian dollar due to cash at bank deposits. There was minimum or insignificant exposure to the GBP, Euro and CAD during the current financial year.

Significant assumptions used in the foreign currency exposure sensitivity analysis include:

(a) The reasonably possible movement of 10% was calculated by taking the currency spot rates as of balance date, moving these by 10% and then re-converting the currencies into US with the 'new-spot-rate'. This methodology reflects the translation methodology undertaken by the Group.

(b) The net exposure at balance date is representative of what the Group was and is expecting to be exposed to in the next twelve months from balance date.

(c) Management believes the balance date risk exposures are representative of the risk exposure inherent in the financial instruments.

(iii) Credit risk

Credit risk is associated with those financial assets of the Group which comprise cash and cash equivalents and, receivables. The Group's exposure to credit risk arises from default of the counter party, with a maximum exposure equal to the carrying amount of these investments. Credit risk is considered minimal as the Group transacts with reputable recognized Australian banks.

(iv) Liquidity risk

Liquidity risk arises from the financial liabilities of the Group and the Group's subsequent ability to meet their obligations to repay their financial liabilities as and when they fall due. The Group manages liquidity risk by maintaining adequate reserves and by monitoring forecast and actual cash flows and by matching the maturity profiles of financial assets and liabilities. The financial liabilities of the Group relate to trade payables that are all expected to be paid within 12 months. With the funding agreement that was entered on August 12, 2022 the Group may incur a total payment equal to approximately four times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and variable payments equal to 7% of net sales of sozinibercept for the treatment of wet AMD for each calendar quarter.

The Group's objective is to maintain an appropriate cash asset balance to fund its operations.

The table below reflects undiscounted cash flows of the financial liabilities.

	Consolidated				
	Carrying amount	Less than 3 months	Between 3 months and 2 years	2 years and later	Total
June 30, 2024					
Non-derivative liabilities					
Payables	9,471,882	9,471,882	-	-	9,471,882
Accrued expenses	28,482,603	27,383,742	1,098,861	-	28,482,603
Financial liability - DFA	200,535,758	-	-	731,000,000	731,000,000
Total	**238,490,243**	**36,855,624**	**1,098,861**	**731,000,000**	**768,954,485**

	Consolidated				
	Carrying amount	Less than 3 months	Between 3 months and 2 years	2 years and later	Total
June 30, 2023					
Non-derivative liabilities					
Payables	5,677,858	5,677,858	-	-	5,677,858
Accrued expenses	12,103,789	12,103,789	-	-	12,103,789
Financial liability - DFA	85,660,000	-	-	365,500,000	365,500,000
Total	**103,441,647**	**17,781,647**	**-**	**365,500,000**	**383,281,647**

Note 33. Related Party Disclosures

(a) Subsidiaries

The consolidated financial statements include the financial statements of Opthea Limited and its subsidiaries in the following table:

	Parent entity % equity interest		
	June 30, 2024 %	June 30, 2023 %	June 30, 2022 %
Vegenics Pty Ltd[1]	100	100	100
Opthea US Inc[2]	100	100	100

(1) Opthea Limited is the ultimate parent entity. Vegenics Pty Ltd is incorporated in Australia and has the same financial year as Opthea Limited.

(2) Opthea Limited is the ultimate parent entity. Opthea US Inc was incorporated in the United States in May 2021 and has the same financial year as Opthea Limited.

(b) Transactions with related parties

Balances and transactions between the Company and its subsidiaries, a related party of the Company, have been eliminated on consolidation and are not disclosed in this note. Transactions between the Group and its associates are disclosed below:

Following the appointment of Anshul Thakral (who is the CEO of Launch Tx, Operation Executive of Carlyle and on the board of Saama Technologies) as a Director of Opthea on June 7, 2023, Launch, Ocelot (an affiliate of Carlyle and Abingworth), Carlyle and Saama Technologies became related parties of Opthea.

Trading transactions

During the year, group entities entered into the following transactions with related parties who are not members of the Group.

	Consolidated Purchase of Service (US$)		
	2024	**2023**	**2022**
Ocelot	—	—	—
Launch Tx	2,700,000	900,000	—
Mr Lawrence Gozlan	—	—	—
Saama Technologies	342,762	—	—

Purchase of services assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx.

Transactions with Saama Technologies relate to the purchase of services assisting Opthea with analytical work on clinical trials.

	Consolidated Amounts owed to related parties (US$)		
	2024	**2023**	**2022**
Ocelot	141,554,653	85,660,000	—
Launch Tx	—	900,000	—
Lawrence Gozlan	—	—	—
Saama Technologies	—	—	—

Amounts owed to Ocelot relate to the DFA and carry an effective rate of 23.2% (refer to note 27).

	Consolidated Amounts owed to related parties* (US$)		
	2024	**2023**	**2022**
Ocelot	—	—	—
Launch Tx	3,150,000	—	—
Mr. Lawrence Gozlan	—	—	—
Saama Technologies	24,238	—	—

Amounts paid to Launch Tx relate to the purchase of services assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx which were in a prepayment position at June 30, 2024.

Amounts paid to Saama Technologies in regard to subscription fees for the use of analytical platform, which were in a prepayment position at June 30, 2024.

On August 28, 2023, Mr Lawrence Gozlan, a director of the Company, and the Company have entered into a Consultancy Agreement of up to US$300,000 in respect of the provision of services associated with managing, overseeing and coordinating the conduct and implementation of the Capital Raising. The consultancy agreement is effective for the financial year June 30, 2024. In the opinion of the Directors, these duties are outside the scope of the ordinary duties of a Non-Executive Director. Included in equity are transaction costs paid under this consulting agreement of US$125,000 for the year ended June 30, 2024.

Note 34. Commitments

(i) Contracted and committed Research projects and license commitments

The Group has entered into research and development contracts and intellectual property license agreements with various third parties in respect of services for the Phase 3 wet AMD clinical trial and the clinical grade manufacture of sozinibercept. Expenditure commitments relating to these, and intellectual property license agreements are payable as follows:

	2024 US$	2023 US$	2022 US$
Within one year	27,383,742	12,632,801	39,947,900
After one year but not more than five years	3,504,753	12,302,260	8,007,202
After more than five years	15,000	30,000	45,000
	30,903,495	**24,965,061**	**48,000,102**

Currently, the biggest research contract has a 60 day termination clause and all commitments have been limited to a six month commitment.

(ii) Commercial commitments

	2024 US$	2023 US$	2022 US$
Within one year	63,421	47,415	507,874
After one year but not more than five years	—	—	—
After more than five years	—	—	—
	63,421	**47,415**	**507,874**

Currently, the biggest contract has a 60 day termination clause and all commitments have been limited to a twelve month commitment.

Note 35. Contingencies

The Group is party to various research agreements with respect to which a commitment to pay is contingent on the achievement of research milestones. Assuming all milestones are achieved within the time-frames stipulated in the contracts, those which could become payable in less than one year total US$nil (2023: US$nil) and those which could become payable in more than one year total US$1,084,821 (2023: US$1,086,244).

Under these license/collaboration agreements, payments are to be made only if certain research and clinical development milestones are achieved and royalties may become payable on any eventual sales of products developed under these agreements.

The group had a bank guarantee outstanding at June 30, 2024 in respect of a rental deposit for its office premises of AU$ 64,574 (US$38,210) (2023: AU$64,574 (US$38,036)).

Note 36. Cash Flow Statements Reconciliation

	2024	2023	2022
	US$	US$	US$
(a) Reconciliation to cash at the end of the year			
Cash at bank and in hand (Note 18)	172,471,346	89,188,713	44,631,293
	172,471,346	**89,188,713**	**44,631,293**
(b) Reconciliation of net loss after tax to net cash flows from operations			
Net loss for the year	(220,242,105)	(142,521,085)	(92,817,371)
Adjustments for:			
Income tax benefit recognized in profit or loss	(9,412,196)	(5,926,350)	(6,299,286)
Net loss of disposal of non-current assets	—	—	169
Depreciation of non-current assets	18,799	17,001	11,917
Depreciation of right-of-use assets	84,226	84,226	66,465
Interest expense on DFA* (includes amounts owed to related party $24,698,653 (2023: $13,462,160))	30,263,042	13,462,160	—
Gain on remeasurement of financial liability - DFA2	(387,284)	(12,302,160)	—
Fair value loss on Investor options	11,223,535	—	—
Share-based payments	5,084,613	5,834,686	5,251,572
Net exchange differences	107,001	489,137	2,813,993
	36,981,736	1,658,700	1,844,830
Changes in:			
Payables	19,502,925	7,296,785	8,511,607
Receivables	(789,837)	378,896	307,618
Prepayments	(1,675,274)	6,142,284	5,730,207
Provisions	266,694	136,755	115,259
Net cash flows used in operating activities before tax	(165,955,861)	(126,907,665)	(76,307,850)
R&D tax incentive received	5,926,350	6,299,286	4,972,898
Current US tax paid	(985,843)	—	—
Net cash flows used in operating activities	**(161,015,354)**	**(120,608,379)**	**(71,334,952)**

Note 37. Key Management Personnel

(a) Compensation of Key Management Personnel

	2024	2023	2022
	US$	US$	US$
Short-term employee benefits	3,415,969	2,898,544	1,555,658
Post-employment benefits	105,007	137,168	56,105
Termination benefits	475,000	—	—
Share-based payments expense	3,214,616	4,221,472	4,664,767
	7,210,592	**7,257,184**	**6,276,530**

(b) Other transactions and balances with director and key management personnel and their related parties

There were no director and key management personnel related party transactions during the prior financial year for the current year refer to Note 33(b).

Note 38. Share-Based Payments

(a)Recognized share-based payment expenses

The expense recognized for share-based payments during the year is shown in the table below:

	2024 US$	2023 US$	2022 US$
Expense arising from equity-settled share-based payment transactions:			
Director and employee services received	5,084,613	5,834,686	5,251,572
	5,084,613	**5,834,686**	**5,251,572**

(b)Non-executive director and employee share option plans

During the 2015 financial year, the Group introduced an ownership-based compensation scheme for non-executive directors, executives and senior employees, the Long-Term Incentive Plan (LTIP) and Non-Executive Directors Share and Option Plan (NED Plan). In accordance with the terms of the plans, as approved by shareholders at the 2014 annual general meeting, eligible non-executive directors, executives and senior employees with the Group may be granted options to purchase ordinary shares.

Each employee share option converts into one ordinary share of Opthea Limited on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights and are not transferable. Options may be exercised at any time from the date of vesting to the date of their expiry.

The number of options granted is subject to approval by the board and rewards executives and senior employees to the extent of the Group's and the individual's achievement judged against both qualitative and quantitative criteria as determined by the board on a case by case basis.

The vesting condition of options granted under the LTIP and NED Plan is continuous service.

Options/Rights services	Grant date	Grant date fair value US$	Exercise price US$	Expiry date	Vesting date
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	October 19, 2021
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	October 19, 2022
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	October 19, 2023
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	January 31, 2023
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	November 30, 2022
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	April 30, 2023
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	April 30, 2023
LTIP - employees FY2022	October 19, 2021	0.955	0.000	October 18, 2031	September 30, 2024
LTIP - employees FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2021
LTIP - employees FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2022
LTIP - employees FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2023
LTIP - employees FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2024
LTIP - employees FY2022	June 6, 2022	0.553	1.460	June 5, 2032	June 6, 2022
LTIP - employees FY2022	June 6, 2022	0.553	1.460	June 5, 2032	June 6, 2023
LTIP - employees FY2022	June 6, 2022	0.553	1.460	June 5, 2032	June 6, 2024
LTIP - employees FY2022	June 6, 2022	0.553	1.460	June 5, 2032	June 6, 2025
LTIP - employees FY2022	June 6, 2022	0.553	1.460	June 5, 2032	June 6, 2025
LTIP - employees FY2023	November 16, 2022	0.471	0.658	November 16, 2032	November 16, 2025
LTIP - employees FY2023	November 16, 2022	0.672	0.000	November 16, 2032	November 16, 2025
LTIP - employees FY2023	December 13, 2022	0.459	0.644	December 13, 2032	December 13, 2024
LTIP - employees FY2023	December 13, 2022	0.459	0.644	December 13, 2032	December 13, 2025
LTIP - employees FY2023	December 13, 2022	0.459	0.644	December 13, 2032	December 13, 2026
LTIP - employees FY2024	September 18, 2023	0.153	0.264	September 18, 2033	September 18,2024
LTIP - employees FY2024	September 18, 2023	0.153	0.264	September 18, 2033	September 18,2025
LTIP - employees FY2024	September 18, 2023	0.153	0.264	September 18, 2033	September 18,2026
LTIP - employees FY2024	September 18, 2023	0.153	0.264	September 18, 2033	September 18,2027
LTIP - employees FY2024	October 10, 2023	0.157	0.205	October 10, 2033	October 10, 2024
LTIP - employees FY2024	October 10, 2023	0.157	0.205	October 10, 2033	October 10, 2025
LTIP - employees FY2024	October 10, 2023	0.157	0.205	October 10, 2033	October 10, 2026
LTIP - employees FY2024	October 10, 2023	0.157	0.205	October 10, 2033	October 10, 2027

LTIP - employees FY2024	November 30, 2023	0.236	0.261	November 30, 2033	November 30, 2024
LTIP - employees FY2024	November 30, 2023	0.236	0.261	November 30, 2033	November 30, 2025
LTIP - employees FY2024	November 30, 2023	0.236	0.261	November 30, 2033	November 30, 2026
NED Plan FY2021	October 12, 2020	1.050	3.240	October 11, 2024	October 12, 2020
NED Plan FY2021	October 12, 2020	1.050	3.240	October 11, 2024	October 12, 2021
NED Plan FY2021	October 12, 2020	1.050	3.240	October 11, 2024	October 12, 2022
NED Plan FY2021	October 12, 2020	1.050	3.240	October 11, 2024	October 12, 2023
NED Plan FY2021	October 12, 2020	1.240	2.160	October 11, 2024	October 12, 2020
NED Plan FY2021	October 12, 2020	1.240	2.160	October 11, 2024	October 12, 2021
NED Plan FY2021	October 12, 2020	1.240	2.160	October 11, 2024	October 12, 2022
NED Plan FY2021	October 12, 2020	1.240	2.160	October 11, 2024	October 12, 2023
NED Plan FY2021	January 19, 2021	0.880	1.560	January 18, 2025	January 19, 2021
NED Plan FY2021	January 19, 2021	0.880	1.560	January 18, 2025	January 19, 2022
NED Plan FY2021	January 19, 2021	0.880	1.560	January 18, 2025	January 19, 2023
NED Plan FY2021	January 19, 2021	0.880	1.560	January 18, 2025	January 19, 2024
NED Plan FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2021
NED Plan FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2022
NED Plan FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2023
NED Plan FY2022	October 19, 2021	0.526	0.948	October 18, 2025	October 19, 2024
NED Plan FY2022	April 21, 2022	0.397	0.755	April 20, 2026	April 21, 2022
NED Plan FY2022	April 21, 2022	0.397	0.755	April 20, 2026	April 21, 2023
NED Plan FY2022	April 21, 2022	0.397	0.755	April 20, 2026	April 21, 2024
NED Plan FY2022	April 21, 2022	0.397	0.755	April 20, 2026	April 21, 2025
NED Plan FY2023	November 16, 2022	0.469	0.672	November 16, 2032	November 16, 2025
NED Plan FY2023	November 16, 2022	0.471	0.658	November 16, 2032	November 16, 2025
NED Plan FY2023	November 16, 2022	0.672	0.000	November 16, 2032	November 16, 2025
NED Plan FY2024	November 30, 2023	0.213	0.382	November 30, 2033	November 30, 2024
NED Plan FY2024	November 30, 2023	0.213	0.382	November 30, 2033	November 30, 2025
NED Plan FY2024	November 30, 2023	0.213	0.382	November 30, 2033	November 30, 2026

There has been no alteration of the terms and conditions of the above share-based payment arrangements since the grant date.

(c)Fair value of share options granted

Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting conditions attached to the option), and behavioral considerations. Expected volatility is based on the historical share price volatility over the past 4 or 5 years.

Options/Rights services	Grant date share price US$	Exercise price US$	Fair value per option US$	Expected volatility	Option life	Dividend yield	Risk free interest rate	Model used
LTIP - director FY2019	0.420	0.625	0.150	58.00 %	4 years	0 %	2.04 %	Binomial
LTIP - employees FY2018	0.340	0.920	0.260	66.00 %	5 years	0 %	2.09 %	Binomial
LTIP - employees FY2019	0.480	0.608	0.180	57.00 %	4 years	0 %	2.04 %	Binomial
LTIP - employees FY2022	0.955	0.948	0.526	74.78 %	4 years	0 %	0.25 %	Binomial
LTIP - employees FY2022	0.955	nil	0.955	na	10 years	0 %	n/a	Binomial
LTIP - employees FY2022	0.901	1.460	0.553	75.00 %	6.5 years	0 %	3.40 %	Binomial
LTIP - employees FY2023	0.672	0.658	0.471	75.00 %	6.5 years	0 %	3.60 %	Binomial
LTIP - employees FY2023	0.672	nil	0.672	75.00 %	10 years	0 %	3.70 %	Binomial
LTIP - employees FY2023	0.643	0.644	0.459	75.00 %	7 years	0 %	3.30 %	Binomial
LTIP - employees FY2024	0.238	0.263	0.153	67.50 %	6.5 years	0 %	4.10 %	Binomial
LTIP - employees FY2024	0.225	0.205	0.157	67.50 %	7 years	0 %	4.30 %	Binomial
LTIP - employees FY2024	0.334	0.261	0.236	67.50 %	6.5 years	0 %	4.20 %	Binomial
NED Plan FY2016	0.280	0.360	0.140	65.00 %	5 years	0 %	2.09 %	Binomial
NED Plan FY2019	0.420	0.625	0.150	58.00 %	4 years	0 %	2.04 %	Binomial
NED Plan FY2021	2.190	2.160	1.240	77.25 %	4 years	0 %	0.25 %	Binomial
NED Play FY2021	2.190	3.240	1.050	77.25 %	4 years	0 %	0.25 %	Binomial
NED Plan FY2021	1.560	1.560	0.880	77.01 %	4 years	0 %	0.25 %	Binomial
NED Plan FY2022	0.955	0.945	0.526	74.78 %	4 years	0 %	0.25 %	Binomial
NED Plan FY2022	0.741	0.755	0.397	75.00 %	3.5 years	0 %	2.70 %	Binomial
NED Plan FY2023	0.672	0.658	0.471	75.00 %	6.5 years	0 %	3.60 %	Binomial
NED Plan FY2023	0.672	nil	0.672	75.00 %	10 years	0 %	3.70 %	Binomial
NED Plan FY2024	0.334	0.382	0.334	67.50 %	6.5 years	0 %	4.20 %	Binomial

Fair value of ADS options granted

Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting conditions attached to the option), and behavioral considerations. Expected volatility is based on the historical share price volatility over the past 4 or 5 years.

ADS Options	Grant date share price US$	Exercise price US$	Fair value per ADS option US$	Expected volatility	ADS Option life	Dividend yield	Risk free interest rate	Model used
LTIP - employee 2022	7.240	7.625	4.970	75.00 %	7 years	0 %	1.40 %	Binomial
LTIP - employee 2022	7.500	7.515	5.228	75.00 %	7 years	0 %	1.70 %	Binomial
LTIP - employee 2022	5.925	6.009	4.116	75.00 %	7 years	0 %	1.70 %	Binomial
LTIP - employee 2022	5.915	6.090	4.171	75.00 %	7 years	0 %	2.90 %	Binomial
LTIP - employee 2022	7.000	7.116	4.953	75.00 %	7 years	0 %	2.90 %	Binomial
LTIP - employee 2022	7.309	7.445	5.175	75.00 %	7 years	0 %	3.00 %	Binomial
LTIP - employee 2022	5.500	5.522	3.886	75.00 %	7 years	0 %	3.40 %	Binomial
LTIP - employee 2023	6.600	6.350	4.718	75.00 %	7 years	0 %	2.90 %	Binomial
LTIP - employee 2023	4.810	4.850	3.479	75.00 %	7 years	0 %	4.30 %	Binomial
LTIP - employee 2023	4.850	5.170	3.457	75.00 %	7 years	0 %	4.10 %	Binomial
LTIP - employee 2023	4.959	4.929	3.560	75.00 %	7 years	0 %	3.60 %	Binomial
LTIP - employee 2023	5.450	5.238	3.935	75.00 %	7 years	0 %	3.50 %	Binomial
LTIP - employee 2023	5.030	5.150	3.602	75.00 %	7 years	0 %	3.80 %	Binomial
LTIP - employee 2023	3.360	3.545	2.384	75.00 %	7 years	0 %	3.60 %	Binomial
LTIP - employee 2024	1.660	1.660	1.110	67.50 %	6.5 years	0 %	4.90 %	Binomial
LTIP - employee 2024	1.660	1.660	0.691	67.50 %	7.6 years	0 %	4.90 %	Binomial
LTIP - employee 2024	1.630	1.660	1.082	67.50 %	6.5 years	0 %	4.70 %	Binomial
LTIP - employee 2024	1.920	1.830	1.327	67.50 %	7 years	0 %	4.50 %	Binomial
LTIP - employee 2024	1.920	1.890	1.316	67.50 %	7 years	0 %	4.50 %	Binomial
LTIP - employee 2024	2.760	2.760	1.830	71.71 %	6 years	0 %	3.81 %	Binomial
LTIP - employee 2024	3.030	3.030	2.740	71.64 %	6 years	0 %	4.34 %	Binomial
LTIP - employee 2024	4.140	4.140	3.160	70.68 %	6 years	0 %	4.34 %	Binomial
LTIP - employee 2024	3.950	3.950	3.010	70.68 %	6 years	0 %	4.34 %	Binomial
LTIP - employee 2024	3.750	3.750	2.490	70.72 %	6 years	0 %	4.43 %	Binomial
LTIP - employee 2024	3.290	3.340	2.180	70.76 %	6 years	0 %	4.65 %	Binomial
LTIP - employee 2024	2.660	2.660	1.750	69.85 %	6 years	0 %	4.41 %	Binomial

(d)Movements in share options during the year

The following reconciles the share/rights options outstanding at the beginning and end of the year:

	2024		2023		2022	
	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$
Balance at beginning of year	25,450,000	1.04	22,988,000	1.16	16,644,000	1.28
Granted during the year:						
To employees and directors under the LTIP and NED Plan	9,850,000	0.30	10,050,000	0.58	8,400,000	0.77
Exercised during the year	—	—	(6,613,000)	0.62	(2,056,000)	0.58
Expired during the year	—	—	(975,000)	0.61	—	—
Balance at end of the year	35,300,000	0.89	25,450,000	1.04	22,988,000	1.16
Exercisable at end of year	20,024,203	1.18	10,842,234	1.48	12,857,589	0.97

The share options outstanding at the end of the year had a weighted average exercise price of US $1.18 (2023: US$1.48, 2022: US$0.97) and a weighted average remaining contractual life of 507 days (2023: 555 days, 2022: 567 days).

Movements in ADS options during the year

The following reconciles the ADS options outstanding at the beginning and end of the year:

	2024		2023		2022	
	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$
Balance at beginning of year	1,505,000	5.81	925,000	6.75	—	—
Granted during the year:						
To employees and directors under the LTIP and NED Plan	4,768,000	1.97	755,000	5.07	925,000	6.75
Exercised during the year	—	—	—	—	—	—
Expired during the year	(525,000)	5.62	(175,000)	7.62	—	—
Balance at end of the year	5,748,000	2.64	1,505,000	5.81	925,000	6.75
Exercisable at end of year	537,914	6.01	250,000	6.70	—	—

Movements in contractor ADS options during the year

The following reconciles the contractor ADS options outstanding at the beginning and end of the year:

	2024		2023		2022	
	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$	Number of options and rights	Weighted average exercise price US$
Balance at beginning of year	—	—	—	—	—	—
Granted during the year:						
To contractors under additional terms	277,000	3.14	—	—	—	—
Exercised during the year	—	—	—	—	—	—
Expired during the year	—	—	—	—	—	—
Balance at end of the year	277,000	3.14	—	—	—	—
Exercisable at end of year	39,220	3.16	—	—	—	—

Note 39. Events After the Balance Sheet Date

On July 15, 2024, Opthea announced the completion of the Retail Entitlement offer raising approximately A$55.9 million (US$37.6 million). An additional 139.6 million shares were issued and the listing of 189.4 million 2024 investor options with an exercise price of A$1.00 and with an expiry of June 30, 2026.

Besides the above-mentioned subsequent events, no matters or circumstances have arisen since the end of the reporting period, which significantly affected, or may significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

Exhibit 4.17

OPTHEA US INC.

October 24, 2023

Fred Guerard
8701 Acuarela Ct
Austin, TX 78735
USA

Re: Employment Terms

Dear Fred:

On behalf of OPTHEA US, INC. (the "**Company**"), I am pleased to offer you employment at the Company on the terms set forth in this offer letter agreement (the "**Agreement**"). As discussed, the terms of this Agreement govern with respect to your employment, which is anticipated to start on 27 October 2023 (such actual date of your commencement of employment shall be referred to herein as the "**Start Date**").

1. Employment by the Company.

(a) Position. You will serve as the Company's Chief Executive Officer. During the term of your employment with the Company, you will devote your best efforts and substantially all of your business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies. It is anticipated that such business of the Company will include your providing services to entities that are affiliated with the Company, without further or additional compensation or benefits other than as set forth in this Agreement.

(b) Duties and Location. You will perform those duties and responsibilities as are customary for the position of Chief Executive Officer and as may be directed by the Board, to whom you will report. You will initially work remotely from Austin, Texas; at such time as the Company assigns you to an office (which may include after such an office is opened), that will be your primary office location. Notwithstanding the foregoing, the Company reserves the right to reasonably require you to perform your duties at places other than your primary office location from time to time, and to require reasonable business travel. The Company may modify your job title, work location and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time.

2. Base Salary and Employee Benefits.

(a) Salary. You will be paid a base salary at the rate of USD 550,000 per year, less applicable payroll deductions and withholdings. Your base salary will be paid on the Company's ordinary payroll cycle. Upon achievement of certain performance objectives established and determined by the Board or its Remuneration Committee, in consultation with you, measured over the first twelve (12) months of your employment, your base salary will be increased to be paid at the rate of USD 600,000 per year, less applicable payroll deductions and withholdings. Whether you achieve such objectives, and the effective date of any salary change, will be determined by the Board or a committee thereof, in their discretion. As

an exempt salaried employee, you will be required to work the Company's normal business hours, and such additional time as appropriate for your work assignments and position, and you will not be entitled to overtime compensation.

(b) Annual Bonus. You will be eligible for an annual discretionary performance bonus with a target amount of fifty (50%) of your base salary, less payroll deductions and withholdings, during each full fiscal year of the Company during your employment. The amount of this bonus will be determined in the discretion of the Company and based, in part, on performance objectives (both individual and for the Company, established and determined by the Board or its Remuneration Committee) during the fiscal year, as well as any other criteria the Company deems relevant. The Company will pay you this annual bonus, if any, no later than September 15 occurring following the end of the fiscal year ending the immediately preceding June 30. The bonus is not earned until paid and no pro-rated amount will be paid if your employment terminates for any reason prior to the payment date, other than as set forth in Section 8 below.

(c) Employee Benefits. As a regular full-time employee, you will be eligible to participate in the Company's standard employee benefits offered to executive level employees, as in effect from time to time and subject to the terms and conditions of the benefit plans and applicable Company policies. A full description of these benefits is available upon request. The Company may change your compensation and benefits from time to time in its discretion.

3. Expenses. The Company will reimburse you for reasonable travel, entertainment or other expenses incurred by you in furtherance of or in connection with the performance of your duties hereunder, in accordance with the Company's expense reimbursement policies and practices as in effect from time to time. If relocation is required, you and the Company will mutually discuss whether and to what extent relocation benefits will be extended to you in good faith. In addition, the company shall reimburse you for all reasonable costs and expenses (including fees and disbursements of counsel) incurred by you in negotiating the terms and conditions of this agreement, up to USD 5,000.

4. Equity Awards.

(a) Sign-On Grant. In its sole discretion of, and subject to approval by the Board and compliance with any law or listing rule, as applicable, the Company may grant you an option to purchase 1,400,000 of the Company's American Depositary Shares at the fair market value as determined by the Board as of the date of grant (the "**Option**"). The anticipated Option will be governed by the terms and conditions of the Company's Long-Term Incentive Plan (the "**Plan**") and the applicable grant agreement. Copies of the Plan and applicable grant agreement will be provided to you if and when the Option is granted to you, and will include the following vesting schedule: 25% of the total shares will vest on the one year anniversary of the vesting commencement date, and 1/36th of the total shares will vest monthly thereafter on the same day of the month as the vesting commencement date (or if there is no corresponding day, on the preceding day) as of each such date, and provided you remain in continuous employment at the Company through each such vesting date. In the event of any conflict between this Agreement or the Plan or the applicable grant agreement, the Plan and the applicable grant agreement will supersede this Agreement and control.

(b) Incentive Grant. In its sole discretion of, and subject to approval by, the Board of the Company and compliance with any law or listing rule, as applicable, the Company may grant you an

additional option to purchase 600,000 of the Company's American Depositary Shares at the fair market value as determined by the Board as of the date of grant (the "**Additional Option**"). The anticipated Additional Option will be governed by the terms and conditions of the Plan and applicable grant agreement. The Additional Option will vest in full upon either a) the closing of a Change of Control (as defined below) that occurs prior to December 31, 2027 with an enterprise value at least equal to a value determined by the Board, in its sole discretion, or b) the market capitalization of the company reaching value at least equal to a value determined by the Board, in its sole discretion by December 31, 2028. In the event of any conflict between this Agreement or the Plan or the applicable grant agreement, the Plan and the applicable grant agreement will supersede this Agreement and control. For the avoidance of doubt, you must remain in continuous employment at the Company through the date of either Change of Control or Market Capitalization of company reaching a value at least equal to value determined by the Board to vest into the Additional Option.

5. Compliance with Confidentiality Information Agreement and Company Policies. In connection with your employment with the Company, you will receive and have access to Company confidential information and trade secrets. Accordingly, enclosed with this offer letter is an Employee Confidential Information and Inventions Assignment Agreement (the "**Confidentiality Agreement**") which contains restrictive covenants and prohibits unauthorized use or disclosure of the Company's confidential information and trade secrets, among other obligations. Please review the Confidentiality Agreement and only sign it after careful consideration. In addition, you are required to abide by the Company's policies and procedures (including but not limited to the Company's employee Handbook), as adopted or modified from time to time within the Company's discretion, and acknowledge in writing that you have read and will comply with such policies and procedures (and provide additional such acknowledgements as such policies and procedures may be modified from time to time); *provided*, *however*, that in the event the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

6. Protection of Third Party Information. By signing this Agreement, you are representing that you have full authority to accept this position and perform the duties of the position without conflict with any other obligations and that you are not involved in any situation that might create, or appear to create, a conflict of interest with respect to your loyalty to or duties for the Company. You specifically warrant that you are not subject to an employment agreement or restrictive covenant preventing full performance of your duties to the Company. In addition, you agree not to bring to the Company or use in the performance of your responsibilities at the Company any materials or documents of a former employer that are not generally available to the public, unless you have obtained express written authorization from the former employer for their possession and use. You also agree to honor all obligations to former employers during your employment with the Company.

7. At-Will Employment Relationship. Your employment relationship with the Company is at will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company; and the Company may terminate your employment at any time, with or without Cause or advance notice.

8. Severance in the Event of Qualifying Termination. If, at any time, the Company terminates your employment without Cause (other than as a result of your death or disability) or you resign for Good Reason (either such termination referred to as a "**Qualifying Termination**"), provided such termination or resignation constitutes a Separation from Service (as defined under Treasury Regulation Section

1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), then subject to Sections 10 ("Clawback and Recovery"), 12 ("Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable)"), 13 ("Return of Company Property") and Section 18 ("Exceptions") below and your continued compliance with the terms of this Agreement (including without limitation the Confidentiality Agreement), the Company will, subject to any restrictions on the provision of such benefits arising under Australian law or the ASX Listing Rules which may apply (in which case Section 18 will apply), provide you with the following severance benefits (the "**Severance Benefits**"):

(a) Cash Severance. The Company will pay you, as cash severance, twelve (12) months of your base salary in effect as of your Separation from Service date, less standard payroll deductions and tax withholdings (the "**Severance**"). The Severance will be paid in a single lump sum, paid on the Company's first regular payroll date that is more than sixty (60) days following your Separation from Service date.

(b) COBRA Severance. The Company will continue to pay the cost of your health care coverage in effect at the time of your Separation from Service for a maximum of twelve (12) months, either by reimbursing you for or paying directly (at the Company's discretion) your COBRA premiums to continue such coverage (the "**COBRA Severance**"). The Company's obligation to pay the COBRA Severance on your behalf will cease if you obtain health care coverage from another source (e.g., a new employer or spouse's benefit plan), unless otherwise prohibited by applicable law. You must notify the Company within two (2) weeks if you obtain coverage from a new source. This payment of COBRA Severance by the Company would not expand or extend the maximum period of COBRA coverage to which you would otherwise be entitled under applicable law. Notwithstanding the above, if the Company determines in its sole discretion that it cannot provide the foregoing COBRA Severance without potentially violating applicable law (including, without limitation, Section 2716 of the U.S. Public Health Service Act), the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to the monthly COBRA premium that you would be required to pay to continue your group health coverage in effect on the date of your termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made on the last day of each month regardless of whether you elect COBRA continuation coverage and shall end on the earlier of (x) the date upon which you obtain other coverage or (y) the last day of the twelfth (12th) calendar month following your Separation from Service date.

(c) Pro-Rata Bonus For Year in Which Separation from Service Occurs; Prior Year Bonus. The Company will pay you a *pro rata* bonus for the fiscal year in which the Separation from Service date occurs at 100% of your target Annual Bonus, and prorated based on the number of days in which you were employed by the Company during the fiscal year in with the Separation from Service date occurs, less payroll deductions and withholdings (the "***Pro Rata* Bonus Severance**"). The *Pro Rata* Bonus Severance will be paid at the same time as the first Severance payment pursuant to Section 8(a). In addition, if the Separation from Service date occurs after the close of the Company's fiscal year but prior to the Company determining and paying the Annual Bonus for that previous fiscal year (if any), you will remain eligible for an Annual Bonus for the previous fiscal year, subject to the terms of this Agreement, with such bonus payment determined by the Board in its discretion consistent with Section 2(b) above (the "**Prior Year Bonus Eligibility Severance**"). Such Prior Year Bonus Eligibility Severance payment, if any, will be paid at the same time as such Annual Bonuses are paid to other executive employees of the Company, less payroll deductions and withholdings.

(d)Equity Acceleration. With respect to any equity awards granted to you that vest solely based on your provision of continuous service, you will vest as if you had provided an additional six months of continuous service following the Separation from Service date. In addition, any then-vested options (including the Option and the Additional Option) shall remain outstanding and exercisable until the earlier of (x) the expiration date set forth therein or (y) the date that is six months following your Separation from Service date; provided, however, that such options shall nevertheless be subject to the terms of the Plan, including in connection with a Corporate Control Event (as defined in the Plan).

9. Payment in Connection with a Change of Control. Subject to Sections 10 ("Clawback and Recovery"), 12 ("Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable)"), 13 ("Return of Company Property") and Clause 18 "Exceptions") below and your continued compliance with the terms of this Agreement (including without limitation the Confidentiality Agreement), then Company will, subject to any restrictions on the making of such payment arising under Australian law or the ASX Listing Rules which may apply, if applicable (in which case clause 18 will apply), pay you an amount equivalent to 50% of your annual base salary then in effect (provided that any reduction in salary, benefits, or other remuneration that served as the basis for a resignation for Good Reason shall be disregarded), within thirty (30) days following the closing of a Change of Control (the "**Change of Control Payment**"), less payroll deductions and withholdings where applicable. You must either remain employed through the closing date of such Change of Control, or have experienced a Qualifying Termination within thirty (30) days prior to such closing date, to receive the Change of Control Payment.

10. Clawback and Recovery. Any and all Severance Benefits or the Change of Control Payment provided under this Agreement will be subject to recoupment in accordance with any clawback policy that the Company has adopted or is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law or rule or regulation thereunder. In addition, the Board may impose such other clawback, recovery or recoupment provisions as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired ordinary shares, including ordinary shares underlying American Depositary Shares, of the Company or other cash or property upon the occurrence of a termination of employment for Cause.

11. Resignation Without Good Reason; Termination for Cause; Death or Disability. If, at any time, you resign your employment without Good Reason, or the Company terminates your employment for Cause, or if either party terminates your employment as a result of your death or disability, you will receive your base salary accrued through your last day of employment, as well as any unused vacation (if applicable) accrued through your last day of employment. Under these circumstances, you will not be entitled to any other form of compensation from the Company, including any Severance Benefits , other than your rights to the vested portion of your Option and any other rights to which you are entitled under the Company's benefit programs.

12. Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable). Prior to and as a condition to your receipt of the Severance Benefits or the Change of Control Payment (if applicable), you shall execute and deliver to the Company an effective release of claims in favor of and in a form acceptable to the Company (the "**Release**") within the timeframe set forth therein, but not later than forty-five (45) days following your Separation from Service date, and allow the Release to become

effective according to its terms (by not invoking any legal right to revoke it) within any applicable time period set forth therein (such latest permitted effective date, the "**Release Deadline**").

13. Return of Company Property. Upon the termination of your employment for any reason, as a precondition to your receipt of the Severance Benefits, within five (5) days after your Separation from Service date (or earlier if requested by the Company), you must return to the Company all Company documents (and all copies thereof) and other Company property in your possession, custody or control, including, but not limited to, Company files, notes, financial and operational information, password and account information, customer lists and contact information, prospect information, product and services information, research and development information, drawings, records, plans, forecasts, pipeline reports, sales reports or other reports, payroll information, spreadsheets, studies, analyses, compilations of data, proposals, agreements, sales and marketing information, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, tablets, handheld devices, and servers), credit cards, entry cards, identification badges and keys, and any materials of any kind which contain or embody any proprietary or confidential information of the Company, and all reproductions thereof in whole or in part and in any medium. You further agree that you will make a diligent search to locate any such documents, property and information and return them to the Company within the timeframe provided above. You also must provide the Company all passwords, log-ins, administrative access, and any other information or access for and relating to any Company computer or other device that you have used to access or use the Company's network, as well as any Company database or Company accounts with third parties which you established, administered, or to which you had access, and must terminate your access to such network and accounts and otherwise comply with any Company requests regarding all such access and accounts. In addition, if you have used any personal computer, server, or email system to receive, store, review, prepare or transmit any confidential or proprietary data, materials or information of the Company, then within five (5) days after your Separation from Service date (or earlier if requested by the Company) you must provide the Company with a computer-useable copy of such information and permanently delete and expunge such confidential or proprietary information from those systems without retaining any reproductions (in whole or in part); and you agree to provide the Company access to your system, as requested, to verify that the necessary copying and deletion is done. If requested, you shall deliver to the Company a signed statement certifying compliance with this Section prior to the receipt of the Severance Benefits.

14. Outside Activities. Throughout your employment with the Company, you will be allowed to continue your on-going non-executive director positions. You may also engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of your duties hereunder or present a conflict of interest with the Company. You will seek approval from the Nominating and Governance committee of the company before committing to other non-executive director roles. During your employment by the Company, except on behalf of the Company, you will not directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any other person, corporation, firm, partnership or other entity whatsoever known by you to compete with the Company (or is planning or preparing to compete with the Company), anywhere in the world, in any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that you may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (but without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

15. Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"**Cause**" for termination will mean your (a) commission or conviction (including a guilty plea or plea of *nolo contendere*) of any felony or any other crime involving fraud, dishonesty or moral turpitude; (b) your commission or attempted commission of or participation in a fraud or act of dishonesty or misrepresentation against the Company; (c) material breach of your duties to the Company; (d) intentional damage to any property of the Company; (e) misconduct, or other violation of Company policy that causes harm; (f) your material violation of any written and fully executed contract or agreement between you and the Company, including without limitation, material breach of your Confidentiality Agreement, or of any Company policy, or of any statutory duty you owe to the Company; or (g) conduct by you which in the good faith and reasonable determination of the Company demonstrates gross unfitness to serve. The determination that a termination is for Cause shall be made by the Company in its sole discretion.

You shall have "**Good Reason**" for resigning from employment with the Company if any of the following actions are taken by the Company without your prior written consent: (a) a material reduction in your base salary, which the parties agree is a reduction of at least 10% of your base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); (b) a material reduction in your duties (including responsibilities and/or authorities), *provided, however*, that a change in job position (including a change in title) shall not be deemed a "material reduction" in and of itself unless your new duties are materially reduced from the prior duties; or (c) relocation of your principal place of employment to a place that increases your one-way commute by more than fifty (50) miles as compared to your then-current principal place of employment immediately prior to such relocation, *provided, however*, that neither your transition from remote work to a Company office nor to remote work from a Company office will be considered a relocation of your principal place of employment with the Company for purposes of this definition. In order to resign for Good Reason, you must provide written notice to the Board within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for your resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, you must resign from all positions you then hold with the Company not later than 30 days after the expiration of the cure period.

"**Change of Control**" shall have the same meaning as "Corporate Control Event" as set forth in the Plan, excluding sections (b) and (h) of such definition; provided, however, that for purposes of the Change of Control Payment, a transaction that does not constitute a "change in control event" under Sections 1.409A-3(i)(5)(v) or 1.409A-3(i)(5)(vii) of the Treasury Regulations under Section 409A ("**Section 409A**")) of the U.S. Internal Revenue Code of 1986, as amended (the "**Code**"), will not constitute a Change of Control.

16. Compliance with Section 409A. It is intended that the Severance Benefits and the Change of Control Payment (if applicable) set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute "deferred compensation" under Section 409A and you are, on the date of

your Separation from Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "**Specified Employee**"), then, solely to the extent necessary to avoid the incurrence of adverse personal tax consequences under Section 409A, the timing of the Severance Benefits shall be delayed until the earliest of: (i) the date that is six (6) months and one (1) day after your Separation from Service date, (ii) the date of your death, or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments or benefits deferred pursuant to this Section shall be paid in a lump sum or provided in full by the Company (or the successor entity thereto, as applicable), and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. If the Severance Benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which you have a Separation from Service, the Release will not be deemed effective any earlier than the Release Deadline. The Severance Benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly. Notwithstanding anything to the contrary herein, to the extent required to comply with Section 409A, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A. With respect to reimbursements or in-kind benefits provided to you hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of your taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of your taxable year following the taxable year in which the expense was incurred, (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

17. Section 280G; Parachute Payments.

(a) If any payment or benefit you will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment provided pursuant to this Agreement (a "**Payment**") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for you. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

(b) Notwithstanding any provision of subsection (a) above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) Unless you and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section 17 ("Section 280G; Parachute Payments"). The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a 280G Payment becomes reasonably likely to occur (if requested at that time by you or the Company) or such other time as requested by you or the Company.

(d) If you receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 17(a) and the U.S. Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, you agree to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 17(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 17(a), you shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

18. Exceptions. Notwithstanding any other provision of this Agreement, if this Agreement requires payment of an amount or provision of a benefit that is not able to be paid in compliance with Australian law or the ASX Listing Rules, then, to the extent such payment is not permitted by applicable law, that obligation to make payment or provide the benefit will be null and void. If such payment may be made or benefit may be provided if approved by shareholders of the Company and/or the shareholders of Opthea Limited, the Company agrees to make that payment if such approval is obtained.

19. Dispute Resolution. To aid the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, and in exchange for the mutual promises contained in this offer letter, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this letter agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("**JAMS**") or its successor, under JAMS'

then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: (i) https://www.jamsadr.com/rules-employment-arbitration/) and (ii) https://www.jamsadr.com/rules-comprehensive-arbitration/) at a location closest to where you last worked for the Company or another mutually agreeable location. Notwithstanding the foregoing, if JAMS is unavailable due to location or otherwise, or if the parties mutually agree, then the arbitration shall be conducted by the American Arbitration Association ("AAA") or its successor, under AAA's then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: https://www.adr.org/sites/default/files/EmploymentRules-Web.pdf), at a location closest to where you last worked for the Company or another mutually agreeable location. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge.** The Federal Arbitration Act, 9 U.S.C. § 1 et seq., will, to the fullest extent permitted by law, govern the interpretation and enforcement of this arbitration agreement and any arbitration proceedings. This provision shall not be mandatory for any claim or cause of action to the extent applicable law prohibits subjecting such claim or cause of action to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"), such as non-individual claims that cannot be waived under applicable law, claims or causes of action alleging sexual harassment or a nonconsensual sexual act or sexual contact, or unemployment or workers' compensation claims brought before the applicable state governmental agency. In the event you or the Company intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You acknowledge and agree that proceedings of any non-individual claim(s) under the California Private Attorneys General Act ("**PAGA**") that may be brought in court shall be stayed for the duration and pending a final resolution of the arbitration of any individual or individual PAGA claim. Nothing herein prevents you from filing and pursuing proceedings before a federal or state governmental agency, although if you choose to pursue a claim following the exhaustion of any applicable administrative remedies, that claim would be subject to this provision. In addition, with the exception of Excluded Claims arising out of 9 U.S.C. § 401 et seq., all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class, representative, or collective proceeding, nor joined or consolidated with the claims of any other person or entity. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive all rights to have any dispute be brought, heard, administered, resolved, or arbitrated on a class, representative, or collective action basis**. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. If a court finds, by means of a final decision, not subject to any further appeal or recourse, that the preceding sentences regarding class, representative, or collective claims or proceedings violate applicable law or are otherwise found unenforceable as to a particular claim or request for relief, the parties agree that any such claim(s) or request(s) for relief be severed from the arbitration and may proceed in a court of law rather than by arbitration. All other claims or requests for relief shall be arbitrated. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration and procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator to decide, provided however, that if required by applicable law, a court and not the arbitrator may determine the enforceability of this paragraph with respect to Excluded Claims. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by

the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. You and the Company shall equally share all arbitration administrative fees, or such fees shall be paid in such other manner to the extent required by, and in accordance with, applicable law or rules to effectuate your and the Company's agreement to arbitrate. To the extent the arbitration service does not collect or you otherwise do not pay an equal share of all arbitration administrative fees, and the Company pays your share, you acknowledge and agree that the Company shall be entitled to recover from you in a federal or state court of competent jurisdiction half of the arbitration fees invoiced to the parties (less any amounts you paid to the arbitration service). Each party is responsible for its own attorneys' fees, except as may be expressly set forth in your Confidentiality Agreement or as otherwise provided under applicable law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

20. Miscellaneous. This offer is contingent upon a satisfactory reference check and satisfactory proof of your right to work in the United States. If the Company informs you that you are required to complete a background check or drug test, this offer is contingent upon satisfactory clearance of such background check and/or drug test. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions. This Agreement, together with your Confidentiality Agreement, forms the complete and exclusive statement of your employment agreement with the Company. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's or the Board's discretion in this Agreement, require a written modification approved by the Company and signed by a duly authorized officer of the Company (other than you). This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This Agreement shall be construed and enforced in accordance with the laws of the State of Texas without regard to conflicts of law principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

Please sign and date this Agreement and the enclosed Confidentiality Agreement and return them to me on or before **25 October 2023** if you wish to accept employment at the Company under the terms described above. The offer of employment herein will expire if I do not receive this signed letter by that date. I would be happy to discuss any questions that you may have about these terms.

We are delighted to be making this offer and the Company looks forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ Jeremy Levin
Dr. Jeremy Levin, Chairman

Reviewed, Understood, and Accepted:

/s/ Fred Guerard	25 October 2023
Fred Guerard	Date

Exhibit A: Confidentiality Agreement

Exhibit 4.18

OPTHEA US INC.

October 24, 2023

Peter F. Lang
51 5th Avenue
Apt. 10BF
New York, NY 10003

Re: Employment Terms

Dear Peter:

On behalf of OPTHEA US, INC. (the "**Company**"), I am pleased to offer you employment at the Company on the terms set forth in this offer letter agreement (the "**Agreement**"). As discussed, the terms of this Agreement govern with respect to your employment, which is anticipated to start on October 27, 2023 (such actual date of your commencement of employment shall be referred to herein as the "**Start Date**").

1. Employment by the Company.

(a) Position. You will serve as the Company's Chief Financial Officer. During the term of your employment with the Company, you will devote your best efforts and substantially all of your business time and attention to the business of the Company, except for management of your personal finances and investments and independent contractor services with a registered broker-dealer as set forth in the "Outside Activities" section of this Agreement below, approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies and/or applicable law. It is anticipated that such business of the Company will include your providing services to entities that are affiliated with the Company to the extent reasonable and within the scope of your role as the Company's CFO, without further or additional compensation or benefits other than as set forth in this Agreement, except that, for clarity, such services shall not include any additional roles or offices as a director, managing member, or officer (beyond your role as CFO for the Company) of any entity without your express agreement (acting reasonably) in a signed writing.

(b) Duties and Location. You will perform those duties and responsibilities as are reasonable and customary for the position of Chief Financial Officer and as may be directed by the Chief Executive Officer, to whom you will report, including the authority to build out the Company's management team and employee base with Board approval. You will initially work remotely from New York, NY; at such time as the Company assigns you to an office (which may include after such an office is opened), that will be your primary office location, provided that if such primary office location increases your one-way commute by more than 25 miles and you are not permitted by the Company to continue to work remotely, the Company shall provide you a relocation benefit which will include net of taxes payment covering any and all costs associated with such assignment, closing costs with respect to your primary residence, moving expenses, brokerage and real estate agent fees, and temporary housing costs. Notwithstanding the foregoing, the Company reserves the right to reasonably require you to temporarily perform your duties at places other than your primary office location such as reasonable business travel. The Company

may reasonably modify your job work duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time provided that your duties and authority remain commensurate with the duties and authority of a CFO at other U.S.-based publicly- traded pharmaceutical companies.

2. Base Salary and Employee Benefits.

(a) Salary. You will be paid a base salary at the rate of $500,000 per year, less applicable payroll deductions and withholdings. Your base salary will be paid on the Company's ordinary payroll cycle. Upon achievement of certain reasonable performance objectives, which the Company shall set forth in writing and in advance of the performance year, and as established and determined by the Chief Executive Officer and the Board of Directors of the Company (the "***Board***") or its Remuneration Committee, in consultation with you, measured within the first twelve (12) months of your employment, your base salary will be increased, effective on the first day of the month following the Board's evaluation of your achievement of your performance objectives, to be paid at the rate of not less than $550,000 per year, less applicable payroll deductions and withholdings. As an exempt salaried employee, you will be required to work the Company's normal business hours, and such additional time as appropriate for your work assignments and position, except for approved and/or legally-entitled vacations, sick leave, and other paid time off and leaves of absence, and you will not be entitled to overtime compensation.

(b) Annual Bonus. You will be eligible for an annual discretionary performance bonus with a target amount of fifty (50%) of your base salary, less payroll deductions and withholdings, during each full fiscal year of the Company during your employment, based on the performance of certain performance objectives, which the Company shall set forth in writing and with respect to which the Company will use reasonable efforts to establish in advance of the performance year. The amount of this bonus will be reasonably determined in the discretion of the Company. The Company will pay you this annual bonus, if any, no later than September 15 occurring following the end of the fiscal year ending June 30 of that year. Such bonus is not earned until paid.

(c) Employee Benefits. As a regular full-time employee, you will be eligible to participate in the Company's standard employee benefits offered to C-Suite executive level employees, as in effect from time to time and subject to the terms and conditions of the benefit plans and applicable Company policies pertaining to C-Suite executive level employees. A full description of these benefits is available upon request, which the Company agrees is hereby requested. The Company may change your benefits from time to time in its discretion provided that such changes equally affect all similarly situated C-Suite executive level employees. Notwithstanding anything to the contrary in this Agreement or otherwise, you shall be entitled to paid vacation in accordance with Company policy as in effect from time to time, in addition to nationally recognized holidays and sick days provided as part of the Company's benefit programs. You will be eligible to participate in the Company's 401(k) plan on the same terms and conditions as apply to employees generally.

3. Expenses. The Company will reimburse you for reasonable travel, entertainment and other expenses incurred by you in furtherance of or in connection with the performance of your duties hereunder, in accordance with the Company's expense reimbursement policies and practices as in effect from time to time, provided that in all circumstances if cross-continental or international travel is required, then any travel shall, to ensure your are rested and able to perform your duties, be booked at a service level of business-class or higher.

4. Equity Awards.

(a) Sign-On Grant. Subject to limitations due to compliance with any applicable law or listing rule, as applicable, the Company will grant you an option to purchase 1,300,000 of the Company's American Depositary Shares on the Start Date, or soon as practicable, at the fair market value at the time of grant as determined by the Board as of the date of grant (the "***Option***"). The Option will be governed by the terms and conditions of the Company's Long-Term Incentive Plan (the "***Plan***") and the applicable grant agreement. This grant will include the following vesting schedule: 25% of the total shares will vest on the one year anniversary of the vesting commencement date, which shall be no later than your Start Date, and 1/24th of the total shares will vest monthly thereafter on the same day of the month as the vesting commencement date (or if there is no corresponding day, on the preceding day) as of each such date until fully vested after 2 years, or for so long as you remain in continuous service as an employee of the Company. The Option will vest in full upon the closing of a Change of Control (as defined below) provided you either (1) remain employed through such closing date or (2) are subject to a Qualifying Termination (as defined below) within three (3) months prior to the closing date of such Change of Control.

(b) Incentive Grant. Subject to approval by the Board and compliance with any applicable law or listing rule, as applicable, the Company will grant you an additional option to purchase 300,000 of the Company's American Depositary Shares on the Start Date, or soon as practicable, at the fair market value as reasonably determined by the Board as of the date of grant (the "**Additional Option**"). The anticipated Additional Option will be governed by the terms and conditions of the Plan and applicable grant agreement. The Additional Option will vest in full upon the closing of a Change of Control (as defined below) that occurs prior to December 31, 2027 with an enterprise value at least equal to a value determined by the Board, in its sole discretion, provided you either (1) remain employed through such closing date or (2) are subject to a Qualifying Termination) within three (3) months prior to the closing date of such Change of Control. In the event of any conflict between this Agreement or the Plan or the applicable grant agreement, the Plan and the applicable grant agreement will supersede this Agreement and control.

5. Compliance with Confidentiality Information Agreement and Company Policies. In connection with your employment with the Company, you will receive and have access to Company confidential information and trade secrets. Accordingly, enclosed with this offer letter is an Employee Confidential Information and Inventions Assignment Agreement (the "**Confidentiality Agreement**") which contains restrictive covenants and prohibits unauthorized use or disclosure of the Company's confidential information and trade secrets, among other obligations. Please review the Confidentiality Agreement and only sign it after careful consideration. In addition, you are required to abide by the Company's policies and procedures (including but not limited to the Company's employee Handbook) to the extent applicable to all C-Suite executive level employees of the Company, as adopted or modified from time to time within the Company's discretion, and acknowledge in writing that you have read and will comply with such

policies and procedures (and provide additional such acknowledgements as such policies and procedures may be modified from time to time to the extent such modifications are consistent with this Agreement and the other agreements and documents referenced in this Agreement); *provided*, *however*, that in the event the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, now or in the future, this Agreement shall control.

6. Protection of Third Party Information. By signing this Agreement, you are representing that you have full authority to accept this position and perform the duties of the position without conflict with any other obligations and that you are not involved in any situation that might create, or appear to create, a conflict of interest with respect to your loyalty to or duties for the Company. You specifically warrant that you are not subject to an employment agreement or restrictive covenant (if any) preventing full performance of your duties to the Company as contemplated under this Agreement. In addition, you agree not to bring to the Company or use in the performance of your responsibilities at the Company any materials or documents of a former employer that are not generally available to the public, unless you have obtained express written authorization from the former employer for their possession and use. You also agree to honor all post-termination obligations owed (if any) to former employers during your employment with the Company.

7. At-Will Employment Relationship. Your employment relationship with the Company is at will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company; and the Company may terminate your employment at any time, with or without Cause or advance notice provided that the pay, benefits, equity acceleration, and other remuneration contemplated herein, if applicable, are timely paid and effectuated by the Company through and including the effective date of such termination.

8. Severance in the Event of Qualifying Termination. If, at any time, the Company terminates your employment without Cause (including as a result of your death or Disability) or you resign for Good Reason (any such termination referred to as a "**Qualifying Termination**"), provided such termination or resignation constitutes a Separation from Service (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), then subject to Sections 10 ("Clawback and Recovery"), 12 ("Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable)"), 13 ("Return of Company Property" and Clause 18 "Exceptions") below and your continued compliance with the material terms of this Agreement (including without limitation the Confidentiality Agreement), the Company will, subject to reduction due to any restrictions on the provision of such benefits arising under Australian law or the ASX Listing Rules to the extent they may apply (in which case clause 18 will apply), provide you with the following severance benefits (the "**Severance Benefits**") in addition to your base salary and other remuneration, reimbursable expenses, and unused vacation through your last day of employment (if and as applicable):

(a) Cash Severance. The Company will pay you, as cash severance, twelve (12) months of your base salary in effect as of your Separation from Service date (provided that any reduction in salary, benefits, or other remuneration that served as the basis for a resignation for Good Reason shall be disregarded), less standard payroll deductions and tax withholdings (the "**Severance**"). The Severance will be paid in installments in the form of continuation of your base salary payments, paid on the Company's ordinary payroll dates, commencing **no later than** on the Company's first regular payroll date that is more than sixty (60) days following your Separation from Service date, and shall be for any accrued base salary for the sixty (60)-day period plus the period from the sixtieth (60th) day until the first regular

payroll date, if applicable, and all salary continuation payments thereafter, if any, shall be made on the Company's regular payroll dates.

(b)COBRA Severance. The Company will continue to pay the full cost, net of any applicable taxes, of your health, vision, and dental care coverage in effect at the time of your Separation from Service for a maximum of twelve (12) months (or, if such Qualifying Termination occurs within 12 months following a Change of Control, eighteen (18) months), either by reimbursing you for or paying directly (at the Company's discretion) your COBRA premiums and/or such other amounts required for you to continue such coverage (the "**COBRA Severance**"). The Company's obligation to pay the COBRA Severance on your behalf will cease if you obtain health care coverage from another source (e.g., a new employer or spouse's benefit plan), unless otherwise prohibited by applicable law. You must notify the Company within two (2) weeks if you obtain coverage from a new source. This payment of COBRA Severance by the Company would not expand or extend the maximum period of COBRA coverage to which you would otherwise be entitled under applicable law. Notwithstanding the above, if the Company determines in its sole discretion that it cannot provide the foregoing COBRA Severance without potentially violating applicable law (including, without limitation, Section 2716 of the U.S. Public Health Service Act), or if the Company's health plan shall terminate for any reason, the Company shall in lieu thereof provide to you a monthly payment in an amount net of any applicable taxes or fees equal to the monthly COBRA premium that you would be required to pay to obtain the same group health, vision, and dental coverage as was in effect on the date of your termination (which amount shall be based on the premium for the first month of COBRA coverage had such COBRA coverage been, or remained, in effect), which payments shall be made on the last day of each month regardless of whether you elect COBRA continuation coverage and shall end on the earlier of (x) the date upon which you obtain other coverage or (y) the last day of the twelfth (12th) calendar month following your Separation from Service date.

(c) Pro-Rata Bonus For Year in Which Separation from Service Occurs; Prior Year Bonus. The Company will pay you a *pro rata* bonus for the fiscal year in which the Separation from Service date occurs at 100% of your target Annual Bonus, and prorated based on the number of days in which you were employed by the Company during the fiscal year in with the Separation from Service date occurs, less payroll deductions and withholdings (the "***Pro Rata* Bonus Severance**"). The *Pro Rata* Bonus Severance will be paid at the same time as the first Severance payment pursuant to Section 8(a). In addition, if the Separation from Service date occurs after the close of the Company's fiscal year but prior to the Company determining and paying the Annual Bonus for that previous fiscal year (if any), you will remain eligible for an Annual Bonus for the previous fiscal year, subject to the terms of this Agreement, with such bonus payment determined by the Board in its discretion consistent with Section 2(b) above (the "**Prior Year Bonus Eligibility Severance**"). Such Prior Year Bonus Eligibility Severance payment, if any, will be paid at the same time as such Annual Bonuses are paid to other executive employees of the Company, less payroll deductions and withholdings.

(d)Equity Acceleration. With respect to any equity awards granted to you that vest principally based on your provision of continuous service, you will vest as if you had provided an additional **six (6)** months of continuous service following the Separation from Service date. In addition, any then-vested options (including the Option and the Additional Option) shall remain outstanding and exercisable until the earlier of (x) the expiration date set forth therein or (y) the date that is six (6) months following your Separation from Service date; provided, however, that such options shall nevertheless be subject to the terms of the Plan, including in connection with a Corporate Control Event (as defined in the

Plan). Moreover, you shall remain eligible for any other Change of Control acceleration provided for elsewhere in this Agreement.

(e) Outplacement Services. You will be provided executive level outplacement services provided through Lee Hecht Harrison, or other comparable firm, for at least one year following your Separation of Service, paid in full by the Company.

9. Payment in Connection with a Change of Control. Subject to Sections 10 ("Clawback and Recovery"), 12 ("Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable)"), 13 ("Return of Company Property") and Clause 18 "Exceptions") below and your continued compliance with the terms of this Agreement (including without limitation the Confidentiality Agreement), then Company will, subject to any restrictions on the making of such payment arising under Australian law or the ASX Listing Rules which may apply, if applicable (in which case clause 18 will apply), pay you an amount equivalent to 50% of your annual base salary then in effect (provided that any reduction in salary, benefits, or other remuneration that served as the basis for a resignation for Good Reason shall be disregarded), within thirty (30) days following the closing of a Change of Control (the "**Change of Control Payment**"), less payroll deductions and withholdings where applicable. You must either remain employed through the closing date of such Change of Control, or have experienced a Qualifying Termination within thirty (30) days prior to such closing date, to receive the Change of Control Payment.

10. Clawback and Recovery. Any and all Severance Benefits or the Change of Control Payment provided under this Agreement will be subject to recoupment in accordance with any clawback policy that the Company has adopted or is required to adopt pursuant to any applicable listing standards of any national securities exchange or association on which the Company's securities are listed (including the Australian Securities Exchange) or as is otherwise required by applicable law or regulation, including the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law or rule or regulation thereunder.

11. Resignation Without Good Reason; Termination for Cause. If, at any time, you resign your employment without Good Reason, or the Company terminates your employment for Cause, you will receive your base salary accrued through your last day of employment, as well as all benefits, other remuneration, reimbursable expenses, and any unused vacation (if applicable) accrued through your last day of employment. Under these circumstances, you will not be entitled to any other form of compensation from the Company, including any Severance Benefits, other than your rights to the vested portion of your Option and any other rights to which you are entitled under the Company's benefit programs.

12. Conditions to Receipt of Severance Benefits or Change of Control Payment (if applicable). Prior to and as a condition to your receipt of the Severance Benefits or the Change of Control Payment (if applicable), you shall execute and deliver to the Company an effective release of claims in favor of and in a form acceptable and the Company (the "**Release**") within the timeframe set forth therein, but not later than forty-five (45) days following your Separation from Service date, or with respect to the Change of Control Payment, within forty-five (45) days after such Change of Control Payment) and allow the Release to become effective according to its terms (by not invoking any legal right to revoke it) within any applicable time period set forth therein (such latest permitted effective date, the "**Release Deadline**").

13. Return of Company Property. Upon the termination of your employment for any reason, as a precondition to your receipt of the Severance Benefits, within ten (10) days after your Separation from Service Date (or earlier if requested by the Company), you must return to the Company all Company documents (and all copies thereof) and other Company property in your possession, custody or control, including, but not limited to, Company files, notes, financial and operational information, password and account information, customer lists and contact information, prospect information, product and services information, research and development information, drawings, records, plans, forecasts, pipeline reports, sales reports or other reports, payroll information, spreadsheets, studies, analyses, compilations of data, proposals, agreements, sales and marketing information, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, tablets, handheld devices, and servers), credit cards, entry cards, identification badges and keys, and any materials of any kind which contain or embody any proprietary or confidential information of the Company, and all reproductions thereof in whole or in part and in any medium. You further agree that you will make a single reasonably diligent search to locate any such documents, property and information and return them to the Company within the timeframe provided above. You also must provide the Company all passwords, log-ins, administrative access, and any other information or access for and relating to any Company computer or other device that you have used to access or use the Company's network, as well as any Company database or Company accounts with third parties which you established, administered, or to which you had access, and must terminate your access to such network and accounts and otherwise comply with any Company requests regarding all such access and accounts. If requested, you shall deliver to the Company a signed statement certifying compliance with this Section prior to the receipt of the Severance Benefits.

14. Outside Activities. Throughout your employment with the Company, you may engage in personal financial and investment management, may maintain your securities/FINRA licenses with a registered broker-dealer for this purpose, may engage in civic activities, and may engage in not-for-profit activities, so long as any such activities do not interfere with the performance of your duties hereunder or present a conflict of interest with the Company. During your employment by the Company, except on behalf of the Company, you will not directly or indirectly become an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any other person, corporation, firm, partnership or other entity whatsoever known by you to compete with the Company (or is planning or preparing to compete with the Company), anywhere in the world, in any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that you may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (but without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

15. Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"**Cause**" for termination will mean your (a) commission or conviction (including a guilty plea or plea of *nolo contendere*) of any felony or any other crime involving fraud, dishonesty or moral turpitude; (b) your commission or attempted commission of or participation in a fraud or act of dishonesty or misrepresentation against the Company; (c) material breach of your duties to the Company; (d) intentional damage to any property of the Company; (e) misconduct, or other violation of Company policy that causes harm; (f) your material violation of any written and fully executed contract or agreement between you and the Company, including without limitation, material breach of your Confidentiality Agreement, or of any

Company policy, or of any statutory duty you owe to the Company; or (g) conduct by you which in the good faith and reasonable determination of the Company demonstrates gross unfitness to serve. The determination that a termination is for Cause shall be made by the Company in its sole discretion acting in good faith.

"**Change of Control**" shall have the same meaning as "Corporate Control Event" as set forth in the Plan, excluding sections (b) and (h) of such definition; provided, however, that for purposes of the Change of Control Payment, a transaction that does not constitute a "change in control event" under Sections 1.409A-3(i)(5)(v) or 1.409A-3(i)(5)(vii) of the Treasury Regulations under Code Section 409A (together with any state law of similar effect, "**Section 409A**")), will not constitute a Change of Control.

"**Code**" shall mean the U.S. Internal Revenue Code of 1986, as amended.

"**Disability**" shall mean your inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

You shall have "**Good Reason**" for resigning from employment with the Company if any of the following actions are taken by the Company without your prior written consent: (a) a material reduction in your base salary, which the parties agree is a reduction of at least 10% of your base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); (b) a material reduction in your duties (including responsibilities and/or authorities), *provided, however*, that a change in job position (including a change in title) shall not be deemed a "material reduction" in and of itself unless your new duties are materially reduced from the prior duties; or (c) relocation of your principal place of employment to a place that increases your one-way commute by more than fifty (50) miles as compared to your then-current principal place of employment immediately prior to such relocation, *provided, however*, that provided the Company fulfills all of its obligations under this Agreement, neither your transition from remote work to a Company office nor to remote work from a Company office will be considered a relocation of your principal place of employment with the Company for purposes of this definition. In order to resign for Good Reason, you must provide written notice to the Board within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for your resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, you must resign from all positions you then hold with the Company not later than 30 days after the expiration of the cure period.

16. Compliance with Section 409A. It is intended that the Severance Benefits and Change of Control Payment set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute "deferred compensation" under Section 409A and you are, on the date of your Separation from Service, a

"specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "**Specified Employee**"), then, solely to the extent necessary to avoid the incurrence of adverse personal tax consequences under Section 409A, the timing of the Severance Benefits shall be delayed until the earliest of: (i) the date that is six (6) months and one (1) day after your Separation from Service date, (ii) the date of your death, or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments or benefits deferred pursuant to this Section shall be paid in a lump sum or provided in full by the Company (or the successor entity thereto, as applicable), and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. If the Severance Benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which you have a Separation from Service, the Release will not be deemed effective any earlier than the Release Deadline. The Severance Benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly. Notwithstanding anything to the contrary herein, to the extent required to comply with Section 409A, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A. With respect to reimbursements or in-kind benefits provided to you hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of your taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of your taxable year following the taxable year in which the expense was incurred, (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

17. Section 280G; Parachute Payments.

(a) If any payment or benefit you will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment provided pursuant to this Agreement (a "**Payment**") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for you. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

(b) Notwithstanding any provision of subsection (a) above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) Unless you and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section 17 ("Section 280G; Parachute Payments"). The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a 280G Payment becomes reasonably likely to occur (if requested at that time by you or the Company) or such other time as requested by you or the Company.

(d) If you receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 17(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, you agree to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 17(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 17(a), you shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

18. Exceptions. Notwithstanding any other provision of this Agreement, if this Agreement requires payment of an amount or provision of a benefit that is not able to be paid in compliance with any applicable Australian law or the ASX Listing Rules, then, to the extent such payment is not permitted by such applicable Australian law or ASX Listing Rules (if any), that obligation to make payment or provide the benefit will be reduced, but such reduction shall be minimized so that the payment or benefit is the maximum amount permitted under applicable law. If such payment may be made or benefit may be provided if approved by shareholders of the Company and/or the shareholders of Opthea Limited, the Company agrees: (i) upon your written request, seek such approval at the next general meeting of the Company or Opthea Limited as the case may be (and for the avoidance of doubt, there is no obligation on the Company or Opthea Limited to convene a general meeting for the purpose of seeking such approval); and (ii) to make that payment (provided the Company is otherwise obliged to make that payment) if the relevant shareholder approval is obtained.

19. Professional Insurance. You shall be provided the following:

(i) You will be designated as aninsured (in your capacity as Chief Financial Officer) on a directors' and officers' liability insurance the Company must have and maintain for your benefit with coverage levels consistent with those of other executive officers, which shall remain in effect throughout your employment and provide tail coverage to ensure you remain covered by this policy after termination of employment (consistent with those of other executive officers).

(ii) The Company will provide you, at the Company's expense, with a life insurance benefit plan on the same terms and conditions as apply to the Company's other employees.

20. Dispute Resolution. To aid the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, and in exchange for the mutual promises contained in this offer letter, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this letter agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("**JAMS**") or its successor, under JAMS' then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: (i) https://www.jamsadr.com/rules-employment-arbitration/) and (ii) https://www.jamsadr.com/rules-comprehensive-arbitration/) at a location closest to where you last worked for the Company or another mutually agreeable location. Notwithstanding the foregoing, if JAMS is unavailable due to location or otherwise, or if the parties mutually agree, then the arbitration shall be conducted by the American Arbitration Association ("AAA") or its successor, under AAA's then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address: https://www.adr.org/sites/default/files/EmploymentRules-Web.pdf), at a location closest to where you last worked for the Company or another mutually agreeable location. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge.** The Federal Arbitration Act, 9 U.S.C. § 1 et seq., will, to the fullest extent permitted by law, govern the interpretation and enforcement of this arbitration agreement and any arbitration proceedings. This provision shall not be mandatory for any claim or cause of action to the extent applicable law prohibits subjecting such claim or cause of action to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"), such as non-individual claims that cannot be waived under applicable law, claims or causes of action alleging sexual harassment or a nonconsensual sexual act or sexual contact, or unemployment or workers' compensation claims brought before the applicable state governmental agency. In the event you or the Company intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You acknowledge and agree that proceedings of any non-individual claim(s) under the California Private Attorneys General Act ("**PAGA**") that may be brought in court shall be stayed for the duration and pending a final resolution of the arbitration of any individual or individual PAGA claim. Nothing herein prevents you from filing and pursuing proceedings before a federal or state governmental agency, although if you choose to pursue a claim following the exhaustion of any applicable administrative remedies, that claim would be subject to this provision. In addition, with the exception of Excluded Claims arising out of 9 U.S.C. § 401 et seq., all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class, representative, or collective

proceeding, nor joined or consolidated with the claims of any other person or entity. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive all rights to have any dispute be brought, heard, administered, resolved, or arbitrated on a class, representative, or collective action basis**. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. If a court finds, by means of a final decision, not subject to any further appeal or recourse, that the preceding sentences regarding class, representative, or collective claims or proceedings violate applicable law or are otherwise found unenforceable as to a particular claim or request for relief, the parties agree that any such claim(s) or request(s) for relief be severed from the arbitration and may proceed in a court of law rather than by arbitration. All other claims or requests for relief shall be arbitrated. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration and procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator to decide, provided however, that if required by applicable law, a court and not the arbitrator may determine the enforceability of this paragraph with respect to Excluded Claims. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a detailed and reasoned written statement and award signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. You and the Company shall equally share all arbitration administrative fees, or such fees shall be paid in such other manner to the extent required by, and in accordance with, applicable law or rules to effectuate your and the Company's agreement to arbitrate. To the extent the arbitration service does not collect or you otherwise do not pay an equal share of all arbitration administrative fees, and the Company pays your share, you acknowledge and agree that the Company shall be entitled to recover from you in a federal or state court of competent jurisdiction half of the arbitration fees invoiced to the parties (less any amounts you paid to the arbitration service). Each party is responsible for its own attorneys' fees, except as may be expressly set forth in your Confidentiality Agreement or as otherwise provided under applicable law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive, equitable, or declaratory relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

21. Miscellaneous. This offer is contingent upon satisfactory proof of your right to work in the United States. You agree to assist as needed and to complete any documentation at the Company's request to meet this condition. This Agreement, together with your Confidentiality Agreement, your equity grant documents, agreements, and plans, as well as any other agreements and documents referenced herein, form the complete and exclusive statement of your employment agreement with the Company. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's or the Board's discretion in this Agreement, require a written modification approved by the Company and signed by a duly authorized officer of the Company (other than you). This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a

manner consistent with the intent of the parties insofar as possible under applicable law. This Agreement shall be construed and enforced in accordance with the laws of the State of New York without regard to conflicts of law principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement may be delivered and executed in wet ink, via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

Please sign and date this Agreement and the enclosed Confidentiality Agreement and return them to me on or before October 27, 2023 if you wish to accept employment at the Company under the terms described above. The offer of employment herein will expire if I do not receive this signed letter by that date. I would be happy to discuss any questions that you may have about these terms.

We are delighted to be making this offer and the Company looks forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ Jeremy Levin
Jeremy Levin, Chairman

Reviewed, Understood, and Accepted:

/s/ Peter F. Lang	24/10/2023
Peter F. Lang	Date

Exhibit A: Confidentiality Agreement

Exhibit 4.19

Execution Version

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE OF INFORMATION THAT OPTHEA TREATS AS PRIVATE OR CONFIDENTIAL

AMENDED AND RESTATED DEVELOPMENT FUNDING AGREEMENT

BY AND BETWEEN

OPTHEA LIMITED
OCELOT SPV LP, AS COLLATERAL AGENT,
AND
THE INVESTORS FROM TIME TO TIME PARTY HERETO

December 22, 2023

AMENDED AND RESTATED DEVELOPMENT FUNDING AGREEMENT

This Amended and Restated Development Funding Agreement (this "Agreement"), dated December 22, 2023 (the "Restatement Effective Date"), is by and among Opthea Limited ACN 006 340 567, a company incorporated under the laws of Victoria, Australia ("Opthea"), and the Persons party hereto as investors from time to time (collectively, the "Investors") and Ocelot SPV LP, a Delaware limited partnership, as collateral agent and security trustee for the Investors (the "Collateral Agent"). Each of the Investors, Collateral Agent and Opthea may be referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Opthea and Ocelot SPV LP, a Delaware limited partnership are party to that certain Development Funding Agreement dated August 12, 2022 (as amended or modified prior to the Restatement Effective Date, the "Existing Agreement", and the date of such agreement, the "Original Effective Date") and wish to amend and restate the Existing Agreement as further set forth in this Agreement;

WHEREAS, it is the intent of the parties hereto that this Agreement not constitute a novation of the obligations and liabilities of the Parties under the Existing Agreement or be deemed to evidence or constitute full repayment of such obligations and liabilities, but that this Agreement amend and restate in its entirety the Existing Agreement and re-evidence the obligations and liabilities of Opthea outstanding thereunder, which shall be payable in accordance with the terms hereof;

WHEREAS**,** it is also the intent of the Parties to confirm that all obligations under the Existing Agreement and "Transaction Agreements" (as referred to and defined in the Existing Agreement) shall continue in full force and effect as modified and/or restated hereby and that, from and after the Restatement Effective Date, all references to the "Agreement" contained in any such existing "Transaction Agreements" shall be deemed to refer to this Agreement; and

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1

ARTICLE 1 DEFINITIONS

1.1Defined Terms. Initially capitalized terms will have the meaning ascribed to such terms in this Agreement, including the following terms which will have the following respective meanings:

1.1.1 "AAA" means the American Arbitration Association.

1.1.2 "Accounting Standards" means IFRS (unless and until Opthea adopts GAAP as the accounting principles for Opthea, after which time "Accounting Standards" shall mean GAAP), in each case consistently applied.

1.1.3 "AdComm Chairperson:" has the meaning ascribed to such term in Section 5.3.3.

1.1.4 "AdComm Representatives" has the meaning ascribed to such term in Section 5.3.1.

1.1.5 "Adverse Patent Impact" has the meaning ascribed to such term in Section 13.4.9.

1.1.6 "Advisory Committee" has the meaning ascribed to such term in Section 5.3.1.

1.1.7 "Affiliate" means with respect to any particular Person, any other Person directly or indirectly controlling, controlled by or under common control with such particular Person. For the purposes of this definition, "controlling," "controlled", and "control" mean the possession, directly (or indirectly through one or more intermediary entities), of the power to direct the management or policies of a Person, including, but not limited to, through ownership of more than fifty percent (50%) of the voting securities of such Person (or, in the case of a Person that is not a corporation, ownership of more than fifty percent (50%) of the corresponding interest for the election of the Person's managing authority), and shall not include any private equity fund, venture capital fund or registered investment company now or hereafter existing that is controlled by one (1) or more general partners, managing members or investment advisers of, or shares the same management company or investment adviser with, such Person. Notwithstanding the foregoing, with respect to [***]: (a) solely with respect to transfers by, or any other rights afforded to, [***] or any of its Affiliates, all references to "Affiliate" or "Affiliates" with respect to [***] shall include (i) [***] and any individual, corporation, partnership, firm, joint venture, investment fund, association, trust, unincorporated association or organization, governmental body or other entity, which controls, is controlled by or is under common control with, [***]; and (ii) government entities or instrumentalities of, or entities that are wholly-owned or controlled by [***] or any entities that are wholly-owned or controlled by any one or more of the foregoing; and (b) for all other purposes, references to "Affiliate" or "Affiliates" of [***] shall refer to [***] and legal entities which are majority-owned directly or indirectly by [***] and are managed on a day-to day-basis by [***].

1.1.8 "Agreement" has the meaning ascribed to such term in the Preamble.

1.1.9 "Alliance Manager" has the meaning ascribed to such term in Section 5.1.5.

1.1.10"Anti-Corruption Laws" means the U.S. Foreign Corrupt Practices Act, as amended, and any other U.S., Australian, or other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.1.11"Appellate Rules" has the meaning ascribed to such term in Section 14.10.2.5.

1.1.12"Applicable Law" means the applicable laws, statutes, rules, regulations, guidelines, or other requirements of any Governmental Authorities (including any Regulatory

Authorities) or stock exchange on which securities of Opthea are quoted for trading that may be in effect from time to time in any country or regulatory jurisdiction. For clarity, Applicable Laws will include the FFDCA, the Anti-Corruption Laws, and all laws, regulations, and guidelines applicable to the Product Clinical Trials, including GCP, GLP, GMP and ICH guidelines.

1.1.13"Approval Buy-Out Option" has the meaning ascribed to such term in Section 6.7.1.

1.1.14"Approval Buy-Out Payment" has the meaning ascribed to such term in Section 6.7.1.

1.1.15"Approved CRO" has the meaning ascribed to such term in Section 2.5.1.

1.1.16"Approved Vendor" has the meaning ascribed to such term in Section 2.5.2.

1.1.17"Australian Corporations Act" means the *Corporations Act 2001* (Cth) of Australia.

1.1.18"Australian General Security Deed" means the general security deed in the form attached hereto as Exhibit M.

1.1.19"Australian PPSA" means the *Personal Property Securities Act 2009* (Cth) of Australia.

1.1.20"Background Materials" has the meaning ascribed to it in Section 2.6.1.

1.1.21"BLA" means a biologics license application, including a supplement to a biologics license application, submitted to FDA or similar application or supplemental application submitted to a Regulatory Authority outside of the U.S. for the purpose of obtaining Regulatory Approval to market and sell the Product.

1.1.22"Board of Directors" means the board of directors of Opthea.

1.1.23"Business Day" means a day that is not a Saturday or Sunday or day on which banks in New York, New York or Victoria, Australia are required or permitted by law to be closed. For the avoidance of doubt, with respect to any notice or other communication required to be given or delivered hereunder, limitations on the operations of commercial banks due to the outbreak of a contagious disease, epidemic or pandemic (including COVID-19), or any quarantine, shelter-in-place or similar or related directive, will not prevent a day that would otherwise be a Business Day hereunder from so being a Business Day.

1.1.24"Calendar Quarter" means each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that, the (a) the first Calendar Quarter will begin on the Original Effective Date and end on the last day of the Calendar Quarter in which the Original Effective Date falls, and (b) the final Calendar Quarter will end on the last day of the Term.

1.1.25"Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, (a) the first Calendar Year will begin on the Original Effective Date and end on December 31 of the Calendar Year in which the Original Effective Date falls, and (b) the final Calendar Year will end on the last day of the Term.

1.1.26"Cash Management Services" means treasury, depository, overdraft, cash pooling, netting, credit or debit card (including non-card electronic payables), credit card processing services, electronic funds transfer (including automated clearing house funds transfers) and other similar cash management arrangements.

1.1.27"Cash Management Obligations" means obligations in respect of Cash Management Services.

1.1.28"Change of Control" means (a) a merger, reorganization or consolidation with a Third Party which results in the voting securities of Opthea outstanding immediately prior thereto ceasing to represent, or being converted into or exchanged for voting securities that do not represent, at least fifty percent (50%) of the combined voting power of the voting securities of the surviving entity or the parent corporation of the surviving entity immediately after such merger, reorganization or consolidation, (b) a transaction in which a Third Party becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of Opthea, other than any such transaction in which the holders of the outstanding voting securities of Opthea prior to such transaction own, directly or indirectly, more than 50% of the combined voting power of the outstanding securities of such Third Party or the direct or indirect parent thereof immediately after such transaction; or (c) the sale or other transfer of all or substantially all of Opthea's business or assets relating to the Product; provided that an Excluded Licensing Transaction or other Out-License that is approved by the Required Investors pursuant to Section 7.3.4 shall not, absent meeting the criteria described in this Section 1.1.28(c), constitute a Change of Control.

1.1.29"Change of Control Payment" has the meaning ascribed to such term in Section 6.7.3.

1.1.30"Claim" means any claim, demand, suit or cause of action.

1.1.31"Clinical Hold" means, in the U.S., an order issued by FDA to the sponsor of a Clinical Trial to delay or suspend, in full or in part, an ongoing Clinical Trial, as set forth in 21 U.S.C. §312.42, or outside of the U.S., the foreign equivalent thereof issued by the applicable Regulatory Authority.

1.1.32"Clinical Investigator" means the principal investigator and/or any sub-investigator at each Site.

1.1.33"Clinical Trial" means a Phase 1 Clinical Trial, a Phase 2 Clinical Trial, a Phase 3 Clinical Trial, as may be conducted in combination, or any supplemental clinical trial (including a bridging study or a post-approval clinical study) required for the purpose of obtaining Regulatory Approval.

1.1.34"Clinical Trial Activity" has the meaning ascribed to such term in Section 2.4.1.

1.1.35"Clinical Trial Agreement" has the meaning ascribed to such term in Section 3.1.2.

1.1.36"Clinical Trials Database" has the meaning ascribed to such term in Section 3.1.3.2.

1.1.37"CMC" means chemistry, manufacturing and controls.

1.1.38"CMC Information" means the CMC information intended or required for the submission of an IND or BLA.

1.1.39"CMO" means contract manufacturing organization or contract development and manufacturing organization.

1.1.40"COAST Protocol" has the meaning ascribed to such term in Section 2.2.1.

1.1.41"COAST Trial" means the Phase 3 Clinical Trial entitled "OPT-302 With Aflibercept in Neovascular Age-related Macular Degeneration (nAMD) (COAST)" with identifier NCT04757636.

1.1.42"Collateral" has the meaning ascribed to such term in Section 7.1.

1.1.43"Collateral Agent" has the meaning ascribed to such term in the Preamble.

1.1.44"Combination Product" means a product that includes or incorporates the Product with one (1) or more other active ingredient or other products and is either co-formulated, co-administered or sold at a single price point or otherwise sold to be administered together, sequentially or as part of a course of treatment.

1.1.45"Commercial Updates" means a summary of any material updates with respect to Opthea's and any Commercialization Partner's Commercialization activities, which may be comprised of materials provided by Opthea to the Board of Directors and senior management.

1.1.46"Commercialization," "Commercializing" or "Commercialize" means the commercial manufacture, marketing, promotion, sale or distribution of the Product. For clarity, Commercialization excludes all activities associated with development and seeking Regulatory Approval for a Product.

1.1.47"Commercialization License" means any Out-License under which Opthea or any of its Affiliates grants a license to a Third Party to Commercialize the Product (any such Third Party, a "Commercialization Partner").

1.1.48"Commercialization Partner" has the meaning ascribed to such term in the definition of "Commercialization License".

1.1.49"Commercially Reasonable Efforts" means [***].

1.1.50"Commitment" means, for any Investor, the aggregate amount of fixed payments that such Investor is obligated to pay to Opthea in accordance with Section 4.2 of this Agreement. "Commitments" means the aggregate amount of such commitments of all Investors.

1.1.51"Commitment Percentage" means, as to any Investor at any time, the percentage (expressed as a decimal, rounded to the fourth decimal place) of the Commitments represented by such Investor's Commitment at such time.

1.1.52"Competitor" means [***].

1.1.53"Completion Date" means, with respect to a particular Clinical Trial, the earlier of (a) the date of final database lock for such Clinical Trial and (b) the date such Clinical Trial or this Agreement is terminated.

1.1.54 "Confidential Information" of a Party means all information and materials provided or disclosed (including in written form, electronic form or otherwise) by, or on behalf of, such Party or its Representatives to any other Party or its Representatives in connection with this Agreement, including, technical, scientific, regulatory and other information, results, knowledge, techniques, data, analyses, inventions, invention disclosures, plans, processes, methods, know-how, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data and descriptions. In addition, the terms and conditions of this Agreement will be deemed to be Confidential Information of each Investor and of Opthea.

1.1.55"Contingent Obligation" means, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, letter of credit or other debt obligation of another Person, in each case, directly or indirectly guaranteed, endorsed or co-made by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

1.1.56"Control" or "Controlled" means (a) with respect to Intellectual Property, a Party's ability to grant applicable licenses, sublicenses or other rights thereunder and (b) with respect to materials and documents, a Party's ability to provide, or provide access to, such materials or documents, each without violating any contractual obligations to a Third Party. For clarity, if a Party only can grant a license or sublicense or provide rights or access of limited scope, for a specific purpose or under certain conditions due to an encumbrance, "Control" or "Controlled" will be construed to so limit such license, sublicense, provision of rights or access.

1.1.57"Copyrights" means, collectively, all works of authorship, mask works and any and all other registered and unregistered copyrights and copyrightable works, and all applications, registrations, extensions, and renewals thereof.

1.1.58"CRO" means contract research organization.

1.1.59"CSR" means, with respect to each Product Clinical Trial, a clinical study report, or other equivalent document or series of materials, constituting a summary report of the clinical and medical data resulting from such Clinical Trial and prepared for incorporation into submissions seeking Regulatory Approval for the Product, and includes all statistical analyses of such data per the statistical analysis plan.

1.1.60"Data Read-Out" means, with respect to a Product Clinical Trial, the date that the tables, figures, and listings for such Product Clinical Trial are provided to Opthea.

1.1.61"Data Room" means that certain electronic data room established by Opthea via ShareVault and to which Ocelot SPV LP and its advisors were granted access prior to the Original Effective Date.

1.1.62"Defaulting Investor" [***].

1.1.63"Deposit Account Control Agreement" has the meaning ascribed to such term in the definition of "Development Costs Account".

1.1.64"Develop," "Developing," "Developed" or "Development" means all clinical research and development activities conducted after filing an IND, including toxicology, pharmacology test method development and stability testing, process development, formulation development, quality assurance and quality control development, statistical analysis, conducting Clinical Trials, regulatory affairs, and obtaining and maintaining Regulatory Approval.

1.1.65"Development Costs" means all internal and external costs incurred or paid by Opthea in connection with or relating to the Development Program or Commercializing the Product.

1.1.66"Development Costs Account" means a segregated deposit account with Citibank, N.A., subject to a deposit account control agreement between Citibank, N.A., Opthea and the Collateral Agent in the form attached hereto as Exhibit A (the "Deposit Account Control Agreement"), and any successor segregated deposit account established in accordance with Section 7.4.1.

1.1.67"Development Plan" means a written plan for the Development Program, the initial version of which is attached hereto as Exhibit B, and which will be subject to amendment from time to time during the Development Term.

1.1.68"Development Program" means a CMC, clinical and regulatory development program to be undertaken by Opthea to develop the Product for the Indication, carry out Clinical Trials therefor, and seek Regulatory Approval for the Product for the Indication.

1.1.69"Development Term" means the period commencing on the Original Effective Date and ending on the earlier of (a) the receipt of Regulatory Approval for the Product in the Indication in the United States, and (b) the date on which all efforts in pursuit of Regulatory Approval of the Product have been concluded or terminated.

1.1.70"Disclosing Party" has the meaning ascribed to such term in Section 9.1.

1.1.71"Dispose" has the meaning ascribed to such term in Section 7.3.4. "Disposition" shall have a corollary meaning.

1.1.72"Dispute" has the meaning ascribed to such term in Section 14.10.

1.1.73"Eligible Foreign Subsidiary" means any foreign Subsidiary whose pledge of shares would not reasonably be expected to result in a material adverse tax consequence to Opthea.

1.1.74"EMA" means the European Medicines Agency and any successor agency thereto in the EU having substantially the same function.

1.1.75"Escalation Designees" means the designees of each of Opthea and Ocelot SPV LP identified on Exhibit C.

1.1.76"EU" means the European Union or any successor union of European states thereto having a substantially similar function. For purposes of this Agreement, EU shall include the United Kingdom, unless the context otherwise requires.

1.1.77"Event of Default" means (a) the failure by Opthea to make any payment to an Investor under this Agreement when due, which failure shall continue for more than thirty (30) days following the date such payment is due, (b) commencement by or against Opthea of any bankruptcy or insolvency proceeding (including administration or receivership) and, with respect to involuntary bankruptcy or insolvency proceedings (including administration or receivership), such has continued without dismissal or stay for a period of forty-five (45) days or an order granting the relief requested in such case or proceeding is entered, or (c) the occurrence and continuation of a termination event set forth in Sections 13.4.2, Section 13.4.3, Section 13.4.6, or Section 13.5.

1.1.78"Excluded Account" means (a) escrow accounts and trust accounts; (b) payroll accounts; (c) accounts used for payroll taxes and/or withheld income taxes; (d) accounts used for employee wage and benefit payments; (e) accounts pledged to secure performance (including to secure letters of credit and bank guarantees) to the extent constituting Permitted Liens; (f) custodial accounts; (g) zero balance accounts; and (h) accounts established and used solely for Cash Management Services to the extent a Lien thereon is prohibited by the applicable agreement governing such accounts, in each case, to the extent exclusively used for such purpose.

1.1.79"Excluded IP" has the meaning ascribed to it in Section 7.1.3.

1.1.80"Excluded Licensing Transaction" means, collectively:

(a) any Out-License under which Opthea or any of its Affiliates grants an exclusive license or sublicense to a Third Party to Develop the Product in all or a portion of the world outside of the U.S.;

(b) any Commercialization License under which Opthea or any of its Affiliates grants an exclusive license or sublicense to a Third Party to Commercialize the Product in all or a portion of the world solely outside of the U.S.;

(c) any Out-License under which Opthea or any of its Affiliates grants a Third Party contract testing organization, contract development organization, contract research organization and/or contract manufacturing organization a license or sublicense to Develop or commercially manufacture the Product on behalf of Opthea or its Affiliates, without any license or sublicense to engage in any Commercialization activities with respect to the Product;

(d) any Out-License under which Opthea or any of its Affiliates grants a Third Party wholesaler, distributor or distribution logistics services provider, a license or sublicense to distribute the Product (and/or conduct other typical distribution activities) on behalf of Opthea or its Affiliates, without any license or sublicense to engage in any other Development or Commercialization activities with respect to the Product;

(e) any Out-License of Excluded IP; and

(f) any Out-Licenses solely between or among Opthea and its Subsidiaries.

1.1.81"Existing Contract Manufacturing Agreement" has the meaning ascribed to it in Section 12.2.3.

1.1.82"Existing In-License" has the meaning ascribed to it in Section 12.2.11.8.

1.1.83"FATCA" means (a) Sections 1471 to 1474 of the Code (or any amendment or successor thereto), any current or future regulations or official interpretations thereof and any agreement entered into pursuant to Section 1471(b)(1) of the Code; (b) any treaty, law, regulation or other official guidance of any other jurisdiction, or relating to an intergovernmental agreement between the US and any other jurisdiction, which (in either case) facilitates the implementation of any law, regulation or interpretation referred to in paragraph (a) above; or (c) any agreement pursuant to the implementation of any treaty, law, regulation or other guidance referred to in paragraphs (a) or (b) above with the US Internal Revenue Service, the US government or any governmental or taxation authority in any other jurisdiction.

1.1.84"FATCA Deduction" means a deduction or withholding from a payment under this Agreement required by FATCA.

1.1.85"FDA" means the U.S. Food and Drug Administration and any successor agency thereto in the U.S. having substantially the same function.

1.1.86"FFDCA" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations, requirements and guidance promulgated or issued thereunder (including all additions, supplements, extensions and modifications thereto).

1.1.87"Financial Statements" has the meaning ascribed to such term in Section 3.8.3.

1.1.88"First Commercial Sale" means, the first sale for use or consumption by the general public of the Product after Regulatory Approval of the Product has been granted. For clarity, First Commercial Sale shall not include any sale or transfer of the Product prior to receipt of Regulatory Approval, such as so-called "treatment IND sales," "named patient sales," "compassionate use sales" and any sale or other distribution for use in a Product Clinical Trial.

1.1.89"Fixed Return Cap" means Six Hundred and Eighty Million U.S. Dollars ($680,000,000).

1.1.90"Fixed Success Payments" has the meaning ascribed to such term in Section 6.1.1.

1.1.91"Force Majeure Event" means military action or war (whether or not declared), terrorism, riot, fire, explosion, accident, flood, sabotage, changes in Applicable Laws, actions of Governmental Authorities, pandemics (other than the current COVID-19 pandemic or any government response thereto), earthquakes, hurricanes, tsunamis, tornadoes, floods, mudslides, wildfires, or other natural disasters or weather conditions.

1.1.92"GAAP" means generally accepted accounting principles in the U.S., as consistently applied by the applicable Party.

1.1.93"General Buy-Out Notice" has the meaning ascribed to such term in Section 6.7.2.

1.1.94"General Buy-Out Option" has the meaning ascribed to such term in Section 6.7.2.

1.1.95"General Buy-Out Payment" has the meaning ascribed to such term in Section 6.7.2.

1.1.96"Going Concern Notice" has the meaning ascribed to such term in Section 3.8.3.

1.1.97"Going Concern Funding" has the meaning ascribed to such term in Section 3.8.3.

1.1.98"Good Clinical Practices" or "GCP" means all applicable requirements, standards, practices, and procedures for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of Clinical Trials including (i) FDA's good clinical practice requirements under the FFDCA and 21 CFR Parts 11, 50, 54, 56, and 312, (ii) all requirements

referred to in EudraLex Volume 10 (Guidelines for Clinical Trials) as well as all corresponding Applicable Laws implemented by relevant EU member states, (iii) ICH guidance for Good Clinical Practice, and (iv) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.1.99"Good Laboratory Practices" or "GLP" means all applicable requirements, standards, practices, and procedures for conducting non-clinical laboratory studies, including (i) FDA's good laboratory practice requirements under the FFDCA and 21 CFR Part 58, (ii) the United States Animal Welfare Act, (iii) ICH Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals or the ICH Guidance on Safety Pharmacology Studies for Human Pharmaceuticals, (iv) EU Applicable Laws related to research and related uses of animals within any EU member state, including Directive 2010/63, and (v) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.1.100"Good Manufacturing Practices" or "GMP" means all applicable requirements, standards, practices, and procedures for the manufacture and testing of pharmaceutical materials including, (a) FDA's current good manufacturing practices requirements under the FFDCA and 21 CFR Parts 210 and 211; (b) all requirements referred to in EudraLex Volume 4 (Guidelines for Good Manufacturing Practice), as well as all corresponding Applicable Laws implemented by relevant EU member states; (c) ICH Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.1.101"Governmental Authority" means any supranational, federal, national, state or local court, agency, authority, department, regulatory body or other governmental instrumentality.

1.1.102"Guaranty" means the Amended and Restated Continuing Guaranty between the Investors, Collateral Agent and each of the Guarantors (as defined therein), dated as of the date hereof, in the form attached hereto as Exhibit N.

1.1.103"Health Laws" means any law of any Governmental Authority (including multi-country organizations) the purpose of which is to ensure the safety, efficacy and quality of medicines or pharmaceuticals by regulating the research, development, testing, manufacturing processing, storage, labeling, sale, marketing, advertising, and distribution and importation and exportation of these products, including laws relating to Good Laboratory Practices, Good Clinical Practices, investigational use, product marketing authorization, manufacturing facilities compliance and approval, Good Manufacturing Practices, labeling, advertising, promotional practices, safety surveillance, record keeping and filing of required reports such as the FFDCA, and the Public Health Service Act, as amended, in each case including the associated rules, regulations, requirements and guidance promulgated or issued thereunder (including all additions, supplements, extensions and modifications thereto) and all of their foreign equivalents.

1.1.104"ICDR" means the International Centre for Dispute Resolution.

1.1.105"ICH" means the International Council for Harmonization.

1.1.106"IDMC" means the independent data monitoring committee for a Product Clinical Trial.

1.1.107"IFRS" means International Financial Reporting Standards as issued by the International Accounting Standards Board.

1.1.108"In-License" means any license, settlement agreement or other agreement between Opthea or any of its Affiliates and any Third Party pursuant to which Opthea or any of its Affiliates obtains a license or a covenant not to sue to any Patents or other intellectual property rights of such Third Party that is or was necessary for or material to the research, Development, manufacture, use or Commercialization of the Product.

1.1.109"IND" means an investigational new drug application, Clinical Trial application, Clinical Trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to initiate human clinical testing of a pharmaceutical product in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312, as well as all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.1.110"Indebtedness" means (a) indebtedness for borrowed money or the deferred price of property or services (excluding any trade accounts incurred in the ordinary course of business), such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations (as such term is understood under GAAP as in effect on the date of this Agreement, but it being agreed that all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP prior to adoption of changes described by ASC Topic 842 shall continue to be accounted for as operating leases (and not be treated as or to be recharacterized as capital lease obligations)), and (d) Contingent Obligations.

1.1.111"Indemnified Party" has the meaning ascribed to such term in Section 11.2.1.

1.1.112"Indemnifying Party" has the meaning ascribed to such term in Section 11.2.1.

1.1.113"Indication" means the treatment of wet (neovascular) age-related macular degeneration, or, in the case of a change to the Indication approved by the JSC in accordance with the terms of this Agreement, such other indication.

1.1.114"Information" means technical or scientific know-how, trade secrets, methods, processes, formulae, designs, specifications and data, including biological, chemical, pharmacological, toxicological, pre-clinical, clinical, safety, manufacturing and quality control data and assays; in each case, whether or not confidential, proprietary, patented or patentable.

1.1.115"Intellectual Property" means all intellectual property and intellectual property rights of any kind or nature throughout the world, including all U.S. and foreign, (a) Patents; (b) Trademarks; (c) Copyrights; (d) rights in computer programs (whether in source code, object code, or other form), algorithms, databases, compilations and data, technology supporting the foregoing, and all documentation, including user manuals and training materials, related to any of the foregoing; (e) trade secrets and all other confidential information, know-how, inventions, proprietary processes, formulae, models, and methodologies; (f) rights of publicity, privacy, and rights to personal information; (g) all rights in the foregoing and in other similar intangible assets; and (h) all applications and registrations for the foregoing.

1.1.116"Intellectual Property Security Agreement" means the Intellectual Property Security Agreement between Opthea and Collateral Agent dated as of the Original Effective Date, in the form attached hereto as Exhibit D.

1.1.117"Investment" means any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

1.1.118"Investors" has the meaning ascribed to such term in the Preamble.

1.1.119"Investors Board Observers" has the meaning ascribed to such term in Section 5.6.

1.1.120"Investor Indemnified Parties" has the meaning ascribed to such term in Section 11.1.2.

1.1.121"Investor LPs" means any direct or indirect beneficial owners of an Investor.

1.1.122"Investor Payment" means a Success Payment, Approval Buy-out Payment, General Buy-out Payment, Change of Control Payment, Variable Success Payment, or any other payment made by Opthea to the Investors pursuant to the terms of this Agreement.

1.1.123"Investor Remedy Expenses" means, with respect to each Investor and the Collateral Agent, all of such Party's reasonable and documented out-of-pocket costs and expenses (including reasonable and documented out-of-pocket attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) in connection with exercising the rights and remedies under Section 7.2 of this Agreement.

1.1.124"Investor Security Interests" has the meaning ascribed to such term in Section 7.1.2.

1.1.125"IRB" means institutional review board, or its equivalent.

1.1.126"IRC" means the U.S. Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder.

1.1.127"JSC" has the meaning ascribed to such term in Section 5.1.1.

1.1.128"JSC Chairperson" has the meaning ascribed to such term in Section 5.1.2.

1.1.129"JSC Representative(s)" has the meaning ascribed to such term in Section 5.1.1.

1.1.130"Knowledge of Opthea" means the actual knowledge, after due inquiry, of the Company's Chief Executive Officer, Chief Innovation Officer, Chief Financial Officer, Chief Commercial Officer and Vice President Finance (and, if one is then appointed, Chief Medical Officer).

1.1.131"Launch" means Launch Therapeutics, Inc.

1.1.132[***]

1.1.133"Lien" means a mortgage, deed of trust, levy, charge, pledge, hypothecation, collateral, assignment, deposit arrangement, lien (statutory or otherwise), or preference, priority or other security interest (including any security interest arising under Section 12(1) or 12(2) of the Australian PPSA), preferential arrangement in the nature of a security interest or other encumbrance of any kind or nature whatsoever (including any restriction on use, transfer or exercise of any other attribute of ownership of any kind) in the nature of a security interest, whether voluntarily incurred or arising by operation of law or otherwise against any property (including any conditional sale and any financing lease having substantially the same economic effect as any of the foregoing); provided that, for the avoidance of doubt, neither non-exclusive licenses nor customary anti-assignment provisions shall be deemed to be a "Lien".

1.1.134"Losses" means reasonable liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees).

1.1.135"Major Market Countries" means, collectively, [***] (each, a "Major Market Country").

1.1.136 "Material Adverse Event" means (a) a material adverse effect on the business, operations, prospects or financial condition of Opthea, (b) a material adverse effect on the timing or prospect of payment of the Fixed Success Payments by Opthea, (c) a material adverse effect on the Development of the Product or prospects for Regulatory Approval of the Product for the Indication, (d) a material adverse effect, when considered, individually or in the aggregate, on (i) the legality, validity or enforceability of any of the Transaction Agreements or (ii) the rights of Investors under, or the right or ability of Opthea to perform its obligations under, any of the Transaction Agreements or (e) an adverse effect in any material respect on the timing, value, amount or duration of the Variable Success Payments; *provided however*, that none of the following will constitute, or will be considered in determining whether there has occurred, a Material Adverse Event, except to the extent such changes have had a disproportionate effect on Opthea relative to other participants of Opthea's size in the industries in which Opthea operates: (x) changes in laws or regulations or in the interpretations or methods of enforcement thereof; (y) economic changes in the pharmaceutical or biotechnology industries in general; or (z) any Force Majeure Event; [***].

1.1.137"Material Anti-Corruption Law Violation" means a violation by a Party or its Affiliate of an Anti-Corruption Law relating to the subject matter of this Agreement that would, if it were publicly known, have a material adverse effect on any of the other Parties or its Affiliate because of its relationship with such Party.

1.1.138"Maximum Development Costs" has the meaning ascribed to such term in Section 4.1.

1.1.139"MHRA" means the Medicines and Healthcare products Regulatory Agency.

1.1.140"Minimum Cash Make-Whole" has the meaning ascribed to such term in Section 4.5.3.

1.1.141"Minimum Cash Make-Whole Funding" has the meaning ascribed to such term in Section 4.5.3.

1.1.142"Minimum Cash Threshold" has the meaning ascribed to such term in Section 4.5.3.

1.1.143"Multiplier on Invested Capital" or "MoIC" means 4x.

1.1.144"Net Sales" means [***].

1.1.145"Non-Defaulting Investor" is any Investor that is not a Defaulting Investor.

1.1.146"Opthea" has the meaning ascribed to such term in the Preamble.

1.1.147"Opthea Indemnified Parties" has the meaning ascribed to such term in Section 11.1.1.

1.1.148"Opthea Obligations" means all indebtedness, liabilities and other obligations of Opthea, or any Subsidiary of Opthea party to a Transaction Agreement, to Investors under or in connection with this Agreement or a Transaction Agreement and other documents executed in connection herewith, including all amounts payable to Investors pursuant to Article 6 hereof, any amounts payable to Investors pursuant to the Guaranty, and any and all damages resulting from breach of this Agreement or a Transaction Agreement by Opthea or any Subsidiary of Opthea, all interest accrued thereon, all fees and all other amounts payable by Opthea to Investors thereunder or in connection therewith, whether now existing or hereafter arising, and whether due or to become due, absolute or contingent, liquidated or unliquidated, determined or undetermined, and including interest that accrues after the commencement by or against Opthea of any bankruptcy or insolvency proceeding.

1.1.149"Original Effective Date" means August 12, 2022.

1.1.150"Out-License" means any license, sublicense or other agreement between Opthea or any of its Affiliates and any Third Party pursuant to which Opthea or any of its

Affiliates grants to such Third Party a license or sublicense of, covenant not to sue under, or other similar rights under any Intellectual Property.

1.1.151"Party" or "Parties" has the meaning ascribed to such term in the Preamble.

1.1.152"Patent" will mean patents, patent applications, patent disclosures, and all related continuations, continuations-in-part, divisionals, reissues, re-examinations, substitutions, and extensions thereof.

1.1.153 "Permitted Disposition" means (a) any Permitted Lien, (b) any Excluded Licensing Transaction, (c) a Disposition of inventory or goods held for sale in the ordinary course of business; (d) a Disposition of surplus, obsolete, damaged or worn-out assets, property or equipment in the ordinary course of business (including the abandonment of Intellectual Property consistent with past practice and to the extent not otherwise prohibited hereunder), whether in whole and on a country-by-country basis, that is, in the reasonable judgment of Opthea, no longer economically practicable or commercially reasonable to maintain or useful in any material respect in the conduct of the business of Opthea; (e) Dispositions of receivables in connection with the compromise, settlement or collection thereof in the ordinary course of business or in bankruptcy or similar proceedings and exclusive of factoring or similar arrangements; (f) Disposition of Regulatory Approvals to any wholly-owned Subsidiary or, with respect to any jurisdiction outside the United States, licensees for the purposes of Commercialization of the Product in such jurisdiction, and (g) Dispositions among Opthea and its Subsidiaries to the extent constituting an Investment permitted under Section 7.3.4.

1.1.154"Permitted Equity Derivative" means any forward purchase, accelerated share purchase, call option, warrant transaction or other equity derivative transactions relating to the equity interests of Opthea (or any direct or indirect public parent thereof) provided that the entry into such Permitted Equity Derivative is permitted pursuant to Section 7.3.3 and such Permitted Equity Derivative qualifies for equity accounting treatment under GAAP as if GAAP were applicable.

1.1.155"Permitted Indebtedness" means (a) Opthea Obligations, (b) unsecured Indebtedness, (c) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business, (d) letters of credit issued for the payment of purchase obligations for equipment, materials and inventory, the payment of equipment and/or the payment of real estate lease and other commercial obligations (other than Indebtedness for borrowed money) (including cash collateral and deposits in connection therewith); (e) Indebtedness existing on the Original Effective Date and set forth on Schedule 1.1.150; (f) (i) Indebtedness consisting of capital leases and purchase money financing obligations, in each case incurred by Opthea or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such Person within 180 days of such acquisition, repair, improvement or construction, (ii) obligations in respect of swaps, forwards, futures or derivatives transactions, options or similar agreements in the ordinary course to hedge or mitigate risk and not for speculative purposes; and (iii) [***]; (g) Indebtedness relating to insurance premium financing arrangements in the ordinary course; and (h) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness, provided that the principal amount thereof does not exceed the principal

amount (or accreted value, if applicable) of the Indebtedness so extended, refinanced, modified, amended or restated (plus unpaid accrued interest and premium (including tender premium) thereon, any original issue discount on, and underwriting discounts, fees, commissions and expenses incurred in connection with, such extension, refinancing, modification, amendment or restatement.

1.1.156"Permitted Liens" means (a) any Excluded Licensing Transactions and any Out-License entered into by Opthea or any of its Affiliates after the Original Effective Date that is approved by the Required Investors pursuant to Section 7.3.4; (b) Liens existing on the Original Effective Date and set forth on Schedule 1.1.151; (c) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and, in each case, for which Opthea or the applicable Subsidiary maintains adequate reserves on its books and records; (d) Liens securing capital leases and purchase money financings constituting Permitted Indebtedness, provided that such Liens do not extend to any property of Opthea other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness; (e) leases and subleases granted in the ordinary course of business that do not materially interfere with the business of Opthea and its Subsidiaries; (f) interests of lessors and licensors under leases and licenses to Opthea or any Subsidiary of real property and personal property; (g) Liens of carriers, warehousemen, suppliers, or other persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to inventory, securing liabilities, and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto; (h) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like statutory obligations incurred in the ordinary course of business (other than Liens imposed by ERISA); (i) Liens in favor of custom and revenue authorities arising in the ordinary course of business as a matter of law to secure the payment of custom duties in connection with the importation of goods provided such Liens are restricted to the goods being imported and documents relating thereto; (j) Liens arising from attachments or judgments, orders, or decrees occurring after the Original Effective Date under circumstances not constituting a termination event under Article 13; (k) Liens on, and deposits of cash and cash equivalents securing bids, contracts, letters of credit constituting Permitted Indebtedness, banker's acceptances and other similar obligations; (l) licenses and sublicenses granted in favor of Opthea or any Subsidiary; (m) Liens on property or equity interests of another Person existing at the time such other Person becomes a Subsidiary or is merged with or into or consolidated with Opthea or any Subsidiary, provided that such Liens (i) were in existence prior to such merger or consolidation and are not incurred in contemplation thereof and (ii) do not extend to any other property owned by Opthea (other than proceeds thereof and accessions thereto); (n) Liens on property (including equity interests) existing at the time of acquisition of such property by Opthea or any Subsidiary, provided that such Liens (i) were in existence prior to such acquisition and not incurred in contemplation of such acquisition and (ii) do not extend to any other property owned by Opthea (o) Liens granted in replacement of or substitute for, or to secure any refinancing (or successive refinancings), as a whole or in part, of any Indebtedness or other obligation secured by, a Lien referred to in the foregoing clauses (m) or (n), provided that the new Lien is limited to all or part of the same property and assets that secured or, under the written agreements pursuant to which the original Lien arose, could secure the original Lien (plus improvements and accessions to, such

property or proceeds or distributions thereof); (p) Liens on insurance policies, premiums and proceeds thereof, or other deposits, to secure insurance premium financings and other liabilities to insurance carriers; (q) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into in the ordinary course of business; (r) Liens in the nature of the right of setoff in favor of counterparties to contractual agreements with Opthea or its Subsidiaries in the ordinary course of business; (s) (i) customary Liens incurred to secure Cash Management Obligations, and (ii) Liens in favor of financial institutions arising as a matter of law or under customary contractual provisions encumbering deposits or other funds held at such institutions solely as a result of Opthea's or its Subsidiaries' maintaining deposit accounts and/or securities accounts at such institutions; (t) any encumbrance or restriction (including put and call arrangements) with respect to equity interests of any joint venture, minority investment or similar arrangement pursuant to any joint venture, shareholders, investor rights or similar agreement; (u) Liens to secure contractual payments (contingent or otherwise) payable by Opthea or its Subsidiaries to a seller after the consummation of an acquisition of a product, business, license or other assets, in an amount not to exceed, individually or in the aggregate, Five Hundred Thousand Dollars ($500,000); (v) escrows and deposits (and Liens thereon) in connection with an acquisition, Disposition or Investment, (w) Liens constituting an option or agreement to Dispose any property; provided that such Disposition is not prohibited hereby; (x) Liens in favor of wholesalers, distributors and distribution logistics providers granted in the ordinary course of business, (y) any Liens in the nature of a "back-up security interest" on accounts receivables, payment intangibles, royalties and related assets sold in connection with any royalty or revenue interest sale, financing transaction or other Permitted Disposition, and (z) other Liens securing liabilities in an aggregate amount not to exceed One Million Five Hundred Thousand Dollars ($1,500,000).

1.1.157"Permitted Third Party" means any CRO, Site, Clinical Investigator or Vendor (including Approved CROs and Approved Vendors) to whom Opthea has delegated responsibility or whom Opthea has engaged in connection with the Clinical Trial Activities or any CMO whom Opthea has engaged to perform CMC related activities (including supply of Product for use in the Product Clinical Trials). For clarity, Third Parties that have been delegated responsibility by or engaged by a Permitted Third Party will be considered Permitted Third Parties.

1.1.158"Person" means any individual, corporation, general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity or Governmental Authority.

1.1.159"Personally Identifiable Information" means any information relating to an identified or, in combination with other information, identifiable person or persons captured in an electronic or hardcopy format, including such information as it relates to Clinical Trial subjects (including key-coded patient data), physicians, clinicians, healthcare professionals, consultants, or other persons participating in a Clinical Trial, and any equivalent definition in the Applicable Laws to the extent that such definition is broader than that provided here.

1.1.160"Phase 1 Clinical Trial" means any clinical trial as described in 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the U.S., a similar clinical trial.

1.1.161"Phase 2 Clinical Trial" means any clinical trial as described in 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the U.S., a similar clinical trial.

1.1.162"Phase 3 Clinical Trial" means any clinical trial as described in 21 C.F.R. §312.21(c) (as amended from time to time), or, with respect to a jurisdiction other than the U.S., a similar clinical trial, which clinical trial is intended to generate sufficient data and results (together with data from any prior clinical trials conducted for the applicable product) to support the filing of a BLA for such product.

1.1.163"Phase 3 Success Criteria" means following topline data read out from the ShORe Trial or the COAST Trial, that the results of the ShORe Trial and the COAST Trial meet the primary endpoints set forth in the ShORe Protocol and the COAST Protocol and constitute clinically meaningful results sufficient to support the decision to submit an application for Regulatory Approval for the Product for the Indication.

1.1.164"Pro Rata Share" is, as of any date of determination, with respect to each Investor, a percentage (expressed as a decimal, rounded to the fourth decimal place) determined by *dividing* the sum of (a) such Investor's Commitment, (b) any Going Concern Funding paid by such Investor pursuant to Section 3.8.3 of this Agreement at such time (if applicable), and (c) any Minimum Cash Make-Whole Funding paid by such Investor pursuant to Section 4.5.3 of this Agreement at such time (if applicable) *by* the sum of (i) the aggregate amount of all Commitments of all Investors, (ii) the Going Concern Funding paid by all Investors pursuant to Section 3.8.3 of this Agreement at such time (if applicable), and (iii) the Minimum Cash Make-Whole Funding paid by all Investors pursuant to Section 4.5.3 of this Agreement at such time (if applicable).

1.1.165"Product" means OPT-302, a VEGF-C/D inhibitor, which, as of the Original Effective Date, is being Developed by Opthea for the Indication, as further described on Exhibit E hereto, in any form, formulation, dose or dosage form, including any salt thereof, under any brand name or as a generic product.

1.1.166"Product Clinical Trial" means a Clinical Trial for the Product that is included in the Development Program. For clarity, "Product Clinical Trial" includes the ShORe Trial and the COAST Trial.

1.1.167"Product IP" means all Intellectual Property owned or Controlled by Opthea or its Affiliates that is necessary or useful for the Development, manufacture, use, Commercialization, import, or export of the Product, including Trial Inventions.

1.1.168"Product Patents" has the meaning ascribed to such term in Section 12.2.11.4.

1.1.169"Prohibited Investments" means (a) Investments in securities of privately held companies or capital contributions to any other Person; (b) Investments in or purchases of any real property (excluding real property to be occupied or used by Opthea or its Subsidiaries), commercial or residential mortgages, or mortgage-backed securities; (c) Investments in auction rate securities, corporate high yield bonds (i.e. less than BBB quality),

precious metals, derivatives including margin trades, options, futures, options on futures, short sales, forward contracts, swaps, repurchase agreements and reverse repurchase agreements (other than swaps, forwards, futures or derivatives transactions, options or similar agreements entered into to hedge or mitigate commercial risk and other than Permitted Equity Derivatives); and (d) Investments that are inappropriate or unusual for a biopharmaceutical company that is similarly situated to Opthea; provided that the following shall not be a Prohibited Investment: (i) Investments existing on the Original Effective Date and set forth on Schedule 1.1.163; (ii) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Opthea's business; (iii) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; (iv) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers, or directors relating to the purchase of capital stock of Opthea's pursuant to employee stock purchase plans or other similar agreements approved by the Board of Directors; (v) Investments consisting of travel advances, employee relocation loans, and other employee loans and advances in the ordinary course of business in an aggregate amount not to exceed $250,000 in any fiscal year or $500,000 outstanding at any point in time during the term hereof; (vi) [reserved]; (vii) [***]; and (viii) Investments by Opthea in any Subsidiary of Opthea so long as such Subsidiary of Opthea has executed and delivered, in each case, in form and substance satisfactory to Investors, a joinder agreement pursuant to which such Subsidiary will become a party to this Agreement and grant Investors a security interest in the cash, cash equivalents and other assets of such formed Subsidiary that would constitute Collateral) and (y) such other documentation, certificates, [***] and instruments requested by Investors that are necessary or desirable to perfect the security interest granted by such Subsidiary in its assets or otherwise effect the purposes or intent of this Agreement in each case of (x) and (y), subject to Section 7.4.1(b).

1.1.170"Proposed Discount Rate" has the meaning ascribed to such term in Section 6.7.2.

1.1.171"Protocol" means, with respect to a Product Clinical Trial, the documentation describing the objective, design, methodology, statistical considerations and organization of such Product Clinical Trial. For clarity, "Protocol" includes the ShORe Protocol, including any amendments thereto that are made in accordance with this Agreement, and the COAST Protocol, including any amendments thereto that are made in accordance with this Agreement.

1.1.172"[***] Business Day" means any day other than a Friday, Saturday or one on which banks are authorized or required by law to be closed in [***].

1.1.173"Quarterly Report" has the meaning ascribed to such term in Section 6.2.2.

1.1.174"Receiving Party" has the meaning ascribed to such term in Section 9.1.

1.1.175"Regulatory Approval" means the receipt by Opthea of the conditional, full, or accelerated approval of a BLA for the Product in the Indication: (a) by the FDA in the U.S.; (b) by the EMA in the EU; or (c) by the MHRA in the United Kingdom. For clarity, "Regulatory Approval" excludes any pricing or reimbursement approval that may be necessary or useful for marketing or sale of the Product in any country or regulatory jurisdiction.

1.1.176"Regulatory Authority" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in authorizing an IND to initiate or conduct clinical testing in humans or involved in granting Regulatory Approval, including FDA, EMA, and MHRA.

1.1.177"Related Party" has the meaning ascribed to such term in the definition of "Net Sales".

1.1.178"Release Date" has the meaning ascribed to such term in Section 13.6.

1.1.179"Repayment Amount" means the aggregate amount of Development Costs paid by the Investor to Opthea in accordance with Article 4.

1.1.180"Representatives" means, with respect to a Party, such Party's Affiliates, and its and their respective officers, directors, employees, agents, representatives, consultants, and, as applicable, its Permitted Third Parties engaged in connection with the subject matter of this Agreement.

1.1.181"Required Investors" [***].

1.1.182"Research Results" means all Information arising out of or resulting from the Product Clinical Trials and the CMC activities contemplated by the Development Program, including the Clinical Trials Database.

1.1.183"Restatement Effective Date" has the meaning ascribed to such term in the Preamble.

1.1.184"ROFO Notice" has the meaning ascribed to such term in Section 6.8.2.

1.1.185"ROFO Offer" has the meaning ascribed to such term in Section 6.8.2.

1.1.186"ShORe Protocol" has the meaning ascribed to such term in Section 2.2.1.

1.1.187"ShORe Trial" means the Phase 3 Clinical Trial entitled "OPT-302 With Ranibizumab in Neovascular Age-related Macular Degeneration (nAMD) (ShORe)" with identifier NCT04757610.

1.1.188"Serious Safety Issue" means any SUSAR, or any dose-limiting toxicity, or series of SUSARs directly related to or caused by the administration of the Product in the conduct of a Product Clinical Trial where such SUSAR, series of SUSARs, or toxicity substantially diminishes the probability of receiving Regulatory Approval for the Product, or results in a Regulatory Authority imposing a Clinical Hold on further development of the Product which Clinical Hold is not lifted or removed within [***] days.

1.1.189"Site" has the meaning ascribed to such term in Section 3.1.2.

1.1.190"Subjects" means subjects in Product Clinical Trials.

1.1.191"Subsidiary" means an entity, whether corporate, partnership, limited liability company, joint venture or otherwise, in which Opthea owns or controls 50% or more of the outstanding voting securities and any 'subsidiary' of Opthea within the meaning of Part 1.2 Division 6 of the Australian Corporations Act.

1.1.192"Success Payment Trigger" has the meaning ascribed to such term in Section 6.1.1.

1.1.193"Success Payments" has the meaning ascribed to such term in Section 6.1.1.

1.1.194"SUSAR" means a suspected unexpected serious adverse reaction, without regard to causality, that is life-threatening (i.e., causes an immediate risk of death) or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity (i.e., substantial disruption of the ability to conduct normal life functions); or a congenital anomaly or birth defect. For clarity, a planned medical or surgical procedure is not, in itself, a SUSAR.

1.1.195"Tax" means any tax, levy, impost, duty or other charge or withholding in the nature of a tax (including any penalty, interest or other additional amounts payable in connection with any failure to pay or any delay in paying any of the same).

1.1.196"Tax Deduction" means a deduction or withholding for or on account of Tax from a payment made pursuant to this Agreement.

1.1.197"Term" has the meaning ascribed to such term in Section 13.1.

1.1.198"Third Party" means any Person other than Opthea, Investors, Collateral Agent and their respective Affiliates.

1.1.199"Third Party Claim" has the meaning ascribed to such term in Section 11.1.1.

1.1.200"Third Party Infringement" means any actual or threatened infringement, misappropriation, or other violation by a Third Party of any Intellectual Property Controlled by Opthea that relates to this Agreement or the Product, including the Trial Inventions.

1.1.201"Timeline" has the meaning ascribed to such term in Section 2.4.1.

1.1.202"Timeline Remediation Plan" has the meaning ascribed to such term in Section 2.4.2.

1.1.203"Trademarks" means, collectively, all registered and unregistered marks, trade dress rights, logos, taglines, slogans, Internet domain names, web addresses, and other indicia of origin, together with the goodwill associated with any of the foregoing, and all applications, registrations, extensions and renewals thereof, selected for use on the Product.

1.1.204"Transaction Agreements" means, collectively, this Agreement, the Deposit Account Control Agreement, the Intellectual Property Security Agreement, the Australian General Security Deed, the Notes and the Guaranty.

1.1.205"Trial Invention" has the meaning set forth in Section 10.1.1.3.

1.1.206"Trial Protocols" means the ShORe Protocol and the COAST Protocol (each, a "Trial Protocol").

1.1.207"U.S.", "United States" or "USA" means the United States of America, its territories and possessions, including Puerto Rico.

1.1.208"UCC" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the UCC is used to define any term herein and such term is defined differently in different Articles or Divisions of the UCC, the definition of such term contained in Article or Division 9 will govern; and provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, the Investor Security Interest on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "UCC" will mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions relating to such provisions.

1.1.209"UK" or "United Kingdom" means Great Britain and Northern Ireland.

1.1.210"Variable Success Payment" means, for each Calendar Quarter, an amount equal to 7.0% of Net Sales during such Calendar Quarter.

1.1.211"Withholding Tax" means Tax imposed under Division 11A of the *Income Tax Assessment Act 1936* (Cth) (including any penalty, interest or other additional amounts payable in connection with any failure to pay or any delay in paying any of the same).

1.2Construction. For purposes of this Agreement: (1) words in the singular will be held to include the plural and vice versa as the context requires; (2) the words "including" and "include" will mean "including, without limitation," unless otherwise specified; (3) the terms "hereof," "herein," "herewith," and "hereunder," and words of similar import will, unless

otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; (4) all references to "Section" and "Exhibit," unless otherwise specified, are intended to refer to a Section or Exhibit of or to this Agreement; (5) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or", (6) words of the masculine, feminine or neuter gender will mean and include the correlative words of other genders; (7) unless otherwise specified, references to an agreement or other document include references to such agreement or document as from time to time amended, restated, reformed, supplemented or otherwise modified in accordance with the terms hereof, and include any annexes, exhibits and schedules attached thereto; (8) reference to any Applicable Law will include such Applicable Law as from time to time in effect, including any amendment, modification, codification, replacement or reenactment thereof or any substitution therefor; (9) references to any Person will be construed to include such Person's successors and permitted assigns (subject to any restrictions on assignment, transfer or delegation set forth herein), and any references to a Person in a particular capacity excludes such Person in other capacities; (10) in the computation of a period of time from a specified date to a later specified date, the word "from" means "from and including" and each of the words "to" and "until" means "to but excluding"; (11) where any payment is to be made, any funds are to be applied or any calculation is to be made under this Agreement on a day that is not a Business Day or [***] Business Day (as applicable), unless this Agreement otherwise provides, such payment will be made, such funds will be applied and such calculation will be made on the succeeding Business Day or [***] Business Day (as applicable), and payments will be adjusted accordingly; and (12) the following capitalized terms shall have the meaning given to them in the UCC: Account, Chattel Paper, Commercial Tort Claims, Commodity Account, Deposit Account, Documents, Equipment, Goods, Instrument, Inventory, Letter-of-Credit Right, Money, Proceeds, Record, Securities Account, Securities Intermediary, Security Certificate, Security Entitlement and Supporting Obligations.

1.3Conflicts. In the event of any conflict between the terms of this Agreement, the Protocol or any other Exhibit, the Protocol will control (as applicable), followed by the terms of this Agreement, and followed by any applicable other Exhibit.

ARTICLE 2

THE DEVELOPMENT PROGRAM

2.1The Development Program.

2.1.1 Efforts. Opthea will use Commercially Reasonable Efforts to conduct and complete the Development Program in accordance with this Agreement and the Timelines.

2.1.2 Compliance. Opthea will conduct the Development Program and perform all of its duties and responsibilities hereunder in accordance with the Development Plan (as amended, supplemented or otherwise modified from time to time, in accordance with the terms of this Agreement) and in compliance in all material respects with all Applicable Laws. Opthea will conduct all Product Clinical Trials and perform all other responsibilities assigned to it hereunder in connection with any such Product Clinical Trial in compliance in all material respects with the applicable Protocol. Opthea will oversee the manufacture of the Product for each Major Market Country, and will comply (and require that all Permitted Third Parties of Opthea comply) in all material respects with all Applicable Laws with respect to the research, development, manufacture, testing, analysis, labeling, storage, handling, disposal, transfer and use of the Product in each Major Market Country.

2.2The Protocol.

2.2.1 The Protocol. The Protocol for the ShORe Trial (the "ShORe Protocol") existing on the Original Effective Date is set forth on Schedule 2.2.1(a) hereto. The Protocol for the COAST Trial (the "COAST Protocol") existing on the Original Effective Date is set forth on Schedule 2.2.1(b) hereto.

2.2.2 Changes to the Protocol.

2.2.2.1 Any material change to a Trial Protocol, including any country-specific appendices required by Applicable Law, and material changes made in response to any communications with any Regulatory Authorities that require a submission to a Regulatory Authority, an IRB or other ethics committee, will be diligently prepared by Opthea in the form of draft amendments, [***], which will not be unreasonably withheld or delayed. Such decision will be communicated to Opthea as soon as reasonably practicable following the JSC's receipt of the draft amendment from Opthea.

2.2.3 Protocol Approval. Opthea will be responsible for obtaining any necessary approvals for the ShORe Protocol or the COAST Protocol, including any INDs, prior to commencing the ShORe Trial or the COAST Trial, respectively.

2.3Sponsor. Opthea will be the sponsor of the Product Clinical Trials.

2.4Compliance with the Timeline.

2.4.1 The Timelines. The currently anticipated timelines for conducting the ShORe Trial and the COAST Trial are attached as Exhibit F-1 and F-2 hereto, respectively (the "Timelines" and each, a "Timeline"). In conducting such Product Clinical Trials, Opthea will use Commercially Reasonable Efforts to complete each activity specified on the applicable Timeline (each, a "Clinical Trial Activity") by the date specified for completion of such Clinical Trial Activity on the applicable Timeline. Opthea will promptly notify the JSC and Advisory Committee in writing upon completion or achievement of each Clinical Trial Activity.

2.4.2 Failure to Complete a Clinical Trial Activity. If Opthea fails to, or reasonably believes that it will not, complete a Clinical Trial Activity in accordance with the timeline specified for such Clinical Trial Activity on the applicable Timeline, Opthea will promptly notify the JSC. Within thirty (30) days of such written notice, if Opthea has failed to, or reasonably believes that it will not, complete (a) any Clinical Trial Activity set forth in a Timeline within [***] days of the date for completion of the Clinical Trial Activity set forth in such Timeline or (b) the final Clinical Trial Activity set forth in a Timeline within [***] days of the date for the final Clinical Trial Activity set forth in such Timeline, Opthea will provide the JSC with a written remediation plan summarizing in reasonable detail the means by which, and the date on which, Opthea expects to be able to complete the relevant Clinical Trial Activity (each, a "Timeline Remediation Plan", as the same may be modified from time to time in accordance with this Section 2.4.2). [***].

2.4.3 Failure to Complete a Timeline Remediation Plan. [***].

2.5Approved CROs and Approved Vendors.

2.5.1 Approved CROs. Except as otherwise provided herein, Opthea may delegate any of its responsibilities described in Section 2.3 to its Affiliates (subject to Section 14.1) or any CRO that is listed on Exhibit G, as such exhibit may be updated from time-to-time during the Development Term [***] (any such CRO, an "Approved CRO"), provided that Opthea notifies the JSC of any such delegation. Opthea will be required to enter into a written agreement with each Approved CRO utilized by Opthea on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable Opthea to comply with its obligations hereunder with respect to the delegated responsibilities, including, but not limited to, Section 2.1.2, and the terms pertaining to ownership of Intellectual Property and publications, and treatment of Confidential Information.

2.5.2 Approved Vendors. Opthea will be permitted to contract for services, equipment, tools, materials or supplies required for the Product Clinical Trials or Regulatory Approval with any Person that is either listed on Exhibit H, as such exhibit may be updated from time-to-time during the Development Term [***] (each, an "Approved Vendor"); provided that there shall be no requirement to discuss new vendors with the JSC so long as the payments required to be made to such vendor are under $1,000,000 in the aggregate and such Vendor shall automatically be added to Exhibit H. Opthea will be required to enter into a written agreement with each such Person on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable Opthea to comply with its obligations hereunder with respect to the contracted activities, including, but not limited to, the terms pertaining to publications and ownership of Intellectual Property, and treatment of Confidential Information.

2.5.3 Responsibility. For clarity, Opthea will remain responsible for all of its obligations under this Agreement, notwithstanding any delegation to an Affiliate of Opthea or an Approved CRO or any contracting to an Approved Vendor [***]. Opthea will oversee the services of its Affiliates and any Approved CRO or Approved Vendor utilized by such Party to provide services hereunder.

2.6Reasonable Assistance.

2.6.1 Background Materials. During the Term, Opthea will provide Investors with [***]. For clarity, Opthea will remain the sole owner of, and will retain all right, title and interest in, to and under all Background Materials, including all Intellectual Property related thereto, and the Background Materials will be Confidential Information of Opthea.

2.6.2 Questions Pertaining to the Protocols. Promptly following the Original Effective Date during the Development Term, Opthea will identify one (1) individual with sufficient knowledge of the ShORe Protocol, the COAST Protocol, and the Product, who will be made available at reasonable times and reasonable frequency during normal business hours in such employee's country of residence upon reasonable written advance notice, which shall be submitted at least three (3) Business Days, in advance to answer Investors' questions directly pertaining to such Protocols and the Product.

ARTICLE 3

DEVELOPMENT PROGRAM AND COMMERCIALIZATION RESPONSIBILITIES

3.1Conduct of Clinical Trials.

3.1.1 Responsibility. Opthea will have sole responsibility for the conduct of the Product Clinical Trials, in consultation with the JSC in accordance with this Agreement.

3.1.2 Sites and Clinical Investigators. Opthea will select the study sites to conduct the Product Clinical Trials and will inform the JSC of Opthea's choice of each study site. Opthea will enter, and, to the extent applicable, will ensure that its Affiliates and each Approved CRO likewise enter, into an agreement with each study site (the "Clinical Trial Agreement" and upon execution of such Clinical Trial Agreement, such study site will be deemed a "Site") on commercially reasonable and customary terms, consistent with industry standards for similar agreements.

3.1.3 Data Collection and Data Management.

3.1.3.1 CRF. Opthea will be solely responsible for preparing the form of Case Report Form for each of the Product Clinical Trials in accordance with the applicable Protocol.

3.1.3.2 Clinical Trials Database; Registries. Opthea will use Commercially Reasonable Efforts to establish and maintain a Clinical Trial database for the data collected from each Site for each Product Clinical Trial (the "Clinical Trials Database"). Opthea will be responsible for registering, maintaining and updating any registries pertaining to the Product Clinical Trials to the extent required by any Applicable Laws, including, as applicable, www.clinicaltrials.gov, www.clinicalstudyresults.org, and the PHRMA Website Synopsis.

3.1.4 IRBs and Other Ethics Committees. Opthea will use Commercially Reasonable Efforts to (a) obtain the approval of the IRBs and other ethics committees required prior to commencing, and during, the Product Clinical Trials at every Site, (b) ensure that IRBs and such other relevant ethics committees have current registrations and accreditations as required by Applicable Law, (c) provide all ethics committees, including all IRBs, and Regulatory Authorities, with all necessary documentation prior to, and during the course of, the Product Clinical Trials as required by Applicable Law, and (d) respond to all queries from the IRBs and other ethics committees, will prepare the applicable response and, if such query is material, will provide the JSC Representatives of Ocelot SPV LP with a copy thereof for review and comment reasonably prior to submission.

3.1.5 Completion of the Clinical Trials; Final CSR. Opthea will keep the Sites participating in the Product Clinical Trials operational, to the extent reasonably necessary or desirable to complete the Development Program(s) under which such Product Clinical Trials are being conducted. The CSR for any Product Clinical Trial will be prepared by Opthea in compliance with all Applicable Laws, including ICH E3 guidelines. The final, signed CSR for any Product Clinical Trial will be provided to Investors promptly following the Completion Date of each such Product Clinical Trial. In the event that there are any additional safety or efficacy data pertaining to such Product Clinical Trial that come into the possession of Opthea after it has provided Investors with the final Clinical Trial CSR, Opthea will prepare and promptly provide Investors with a supplement to such CSR.

3.2Audits. Until both of the Product Clinical Trials have been completed, Opthea will conduct quality oversight inspections and audits of the facilities and services of the Permitted Third Parties utilized by Opthea in accordance with its internal written policies and regulatory requirements and will, if available, provide Investors with copies of the resulting audit reports, certificates, or other reporting materials upon request. Further, during the Development Term, Opthea will conduct quality oversight inspections and audits of the manufacturing facilities for the Product in accordance with its internal written policies and regulatory requirements and, if available, Opthea will provide Investors with copies of the resulting audit reports, certificates, or other reporting materials upon request (to the extent the disclosure thereof is not prohibited by any applicable confidentiality obligations).

3.3Supply. Opthea will be responsible for the manufacture of the Product for the Product Clinical Trials and for Commercialization of the Product, either directly or through an Approved Vendor, and will use Commercially Reasonable Efforts to ensure (a) [***] and (b) [***]. Opthea will manufacture or have manufactured the Product for the Product Clinical Trials and for Commercialization in accordance with GMP.

3.4Product Complaints. Opthea will be solely responsible for, and will use Commercially Reasonable Efforts to investigate and resolve, complaints related to the Product, including complaints pertaining to the manufacturing, appearance or general physical characteristics of the Product or other processes at the manufacturing facility, in accordance with all Applicable Laws.

3.5Pharmacovigilance and Safety Information Exchange. Opthea will, within [***], report to the JSC any Serious Safety Issue with respect to (a) Product Clinical Trial subjects, or (b)

individuals otherwise exposed to the Product, whether alone or in combination with Aflibercept or Ranibizumab.

3.6Product Recalls. Opthea will be solely responsible for the operational execution of any recall of the Product; provided that, Opthea will consult with the JSC regarding the decision to initiate any such recall in the U.S. The costs for any such recall will be at Opthea's sole cost and expense.

3.7Commercially Reasonable Efforts.

3.7.1 Conduct of Clinical Trials. Timely performance of the Product Clinical Trials and receipt of Regulatory Approval in the U.S. and, until achievement of Regulatory Approval in the U.S., in the European Union (or, if EMA's centralized review procedure is not used, at least one (1) additional non-U.S. Major Market Country) are important to the success of this Agreement. Opthea will use Commercially Reasonable Efforts to complete each Product Clinical Trial according to the applicable Timeline. In the event that Opthea fails to complete a Product Clinical Trial in accordance with applicable Timeline, then Investors will have the remedies described in Section 2.4.

3.7.2 Regulatory Approval. Upon achievement of the Phase 3 Success Criteria, Opthea will (a) file a BLA for the Product in the Indication in the U.S. within [***] thereafter and (b) otherwise use Commercially Reasonable Efforts to obtain Regulatory Approval for the Product in the Indication in the U.S. and, until achievement of Regulatory Approval in the U.S., in the European Union (or, if EMA's centralized review procedure is not used, at least one (1) additional non-U.S. Major Market Country). In the event that Opthea fails to use Commercially Reasonable Efforts to so obtain Regulatory Approval for the Product or fails to file a BLA for the Product for the Indication in the U.S. within [***] following achievement of the Phase 3 Success Criteria for the Product, and this failure is not cured as set forth in Section 13.4.2, the Required Investors may terminate this Agreement pursuant to Section 13.4.2.

3.7.3 Commercialization. Following receipt of Regulatory Approval for the Product, Opthea will use (and will require its Commercialization Partners to use) Commercially Reasonable Efforts to Commercialize the Product and maximize Net Sales of the Product for the Indication in each jurisdiction in which Regulatory Approval is obtained and maintain such Regulatory Approval(s).

3.8Disclosures by Opthea.

3.8.1 During the Development Term, Opthea will provide to Investors, at least once during each Calendar Quarter, summaries of all data [***].

3.8.2 Opthea shall (a) promptly notify the JSC of achieving the Phase 3 Success Criteria, and (b) promptly notify Investors of achieving Regulatory Approval for the Product (whether in the Indication or in any other indication). At least once each Calendar Quarter during the Term, following request by any Investor, Opthea will provide Investors with [***].

3.8.3 Opthea shall provide Investors with company budgets and financial statements ("Financial Statements") contemporaneously with their provision to the board of directors (or any committee thereof) of Opthea [***].

ARTICLE 4

DEVELOPMENT COSTS; EQUITY INVESTMENT

4.1Development Costs. Investors will (severally and not jointly, as described in Section 4.2 below) pay no less than One Hundred and Twenty Million U.S. Dollars ($120,000,000) and up to One Hundred and Seventy Million U.S. Dollars ($170,000,000) (the applicable amount, the "Maximum Development Costs") of Development Costs, as set forth and in accordance with the funding schedule set forth in Section 4.2. As between Investors and Opthea, any Development Costs in excess of the Maximum Development Costs will be borne by Opthea, and any failure by Opthea to bear any such excess Development Costs shall be deemed to be a material breach of this Agreement by Opthea.

4.2Funding Schedule. Each Investor, severally and not jointly, will fund Development Costs by making a series of payments to Opthea in accordance with the payment schedule set forth in the table below, which payment obligation will cease upon the first to occur of (a) the termination or cessation of both the COAST Trial and the ShORe Trial; or (b) the date on which the aggregate payments under this Section 4.2 reach the Maximum Development Costs. For the avoidance of doubt, no Investor shall be required to make payments in excess of its Commitment. All payments will be made within [***] Business Days following Investors' receipt of an invoice from Opthea for such payment, which invoices will be provided on the timing set forth in the table below.

Invoice Date (or, for amounts funded prior to the Restatement Effective Date, date of funding of Development Costs)	Funding Investor	Amount of Payment
September 14, 2022	Ocelot SPV LP	$50,000,000
December 30, 2022	Ocelot SPV LP	$35,000,000
Promptly after (and in any event within [***] Business Days of) the Restatement Effective Date (or such other date as is requested by Opthea and consented to by all Investors in their sole discretion)	Ocelot SPV LP	$35,000,000
	[***]	$50,000,000
TOTAL		$170,000,000

4.3Use of Proceeds. Opthea will use the payments provided by Investors pursuant to Section 4.1 and Section 4.2 solely for the purposes of funding Development Costs.

4.4Development Costs Account. Payments provided by Investors pursuant to Section 4.1 and Section 4.2 will be funded into, and will be disbursed from, the Development Costs Account. Opthea hereby grants a continuing first-priority security interest in the Development Costs Account to Investors to secure payment of the Opthea Obligations.

4.5Equity Investments.

4.5.1 [Reserved].

4.5.2 [Reserved].

4.5.3 Prior to the earlier of (a) Data Read-Out for the COAST Trial and (b) Data Read-Out for the ShORe Trial, Opthea shall use Commercially Reasonable Efforts to ensure the aggregate cash and cash equivalents held in its deposit accounts (the "Minimum Cash Accounts") are at all times equal to at least Sixty Million U.S. Dollars ($60,000,000). If the cash and cash equivalents held in the Minimum Cash Accounts is at any time less than Fifty Million U.S. Dollars ($50,000,000) (the "Minimum Cash Threshold"), Opthea shall promptly (and in any event within [***] Business Days) notify Investors. Following such notification, and unless otherwise agreed with Required Investors, Opthea shall use reasonable best efforts to consummate a public offering or private placement of its equity securities resulting in aggregate gross proceeds equal to (at least) the difference between Sixty Million U.S. Dollars ($60,000,000) and the amount of cash and cash equivalents held in the Minimum Cash Accounts (such difference, the "Minimum Cash Make-Whole") within [***] thereafter. Opthea shall keep Investors reasonably informed of its progress in consummating such financing. If Opthea is unable to consummate such financing within such [***] period, each Investor shall have the right, but not the obligation, to remedy such condition by increasing the funding payable by such Investor to Opthea by an amount not to exceed such

Investor's Commitment Percentage of the Minimum Cash Make-Whole. If an Investor does not elect to provide its Commitment Percentage of the Minimum Cash Make-Whole, the other Investor may elect (at its sole discretion) to increase the funding payable by it to Opthea by such amount (the aggregate additional funding amount paid by any given Investor pursuant to this Section 4.5.3, the "Minimum Cash Make-Whole Funding"). Any Minimum Cash Make-Whole Funding paid by any Investor shall be deemed to be Development Costs, including for purposes of any adjustments to Fixed Success Payments and the Fixed Return Cap made under Section 6.3.

ARTICLE 5

GOVERNANCE

5.1Joint Steering Committee.

5.1.1 Representatives. Within thirty (30) days after the Original Effective Date, Ocelot SPV LP and Opthea established a joint steering committee (the "JSC"). Ocelot SPV LP, on the one hand, and Opthea, on the other hand, have the right to each appoint three (3) representatives to serve as representatives to the JSC (the "JSC Representatives"), with each JSC Representative having sufficient decision-making authority within the applicable Party to make decisions on behalf of such Party within the scope of the JSC's decision-making authority and, if any such representative is not an employee of the appointing Party, such representative will execute a confidentiality agreement in form and substance reasonably acceptable to the other Party (and, for the avoidance of doubt, the appointing Party will remain responsible to the other Party for any noncompliance by such representative with such confidentiality obligations). Ocelot SPV LP and Opthea may replace one or more of its JSC Representatives at any time upon written notice to the other Party.

5.1.2 Chairperson. The JSC chairperson ("JSC Chairperson") will be designated from the JSC Representatives and will serve for a term of one (1) year. Ocelot SPV LP will appoint the first JSC Chairperson and subsequent appointments will rotate on an annual basis between Opthea and Ocelot SPV LP. The JSC Chairperson will be responsible for drafting and circulating the draft agenda and ensuring minutes are prepared.

5.1.3 Meetings; Dissolution. From the Original Effective Date until the later of (a) the end of the Development Term and (b) the end of the first Calendar Quarter after the date on which the Product has obtained Regulatory Approval in the U.S., the JSC will meet at least once per Calendar Quarter (such meetings to be conducted via teleconference or videoconference unless the Parties' JSC Representatives mutually agree otherwise). Either Opthea or Ocelot SPV LP may call a special meeting of the JSC (by videoconference or teleconference) during the Development Term by providing at least five (5) Business Days prior written notice to the other Party, which notice will include a reasonably detailed description of the matter, in the event Opthea or Ocelot SPV reasonably believes that a significant matter must be addressed prior to the next scheduled meeting. Upon the conclusion of the last meeting of the JSC held in accordance with the first sentence of this Section 5.1.3, the JSC shall be dissolved.

5.1.4 Participants. Ocelot SPV LP and Opthea may invite individuals who are not JSC Representatives to participate in JSC meetings; provided that (a) all JSC Representatives consent to such non-member's participation; and (b) such non-member has executed a confidentiality agreement in form and substance acceptable to the non-inviting Party (and, for the avoidance of doubt, the inviting Party will remain responsible to the non-inviting Party for any noncompliance by such individual with such confidentiality obligations).

5.1.5 Alliance Managers. Ocelot SPV LP, on the one hand, and Opthea, on the other hand, will each appoint an individual to act as an alliance manager with respect to the relationship contemplated by this Agreement (each, an "Alliance Manager") by providing the name and contact information for the Alliance Manager to the JSC. Ocelot SPV LP, on the one hand, and Opthea, on the other hand, may each change its Alliance Manager from time to time in its sole discretion upon written notice to the JSC. The Alliance Managers will be the primary point of contact for the Parties regarding the activities contemplated by the Agreement, and the Parties will use reasonable efforts to ensure that any requests for information and data made outside of the JSC are made through the Alliance Managers. The Alliance Managers will attend all meetings of the JSC. For clarity, the Alliance Managers may also be members of the JSC, but will remain in place for the duration of the Term, regardless of whether the JSC is dissolved pursuant to Section 5.1.3.

5.1.6 Costs. Each Party will bear its own expenses relating to the meetings and activities of the JSC and the Advisory Committee.

5.2JSC Responsibilities and Decision-Making.

5.2.1 Responsibilities [***]. The JSC's responsibilities will include [***] the following:

5.2.1.1 the Product and the progress of Opthea's Development Program including (i) overall clinical, regulatory and commercial strategic direction of the Development Program, (ii) developing strategies to maximize the value of the Product, and (iii) reviewing and commenting on the Development Program and Regulatory Approval strategies for the Product;

5.2.1.2 Opthea's use, including planned use, of the Development Costs provided pursuant to Section 4.2 for Opthea's Development Program (including summaries of budgets for and payments to CROs, CMOs and other Permitted Third Parties);

5.2.1.3 [***];

5.2.1.4 [***]; and

5.2.1.5 [***].

5.2.2 Responsibilities [***]. The JSC's responsibilities will include [***] the following:

5.2.2.1 a change to the indication for the Product set forth in the current Development Plan from the Indication to any other indication;

5.2.2.2 [***];

5.2.2.3 [***];

5.2.2.4 [***];

5.2.2.5 the substitution or addition of any arms in any Product Clinical Trial;

5.2.2.6 a determination to discontinue the Development Program (provided that all Investors unanimously agree to discontinue the Development Program);

5.2.2.7 any material changes to the manufacturing process for either (a) the drug substance utilized in any Product or (b) any final Product that, in either case, will be used in the Product Clinical Trials; or

5.2.2.8 [***].

5.2.3 Reports. At each JSC meeting Opthea will provide material updates on the progress of the Product Clinical Trials and will report on material matters with respect to the progress toward obtaining Regulatory Approvals in the U.S., EU (if the EMA's centralized procedure is to be used, and otherwise the non-U.S. and non-U.K. Major Market Countries) and UK.

5.3Advisory Committee.

5.3.1 Representatives. Within thirty (30) days after the Original Effective Date, the Parties established an advisory committee (the "Advisory Committee"). Opthea and [***] each will have the right [***] to appoint three (3) representatives to serve as representatives to the Advisory Committee (the "AdComm Representatives"), provided that if any such representative is not an employee of the appointing Party, such representative will execute a confidentiality agreement in form and substance reasonably acceptable to the other Parties (and, for the avoidance of doubt, the appointing Party will remain responsible to the other Parties for any noncompliance by such representative with such confidentiality obligations), [***] Investor may replace (or appoint) one or more of its AdComm Representatives at any time upon written notice to the other Parties.

5.3.2 Responsibilities. The Advisory Committee's responsibilities will include [***] the following:

5.3.2.1 [***];

5.3.2.2 the activities related to, the progress of, and the Development Costs incurred in connection with, the Development Program;

5.3.2.3 interactions with Regulatory Authorities in the U.S. and EU (including the Major Market Countries) related to the Product;

5.3.2.4 [***];

5.3.2.5 [***];

5.3.2.6 [***];

5.3.2.7 the Commercialization strategy, activities and progress for the Product in the U.S.; and

5.3.2.8 [***].

5.3.3 Chairperson. The Advisory Committee chairperson ("AdComm Chairperson") will be designated from Opthea's AdComm Representatives. The AdComm Chairperson will be responsible for drafting and circulating the draft agenda and ensuring minutes are prepared.

5.3.4 Meetings; Dissolution. From the Original Effective Date until the end of the later of (a) the end of the Development Term and (b) the end of the first Calendar Quarter after the date on which the Product has obtained Regulatory Approval in the U.S., the Advisory Committee will meet approximately quarterly or on such other frequency as is agreed between the AdComm Representatives from time to time (such meetings to be conducted via teleconference or videoconference unless the Parties' AdComm Representatives mutually agree otherwise). Any AdComm Representative may call a special meeting of the Advisory Committee (by videoconference or teleconference) during the Development Term by providing at least five (5) Business Days' [***] prior written notice to the other AdComm Representatives, which notice will include a reasonably detailed description of the matter, in the event such AdComm Representative reasonably believes that a significant matter must be addressed prior to the next scheduled meeting. Upon the conclusion of the last meeting of the Advisory Committee held in accordance with the first sentence of this Section 5.3.4, the Advisory Committee shall be dissolved.

5.3.5 Participants. The Advisory Committee may invite individuals who are not AdComm Representatives to participate in Advisory Committee meetings; provided that (a) all AdComm Representatives consent to such non-member's participation; and (b) such non-member has executed a confidentiality agreement in form and substance acceptable to the non-inviting Parties (and, for the avoidance of doubt, the inviting Party will remain responsible to the non-inviting Parties for any noncompliance by such individual with such confidentiality obligations).

5.4Limitation on Authority. Notwithstanding anything to the contrary set forth in this Agreement, neither the JSC nor the Advisory Committee will have any authority to (a) amend, modify or waive compliance with this Agreement, or (b) resolve any dispute concerning the validity, interpretation, construction of, or breach of this Agreement.

5.5Decision-Making. [***].

5.6Board Observer. During the Term, Ocelot SPV LP and [***] shall have the right to designate one (1) individual to be present in a non-voting, observational capacity (for clarity, with no right to participate) at all meetings of the Opthea Board of Directors or any committee thereof, including any telephonic meetings but excluding executive sessions of any such meetings (such individuals, the "Investors Board Observers"), provided that [***]'s right to designate an Investor Board Observer shall terminate upon any assignment by [***] of this Agreement, in whole or in part, unless otherwise consented to by Opthea and Ocelot SPV LP. Any materials that are sent by Opthea to the members of the Opthea Board of Directors in their capacity as such shall be sent to the Investors Board Observers simultaneously by means reasonably designed to ensure timely receipt by the Investors Board Observers (provided that Opthea need not provide to the Investors Board Observers any information that, if disclosed to the Investors Board Observers in their capacity as such, would adversely affect the maintenance by Opthea of any applicable attorney-client privilege, any information that relates to (i) the negotiation of any amendment to or restatement of this Agreement, (ii) the strategy with respect to this Agreement as it specifically relates to any Investor (provided that nothing in this clause (ii) shall permit Opthea to withhold information related to the Product or the activities undertaken by Opthea, whether generally or pursuant to this Agreement, in connection with Developing and Commercializing the Product) or (iii) the relationship between Opthea and any Investor, or any information related to internal business matters of Opthea that does not relate to the activities to be undertaken by Opthea pursuant to this Agreement and would not reasonably be expected to have a Material Adverse Event), and Opthea will give the Investors Board Observers notice of such meetings, by the same means as such notices are delivered to the members of the Opthea Board of Directors and at the same time as notice is provided or delivered to the Opthea Board of Directors. Each Investors Board Observer will execute a confidentiality agreement in form and substance reasonably acceptable to the designating Investor (and, for the avoidance of doubt, a designating Investor will remain responsible to Opthea for any noncompliance by its designated Investor Board Observer with such confidentiality obligations).

ARTICLE 6

PAYMENTS TO INVESTOR

6.1Success Payments.

6.1.1 Success Payments. Following receipt of the first Regulatory Approval of the Product (either alone or in combination with another drug) (the "Success Payment Trigger"), Opthea will pay Investors the amounts set forth in the "Fixed Success Payment Schedule" below (in the column entitled "Amount of Payment") on the dates set forth in the column entitled "Date of Payment" in accordance with each Investor's Pro Rata Share (the payments payable pursuant to this Section 6.1.1, the "Fixed Success Payments" and collectively with the Variable Success Payments, the "Success Payments").

Fixed Success Payment Schedule

Date of Payment	Aggregate Amount of Payments to Investors
[***] days after the Success Payment Trigger	[***]
1-Year Anniversary of the Success Payment Trigger	[***]
2-Year Anniversary of the Success Payment Trigger	[***]
3-Year Anniversary of the Success Payment Trigger	[***]
4-Year Anniversary of the Success Payment Trigger	[***]
5-Year Anniversary of the Success Payment Trigger	[***]
6-Year Anniversary of the Success Payment Trigger	[***]
Total	$395,000,000

6.1.2 Execution of Notes. Promptly (but in any event within two (2) Business Days) following the occurrence of the Success Payment Trigger, Opthea shall execute and deliver to each Investor a Note in the principal amount equal to its Pro Rata Share of the Fixed Return Cap in the form attached hereto as Exhibit L (collectively, the "Notes").

6.2Variable Success Payments; Quarterly Reports.

6.2.1 From and after First Commercial Sale until Investors have received Success Payments equal, in the aggregate, to the Fixed Return Cap, Opthea shall pay to Investors, in accordance with their respective Pro Rata Shares, the Variable Success Payment for each Calendar Quarter promptly, but in any event no later than (a) [***] calendar days ([***] calendar days if a Commercialization License has been granted) after the end of each of the first three Calendar Quarters in each Calendar Year and (b) [***] calendar days ([***] calendar days if a Commercialization License has been granted) after the end of the last Calendar Quarter in each Calendar Year.

6.2.2 Concurrently with the payment of each Variable Success Payment, Opthea shall deliver a written report (the "Quarterly Report") to each Investor setting forth, in reasonable detail: (a) (i) the calculation of the Variable Success Payment payable in respect of the last ended Calendar Quarter, (ii) on a country-by-country basis, the number of units of the Product sold by Opthea and its Affiliates and, to the extent available, each counterparty to any Commercialization License, (iii) gross sales generated by or on behalf of Opthea and any of its Affiliates and each counterparty to any Commercialization License, (iv) foreign currency exchange rates used (which shall be rates of exchange determined in a manner consistent with Opthea's method for calculating rates of exchange in the preparation of Opthea's annual financial statements in accordance with Accounting Standards), (v) a detailed break-down of all permitted deductions from gross sales used to determine Net Sales and the Variable Success Payment in respect of the last ended Calendar Quarter and (vi) the cumulative year-to-date aggregate Net Sales for the Product through the end of the last ended Calendar Quarter; and (b) the Commercial Updates. The Quarterly Report shall

also have attached to it copies of any royalty reports or similar communications with respect to Net Sales received by Opthea from the Commercialization Partners to any Commercialization License.

6.2.3 Opthea shall include in each Commercialization License a provision requiring the Commercialization Partner to such Commercialization License to prepare and maintain reasonably complete and accurate records of the information to be disclosed in each Quarterly Report, and to disclose such information to Opthea to enable the disclosures of such information in each Quarterly Report, as contemplated herein. Opthea shall use Commercially Reasonable Efforts to obtain in a timely manner from each such Third Party any information to be disclosed in each Quarterly Report.

6.3Adjustment for Change in Development Costs. In the event that the actual Development Costs paid by Investors hereunder are lower or greater than One Hundred and Seventy Million U.S. Dollars ($170,000,000) (including as a result of Investors paying to Opthea the Going Concern Funding or Minimum Cash Make-Whole Funding), each Fixed Success Payment and the Fixed Return Cap will be multiplied by a fraction, the numerator of which is such actual Development Costs paid to Opthea by Investors hereunder and the denominator of which is One Hundred and Seventy Million U.S. Dollars ($170,000,000).

6.4Method and Timing of Payment. Fixed Success Payments will be due as of the applicable dates set forth in Section 6.1. Variable Success Payments will be due as of the quarterly payment dates set forth in Section 6.2.1. All Success Payments shall be paid by wire transfer of immediately available funds to the accounts specified by each Investor in writing to Opthea from time to time. Opthea will provide each Investor with written notice of each wire transfer to such Investor's account. All amounts payable and calculations under this Agreement will be in U.S. Dollars.

6.5Late Payments. If Opthea fails to pay any amount due under this Agreement on the due date therefore, then, without prejudice to any other remedies that Investors or Collateral Agent or their respective designees may have, such amount will bear interest from the due date until payment of such amount is made, both before and after any judgment, at a rate equal to the higher of (a) [***] and (b) [***] for the actual number of days payment is delinquent or if such rate exceeds the maximum amount permitted by Applicable Law, at such maximum rate.

6.6Taxes.

6.6.1 Tax Treatment.

6.6.1.1 The Parties acknowledge and agree that (i) this Agreement is not intended to be treated as or create a partnership or joint venture between the Parties for any applicable Tax purposes; (ii) as of the date hereof, a portion of each Investor Payment will be subject to a Tax Deduction under Australian Law in an amount equal to (A), in the case of a Fixed Success Payment, the amount by which such payment exceeds the Repayment Amount (with the Repayment Amount for each Fixed Success Payment being calculated based on the percentage that the Fixed Success Payment bears to the total Fixed Success

Payments) and (B), in the case of a Variable Success Payment, the entire amount of the payment; and (iii) as of the date hereof, Investor Payments would only be subject to any Tax Deduction under Australian Law described by subclause (ii) above. The Parties agree to file all Tax returns in a manner consistent with the foregoing, and not take any position, whether in any Tax return, audit, examination, adjustment or action with respect to a Tax, which is inconsistent with such treatment, unless required by a final determination of an applicable Tax authority or a change in Applicable Law.

6.6.1.2 The Parties also agree that, for U.S. federal and applicable state and local Tax purposes, (i) the execution of the Notes is intended to be treated as a realization event for Investors and (ii) the Notes are intended to be treated as a debt instrument issued by Opthea that is subject to Treasury Regulations Section 1.1275-4(c).

6.6.2 Withholding.

6.6.2.1 Opthea shall make all Investor Payments under this Agreement without any Tax Deduction unless such Tax Deduction is required by Applicable Law.

6.6.2.2 Opthea shall promptly upon becoming aware that it must make a Tax Deduction (or that there is any change in the rate or the basis of a Tax Deduction) notify the Investors accordingly.

6.6.2.3 If a Tax Deduction is required by law to be made by Opthea, except in relation to a FATCA Deduction, Opthea must pay an additional amount to the Investor in respect of which such Tax Deduction is imposed, together with the applicable Investor Payment so that, after making any Tax Deduction and any payment required in connection with that Tax Deduction, the Investor affected by such Tax Deduction receives an amount equal to the Investor Payment which would have been due if no Tax Deduction or payment required in connection with that Tax Deduction had been required.

6.6.2.4 If Opthea is required to make a Tax Deduction, Opthea shall make that Tax Deduction and any payment required in connection with that Tax Deduction within the time allowed and in the minimum amount required by law.

6.6.2.5 Within thirty days of making either a Tax Deduction or any payment required in connection with that Tax Deduction, Opthea shall use commercially reasonable efforts to deliver to the Investor affected by such Tax Deduction evidence satisfactory to such Investor, acting reasonably, that the Tax Deduction has been made or (as applicable) any appropriate payment has been paid to the relevant taxing authority.

6.6.3 Tax Indemnity.

6.6.3.1 Opthea shall (within three Business Days of demand by an Investor) pay to such Investor an amount equal to the loss, liability or cost which such Investor reasonably determines has been (directly or indirectly) suffered for or on account of Withholding Tax owed by such Investor in respect of an Investor Payment on account of Opthea's failure to pay additional amounts pursuant to Section 6.6.2.3 or make payments required in connection with a Tax Deduction to a relevant taxing authorities pursuant to Section 6.6.2.4.

6.6.3.2 Section 6.6.3.1 shall not apply to the extent the relevant loss, liability or cost is compensated for by an increased Investor Payment under Section 6.6.2.3.

6.6.4 Tax Cooperation. Each Party shall cooperate to provide and update, if necessary, any applicable forms, certifications or other information requested by any other Party that the first Party is reasonably and legally able to provide to reduce or eliminate any Tax Deduction or to support the intended tax treatment of any Investor Payment under Applicable Law or any applicable Tax treaty or convention as provided in Section 6.6.1. Each Party shall provide commercially reasonable cooperation to any other Party, at such other Party's expense, in connection with any official or unofficial Tax audit or contest relating to Investor Payments or any Tax payments made with respect to amounts paid or payable to such other Party under this Agreement, including pursuant to Section 6.6.2 or 6.6.3.

6.7Accelerated Payments.

6.7.1 Approval Buy-Out Option. Opthea shall have the right (the "Approval Buy-Out Option") to make a one-time payment (an "Approval Buy-Out Payment") in lieu of all Success Payments (as adjusted in accordance with Section 6.2.2) by written notice delivered to Investors no later than [***] after the date of the Success Payment Trigger, which written notice shall set forth the amount of the applicable Approval Buy-Out Payment, the proposed date of closing (which shall occur within [***] after the Success Payment Trigger), and the calculation of the applicable Approval Buy-Out Payment in reasonable detail based upon the proposed closing date. For purposes of this Section 6.7.1, the Variable Success Payments are deemed to be the amounts set forth on Schedule 6.7.1, payable on the dates set forth on Schedule 6.7.1. The Approval Buy-Out Payment will be equal to the present value of future Fixed Success Payments and the Variable Success Payments calculated as follows: [***].

The Approval Buy-Out Payment will be payable in one installment to each Investor, in accordance with its respective Pro Rata Share, in cash at the closing to the accounts specified by each Investor. The discount rate used to calculate the Approval Buy-Out Payment shall be [***] (the "Discount Rate").

6.7.2 General Buy-Out Option. Opthea may, regardless of whether any Success Payment Trigger has been achieved, propose to Investors that Opthea make a one-time payment (the "General Buy-Out Option" and such payment, the "General Buy-Out Payment") in lieu of all Success Payments that are payable or could become payable in the future by written proposal delivered to Investors (the "General Buy-Out Notice"). For purposes of this Section 6.7.2, the Variable Success Payments are deemed to be the amounts set forth on Schedule 6.7.1, payable on

the dates set forth on Schedule 6.7.1. In each case, each Fixed Success Payment shall be as adjusted in accordance with Section 6.3 and each such written proposal shall set forth the amount to be paid by Opthea to Investors, the proposed date of closing (which shall occur within [***] after delivery of such written proposal, subject to acceptance of such written proposal by the Required Investors), the discount rate that Opthea proposes to apply to such General Buy-Out Payment (the "Proposed Discount Rate") and the calculation of the General Buy-Out Payment in reasonable detail. The Required Investors shall have the right, on behalf of all Investors, to determine whether to accept such written proposal. Within [***] following receipt of such written proposal, the Required Investors shall notify Opthea in writing whether or not such written proposal is accepted, which acceptance shall be binding on all Investors. For the avoidance of doubt, if the Required Investors do not accept such written proposal, Opthea may deliver a revised written proposal to Investors, such that Opthea is not limited in the number of written proposals that may be made to Investors.

Each General Buy-Out Payment will be equal to the present value of the applicable future Success Payments calculated as follows: [***].

Any General Buy-Out Payment will be payable in one installment to each Investor, in accordance with its respective Pro Rata Share, in cash at the closing to the accounts specified by each Investor.

6.7.3 Change of Control Payment. Opthea will notify Investors in writing promptly (and in any event within four (4) Business Days) following the entering into of a definitive agreement with respect to a Change of Control. Within [***] days following the closing of a Change of Control, Opthea (or its successor) shall pay to each Investor an amount in cash equal to [***] of Development Costs paid by such Investor hereunder prior to such Change of Control, net of any Success Payments already made to such Investor (and/or, if applicable, its assignee) (such payment, the "Change of Control Payment"). The Change of Control Payment, if any, shall be credited (a) first, toward future Fixed Success Payments starting with the next Fixed Success Payment to be paid and (b) second, if the Change of Control Payment is greater than the total future Fixed Success Payments, toward future Variable Success Payments. For avoidance of doubt, following a Change of Control prior to receipt of Regulatory Approval for the Product, Opthea or its successor will be obligated to continue to exercise Commercially Reasonable Efforts to Develop and obtain Regulatory Approval as set forth herein (including in Section 3.7).

6.8Success Payment Assignment.

6.8.1 In the event that Opthea does not exercise the Approval Buy-Out Option, [***].

6.8.2 In the event that Opthea does not exercise the Approval Buy-Out Option, if an Investor desires to effect a sale of the Success Payments to any Third Party, [***].

ARTICLE 7

SECURITY INTERESTS

7.1Security Interest.

7.1.1 Grant. As security for the prompt payment and performance in full when due of the Opthea Obligations, Opthea hereby pledges and grants to the Collateral Agent, for the benefit of the Investors, effective upon the Restatement Effective Date, a continuing security interest in all of Opthea's right, title and interest (excluding any leasehold interest) in, to and under all of its property (excluding Intellectual Property that is not Product IP), wherever located and whether now existing or owned or hereafter acquired or arising, including the following property (collectively, the "Collateral"):

(a) all Accounts;

(b) books and Records;

(c) Cash;

(d) Chattel Paper;

(e) Commercial Tort Claims;

(f) Deposit Accounts, Securities Accounts and Commodities Accounts;

(g) Documents;

(h) Equipment (including all fixtures);

(i) Instruments;

(j) Inventory;

(k) Investment Property;

(l) Letter-of-Credit rights;

(m) Money;

(n) Goods;

(o) Product IP;

(p) all products, Proceeds and Supporting Obligations of any and all of the foregoing;

(q) the Development Costs Account;

(r) to the extent not covered by clauses (a) through (q) above, all other assets, personal property and rights, whether tangible or intangible, relating to the Product (as defined herein); and

(s) all Proceeds and products of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of, each of the foregoing, and

any and all Proceeds of any insurance, indemnity, warranty or guaranty payable to Opthea from time to time with respect to any of the foregoing.

7.1.2 Priority of Security Interest. Opthea represents, warrants and covenants that, subject to Collateral Agent making and maintaining any filings and actions, including a separate grant in respect of commercial tort claims, necessary to achieve such perfection, the security interests in the Collateral will be and will at all times thereafter continue to be first priority security interests, subject only to the Permitted Liens (the "Investor Security Interests").

7.1.3 Investor Collateral Exclusions. Anything herein to the contrary notwithstanding, in no event will the Collateral include, and Opthea will not grant and will not be deemed to have granted a security interest in (a) Intellectual Property (other than Product IP) (the "Excluded IP"), (b) any "intent to use trademark applications for which a statement of use has not been filed (but only until such statement is file); (c) any Excluded Accounts, (d) more than 65% of the presently existing and hereafter arising issued and outstanding shares of capital stock (or the equivalent thereof) owned by Opthea of any foreign Subsidiary (other than an Eligible Foreign Subsidiary) which shares entitle the holder thereof to vote for directors or any other matter; or (e) any property to the extent that such grant of security interest is prohibited by any Applicable Law of a Governmental Authority or constitutes a breach or default under or results in the termination of or requires any consent (other than the consent of an Affiliate of Opthea) not obtained under, any contract, license, agreement, instrument or other document evidencing or giving rise to such property, except to the extent that such Applicable Law or the term in such contract, license, agreement, instrument or other document providing for such prohibition, breach, default or termination or requiring such consent is ineffective under Section 9-406, 9-407, 9-408 or 9-409 of the Uniform Commercial Code in effect in any applicable jurisdiction (or any successor provision or provisions); provided, however, that such security interest will attach immediately at such time as such Applicable Law is not effective or applicable, or such prohibition, breach, default or termination is no longer applicable or is waived, and to the extent severable, will attach immediately to any portion of the Collateral that does not result in such consequences; provided, further that exclusions referred to in this Section 7.1.3 shall not apply to any Proceeds of any such Collateral.

7.1.4 Authorization to File Financing Statements. Subject to the terms of Section 7.4.1(b), Opthea hereby irrevocably authorizes Collateral Agent to file, on or at any time from time to time after the Original Effective Date, and Opthea will execute and deliver to Collateral Agent (as applicable), financing statements, amendments to financing statements, continuation financing statements, termination statements, security agreements relating to the Collateral, notices and other documents and instruments, in form satisfactory to Collateral Agent as Collateral Agent or any Investor may reasonably request, to perfect and continue perfection, maintain the priority of, enforce or protect the priority of, or provide notice of Collateral Agent's and Investors' security interest in the Collateral and to accomplish the purpose of this Agreement, without notice to Opthea, in all jurisdictions determined by Collateral Agent to be necessary or appropriate. Such financing statements may describe the Collateral in the same manner as described herein or may contain an indication or description of collateral that describes such property in any other manner as Collateral Agent may determine, in its sole discretion, is necessary or advisable to ensure the perfection of the security interest granted or purported to be granted in the Collateral to Collateral Agent herein, including describing such property as "all assets other than Intellectual Property that

is not related to the Product" or "all personal property, whether now owned or hereafter acquired other than Intellectual Property that is not related to the Product" or words of similar effect. Opthea hereby irrevocably authorizes Collateral Agent to file with the United States Patent and Trademark Office and the United States Copyright Office (and any successor office and any similar office in any United States state or other country) the Intellectual Property Security Agreement and any other documents for the purpose of perfecting, confirming, continuing, enforcing or protecting the security interest granted or purported to be granted in the Collateral to Collateral Agent, without the signature of Opthea where permitted by law, and naming Opthea as debtor, and Collateral Agent as secured party.

7.2Specified Rights and Remedies; Etc**.**

7.2.1 Following the achievement of the Success Payment Trigger, if an Event of Default has occurred and is continuing, then without prejudice to any other remedies that Investors or their designees may have, Collateral Agent or the Required Investors, as applicable, in their sole discretion, as applicable, shall have the right, without further notice or demand, to do any or all of the following:

7.2.1.1 accelerate the applicable Success Payments and, upon such acceleration, the applicable Success Payments shall be immediately due and payable;

7.2.1.2 foreclose upon and/or sell or otherwise liquidate the Collateral;

7.2.1.3 commence and prosecute an insolvency proceeding or consent to Opthea commencing any insolvency proceeding;

7.2.1.4 notify the account debtors or obligors under any Accounts constituting Collateral of the assignment of such Accounts to Investors, verify the amounts payable thereunder and direct such account debtors or obligors to make payment of all amounts due or to become due to Opthea thereunder directly to each Investor, enforce collection of any Accounts constituting Collateral and adjust, settle or compromise disputes and claims directly with any account debtors or obligors for amounts and on terms and in any order that Collateral Agent considers advisable;

7.2.1.5 make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral;

7.2.1.6 ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale the Collateral;

7.2.1.7 if at any time Collateral Agent is the sole control party with respect to any Deposit Account constituting Collateral (e.g., a Deposit Account holding cash proceeds of any Collateral), Collateral Agent may (i)

deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Deposit Account control agreement or similar agreements providing control of any Collateral and (ii) may apply the balance from any Deposit Account or instruct the bank at which such Deposit Account is maintained to pay the balance of such Deposit Account to or for the benefit of Investors;

7.2.1.8 demand and receive possession of Opthea books and records, records regarding Opthea assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information;

7.2.1.9 appoint a receiver to seize, manage and realize on any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any Applicable Law; and/or

7.2.1.10 exercise all rights and remedies available to Investors under this Agreement or at law or equity, including all remedies provided under the UCC (including disposal of the Collateral pursuant to the terms thereof).

7.2.2 Marshalling. Neither Collateral Agent nor any Investor shall have any obligation to marshal any of the Collateral.

7.2.3 Access to Collateral. If prior to the Release Date, an Event of Default has occurred and is continuing, upon request by Collateral Agent and at the sole cost and expense of Opthea, Opthea shall assemble the Collateral as directed by Collateral Agent and make it available to Collateral Agent at such location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Opthea hereby grants Collateral Agent an irrevocable license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies.

7.2.4 Licenses Related to Product. For the purpose of enabling Collateral Agent to exercise rights and remedies under this Section 7.2 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), Opthea hereby grants to Collateral Agent, an irrevocable (until the Release Date), nonexclusive, assignable license (which license may be exercised prior to the Release Date and only so long as an Event of Default has occurred and is continuing, without payment of royalty or other compensation to Opthea or any of its Subsidiaries), including the right to practice, use, sublicense or otherwise exploit, solely in connection with the Product or other items in the Collateral, any Intellectual Property now owned or hereafter acquired by Opthea or licensed or sublicensed to Opthea, in each case that is relevant to Product, wherever the same may be located, and including in such license reasonable access to all media in which any of the licensed items may be recorded or stored and to all computer software and programs used for the compilation or printout thereof to the extent that such non-exclusive

license is not prohibited by any Applicable Law; provided that such license and sublicenses with respect to Trademarks shall be subject to the maintenance of quality standards with respect to the goods and services on which such Trademarks are used sufficient to preserve the validity of such Trademarks; provided, further, that nothing in this Section 7.2.4 shall require Opthea to grant any license that is prohibited by any rule of law, statute or regulation, or is prohibited by, or constitutes a breach or default under or results in the termination of any contract, license, agreement, instrument or other document evidencing, giving rise to or theretofore granted, to the extent permitted by this Agreement, with respect to such property or otherwise unreasonably prejudices the value thereof to Opthea. For clarity, Collateral Agent may exercise such license solely upon and during the continuation of an Event of Default; provided that any license, sublicense or other transaction entered into by Collateral Agent in accordance with the provisions of this Agreement shall be binding upon Opthea, notwithstanding any subsequent cure of an Event of Default.

7.2.5 Power of Attorney. Opthea hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact with full authority in the place and stead of Opthea and in the name of Opthea, Collateral Agent or otherwise, from time to time in Collateral Agent's sole discretion following the occurrence and during the continuance of an Event of Default prior to the Release Date, to take any action and to execute any instrument that Collateral Agent may deem necessary or advisable to accomplish the purposes of this Agreement, including (i) to endorse Opthea's name on any checks or other forms of payment or security; (b) to sign Opthea's name on any invoice or bill of lading for any account or drafts against account debtors; (c) to settle and adjust disputes and claims about the accounts directly with account debtors, for amounts and on terms Collateral Agent determines reasonable; (d) to make, settle, and adjust all claims under Opthea's insurance policies; (e) to pay, contest or settle any Lien charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) to transfer the Collateral into the name of Collateral Agent or a third party as the UCC or any Applicable Law permits. The foregoing appointment of Collateral Agent as Opthea's lawful attorney-in-fact, and Collateral Agent's rights and powers, are coupled with an interest and are irrevocable, until indefeasible payment in full in cash of all Opthea Obligations.

7.2.6 Protective Payments. If an Event of Default has occurred and is continuing prior to the Release Date, if Opthea fails to pay any amount which Opthea is obligated to pay to a third party with respect to the Collateral or any covenant of Opthea under Article 7 of this Agreement, Collateral Agent may make such payment, and all amounts so paid by Collateral Agent shall constitute Investor Remedy Expenses and be immediately due and payable and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Opthea with notice of Collateral Agent making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Investors shall be deemed or otherwise construed to constitute an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

7.2.7 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied, first, to reimburse Collateral Agent and the Investors for all Investor Remedy Expenses, and, second, to payment of all of Opthea's payment obligations, including all Opthea Obligations, under this Agreement to each Investor, proportionately in accordance with their Pro Rata Share.

7.2.8 Sales on Credit. If Collateral Agent sells any of the Collateral upon credit, Opthea will be credited only with payments actually made by purchaser and received by Collateral Agent and applied to indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral Agent, Collateral Agent may resell the Collateral and Opthea shall be credited with proceeds of the sale.

7.2.9 Liability for Collateral. So long as Collateral Agent employs reasonable practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent, (i) Collateral Agent, in its capacity as Collateral Agent, shall not be liable or responsible for: (A) the safekeeping of the Collateral; (B) any loss or damage to the Collateral; (C) any diminution in the value of the Collateral; or (D) any act or default of any carrier, warehouseman, bailee, or other Person; and (ii) Opthea shall bear all risk of loss, damage or destruction of the Collateral. Collateral Agent, in its capacity as Collateral Agent, shall be deemed to have exercised reasonable care in the custody and preservation of Collateral in its possession if such Collateral is accorded treatment substantially equal to that which Collateral Agent accords its own property.

7.2.10No Waiver; Remedies Cumulative. Collateral Agent's failure, at any time or times, to require strict performance by Opthea of any provision of this Agreement shall not waive, affect, or diminish any right of Collateral Agent, in its capacity as Collateral Agent, thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and then shall only be effective for the specific instance and purpose for which it is given. Collateral Agent's rights and remedies under this Agreement are cumulative. Collateral Agent has all rights and remedies provided under the UCC, any Applicable Law, by law, or in equity. Collateral Agent's exercise of one right or remedy is not an election, and Collateral Agent's waiver of any Event of Default is not a continuing waiver. Collateral Agent's delay in exercising any remedy is not a waiver, election, or acquiescence.

7.3Negative Covenants.

7.3.1 Incurrence of Certain Indebtedness. Opthea shall not, without the prior written consent of the Required Investors, create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary of Opthea to do so, other than Permitted Indebtedness.

7.3.2 Encumbrances. Opthea will not, and will not permit any Subsidiary of Opthea to, without the prior written consent of the Required Investors:

7.3.2.1 create, incur, assume, allow, or suffer to exist any Lien on any of the Collateral or Excluded IP, whether now owned or hereafter acquired or assign or convey any right to receive royalties, license fees or other income with respect to the Collateral or Excluded IP (other than satisfaction of royalty and other license fee obligations to licensors thereof in accordance with the applicable license agreement (including the sale, transfer or other disposition of any Collateral or Excluded IP)), or permit any of its subsidiaries to do so, other than Permitted Liens; or

7.3.2.2 enter into any agreement, document, instrument or other arrangement (except with or in favor of Investors) with any Person which directly or indirectly prohibits or has the effect of prohibiting Opthea or any Subsidiary of Opthea from assigning, mortgaging, pledging, granting a security interest in or upon or encumbering the Collateral or any Product IP; provided that this Section 7.3.2.2 shall not apply to (i) restrictions in connect with any Permitted Liens that limit the right to dispose the assets subject to such Permitted Lien, (ii) any agreements, documents or other arrangement in effect on the Original Effective Date and set forth on Schedule 7.3.2.2 and any amendments or modifications thereof that do not expand the scope of any such restriction or condition; (iii) agreements, documents, instruments or other arrangements governing other Permitted Indebtedness; (iv) any Applicable Law; (v) customary non-assignment provisions in agreements, leases and licenses, documents, instruments or other arrangements otherwise permitted under this Agreement; (vi) customary restrictions and conditions contained in any agreement relating to any Disposition not prohibited under this Agreement pending the consummation of such Disposition; (vii) provisions limiting the disposition or distribution of assets or property in joint venture agreements, partnership agreements, asset sale agreements, sale-leaseback agreements, stock sale agreements and other similar agreements permitted under this Agreement, which limitation is applicable only to the assets that are the subject of such agreements; (viii) prohibitions, restrictions or conditions on cash or other deposits or net worth imposed by customers under contracts entered into in the ordinary course of business; (ix) any agreement or instrument of, or affecting, any Person or asset existing on or prior to the date on which such Person or asset was acquired by Opthea or any Subsidiary of Opthea (other than any such agreement, document, instrument or arrangement entered into in contemplation of such acquisition); (x) customary provisions contained in leases, sub-leases, Excluded Licensing Transactions and Out-Licenses that are approved by the Required Investors pursuant to Section 7.3.4, including with respect to intellectual property, and other agreements entered into in the ordinary course of business; (xi) customary non-assignment provisions in leases or licenses governing leasehold or license interests to the extent such provisions restrict the transfer of the lease or the property leased or licensed thereunder; (xii) customary restrictions in deposit and security account agreements and agreements relating to Cash Management Services, and (xiii) any amendment, modification, restatement, renewal, increase, supplement, refunding, replacement or refinancing of an agreement document, instrument or arrangement referred to in clauses (i) through (xii) of this Section 7.3.2.2; provided, that such amendment, modification, restatement, renewal, increase, supplement, refunding, replacement or refinancing is not more restrictive, as determined in good faith by Opthea, with respect to such encumbrances and other restrictions taken as a whole than those prior to such amendment, modification, restatement, renewal, increase, supplement, refunding, replacement or refinancing.

7.3.3 Distributions; Investments. Opthea shall not, without the prior written consent of the Required Investors, (a) pay any dividends or make any distribution or payment on account of or redeem, retire or purchase any capital stock, provided that (i) Opthea may convert

any of its equity convertible securities into other equity securities (or cash for partial shares) pursuant to the terms of such equity convertible securities or otherwise in exchange thereof, (ii) Opthea may pay dividends solely in common stock, (iii) Opthea may repurchase the stock of former employees or consultants pursuant to stock repurchase agreements, provided that the aggregate amount of all such repurchases does not exceed One Million U.S. Dollars ($1,000,000) per fiscal year; (iv) Opthea may repurchase capital stock deemed to occur upon the exercise of stock options, warrants or other convertible or exchangeable securities if such capital stock represents a portion of the exercise, conversion or exchange price thereof; (v) Opthea may repurchase stock or restricted stock units deemed to occur upon the withholding of a portion of the capital stock, options or restricted stock units granted or awarded to a current or former officer, director, employee or consultant to pay for the taxes payable by such Person upon such grant or award (or upon vesting thereof); and (vi) Opthea may enter into Permitted Equity Derivatives in connection with (x) the incurrence of any unsecured convertible Indebtedness (and may settle, terminate or unwind any such Permitted Equity Derivatives in connection with any refinancing, early conversion or maturity of such convertible Indebtedness) or (y) at-the-market offerings (and may settle, terminate or unwind any such Permitted Equity Derivatives in accordance with its terms), or (b) directly or indirectly make any Prohibited Investment (including by the formation of or through any Subsidiary), or permit any of its Subsidiaries to do so. For the avoidance of doubt, nothing in this Section 7.3.3 shall limit the ability of Opthea to pay or settle on conversion, repurchase or exchange (in or for cash and/or equity) any convertible indebtedness or any Permitted Equity Derivatives.

7.3.4 Dispositions. Without the prior written consent of the Required Investors, such consent not to be unreasonably withheld or delayed, Opthea shall not, and shall not permit any Subsidiary to, license, sell, convey, assign, dispose, or otherwise transfer (collectively, "Dispose") to any Third Party rights to Develop or Commercialize the Product or the Product IP to any Third Party, provided that this Section 7.3.4 shall not apply to any Excluded Licensing Transaction or a Change of Control. Without limiting the generality of the foregoing, other than Excluded Licensing Transactions or pursuant to a Change of Control, neither Opthea nor any of its Subsidiaries will grant a license, sell, convey, assign, dispose, or otherwise transfer rights with respect to any Product IP to any Third Party if such license, sale, conveyance, assignment, disposal or other transfer of rights would materially limit in any respect the right of Opthea to Develop and Commercialize the Product anywhere in the Major Market Countries.

7.3.5 Fundamental Transactions. Opthea will not, (a) without the prior written consent of the Required Investors, liquidate or dissolve or (b) without at least twenty (20) days prior written notice to each Investor, (i) change its jurisdiction of organization, (ii) change its organizational structure or type, (iii) change its legal name, or (iv) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3.6 Sales of Royalty Streams. Neither Opthea nor any of its Subsidiaries shall, without the prior written consent of the Required Investors, sell, transfer or assign, directly or indirectly, in whole or in part, any rights to receive payments of royalties on sales of the Product, returns on net sales of the Product, revenue share or other compensation or license fees with respect to the Product or the Product IP (including any Accounts with respect to such royalties or license fees), provided that the foregoing shall not prohibit any Permitted Disposition or any royalties payable in respect of in-licenses. Neither Opthea nor any of its Subsidiaries shall, without the prior

written consent of the Required Investors, create, incur, assume or suffer to exist any Lien, other than any Permitted Lien, on any rights to receive payments of royalties on sales of the Product, returns on net sales of the Product, revenue share or other compensation or license fees the Product IP (including any Accounts with respect to such royalties or license fees).

7.3.7 Termination of Negative Covenants. Upon the Release Date, the negative covenants in this Section 7.3 will terminate.

7.4Affirmative Covenants. Opthea will do all of the following:

7.4.1 Execution of Additional Security Agreements and Other Further Assurances. Opthea will, upon request of the Collateral Agent (or at the instruction of the Required Investors) from time to time hereafter, execute such security agreements, Deposit Account control agreements, securities account control agreements and other agreements and documents and take and cause its Subsidiaries to take such further action, as reasonably required or desired to perfect or continue the perfection of the Investor Security Interests or to effect the purposes of this Article 7, including by taking the following actions:

(a) On or before the Restatement Effective Date, Opthea will and, as applicable, will cause its Subsidiaries to, execute and deliver to Collateral Agent the Australian General Security Deed, Guaranty and Deposit Account Control Agreement. In addition to and without limiting the foregoing, Opthea will provide each Investor with five (5) Business Days' prior written notice before establishing any additional Deposit Account at or with any bank or financial institution for the purpose of serving as a Development Costs Account pursuant to Section 4.4. For each such successor Development Costs Account that Opthea at any time maintains after Opthea's receipt of any Investor's first payment under Section 4.2, Opthea will cause the applicable bank or financial institution at or with which any Development Costs Account is maintained to execute and deliver a Deposit Account control agreement, securities account control agreement or other appropriate instrument with respect to such account to perfect Collateral Agent's first-priority security interest in such account in accordance with the terms hereunder within thirty (30) days after the opening of each such account (or, if later, thirty (30) days after Opthea's receipt of the first Development Cost payment), which agreement may not be terminated prior to the Release Date without the prior written consent of the Required Investors.

(b) At Collateral Agent's request, Opthea will promptly execute and deliver (or cause any Affiliate to execute and deliver) any and all further instruments and documents and take all such other action as Collateral Agent may reasonably deem necessary or desirable to maintain in favor of Investors, Liens on the Collateral that are duly perfected in accordance with the requirements of all Applicable Laws. [***].

7.4.2 Government Compliance. Opthea will maintain, and will cause any Subsidiary that is party to a Transaction Agreement to maintain, its existence and good standing in its jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on Opthea's business or operations. Opthea will comply, in all material respects, with all laws, ordinances and regulations to which it is subject and with which noncompliance would reasonably be expected to

have a material adverse effect on the Development or Commercialization of the Product or to otherwise result in a Material Adverse Event.

7.4.3 Regulatory Compliance. Opthea will not become an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Opthea will not become engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Neither Opthea's nor any of its Subsidiaries' properties or assets will be used by Opthea or any Subsidiary in disposing, producing, storing, treating, or transporting any hazardous substance other than legally. Opthea and each of its Subsidiaries will obtain all consents, approvals and authorizations of, make all declarations or filings with, and give all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted, unless such failure could not reasonably be expected to have a material adverse effect on the Development or Commercialization of the Product or to otherwise result in a Material Adverse Event.

7.4.4 Protection of Intellectual Property Rights. Opthea will use, and will cause its Subsidiaries to use, Commercially Reasonable Efforts in the exercise of its business judgment to prosecute, protect, defend and maintain the validity and enforceability of material Product IP.

7.5Conflicts. In the event of any conflict between the provisions of this Article 7 and the Australian General Security Deed, the Australian General Security Deed will prevail.

ARTICLE 8

RECORDS

8.1Accounting. Opthea will maintain and will, as applicable, cause its Subsidiaries to maintain complete and accurate accounting records related to all obligations of Opthea set forth in this Agreement in accordance with Accounting Standards during and for [***] after the conclusion of the Term.

8.2Clinical Trials-Related Records. Opthea will, and will cause its Affiliates and its and their Permitted Third Parties conducting Development of the Product to, maintain, in good scientific manner, timely, complete and accurate books and records pertaining to Development of the Product hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records will (a) be appropriate for patent and regulatory purposes, (b) be in compliance with Applicable Law, (c) properly reflect all work done and results achieved in the performance of its Development activities hereunder, and (d) be retained by such party for such period as may be required by Applicable Law.

8.3Records; Audits.

8.3.1 Following the Original Effective Date, Opthea will keep and maintain accurate and complete records regarding Development Cost expenditures and Net Sales during and for [***] after the conclusion of the Term.

8.3.2 Upon [***] Business Days' prior written notice from the Required Investors and no more frequently than once per Calendar Year, Opthea will permit an independent certified public accounting firm of internationally recognized standing, selected by the Required Investors and reasonably acceptable to Opthea, to examine the relevant books and records of Opthea and its Affiliates, as may be reasonably necessary to verify Opthea's compliance with Section 4.3 and Section 4.4 or to determine the correctness of Variable Success Payments made to Investors under this Agreement. The accounting firm will be provided access to such books and records at Opthea's facility or facilities where such books and records are normally kept and such examination will be conducted during Opthea's normal business hours. Upon completion of the audit, the accounting firm will provide to Opthea and Investors a written report disclosing whether the reports submitted by Opthea are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to Investors. If the report or information submitted by Opthea results in an underpayment or overpayment, the Party owing the underpaid or overpaid amount will promptly pay such amount to such other relevant Party.

8.3.3 Upon [***] Business Days' prior written request from the Required Investors while any Commercialization License remains in effect and no more frequently than once per Calendar Year, Opthea shall exercise any rights it may have under any Commercialization License relating to the Product to cause an inspection and/or audit by an independent public accounting firm of internationally recognized standing, selected by the Required Investors and reasonably acceptable to Opthea, to be made of the books of account of any counterparty thereto for the purpose of determining the correctness of Variable Success Payments made to Investors under this Agreement.

8.3.4 The costs and fees of any audit conducted or requested by the Required Investors under this Section 8.3 will be borne by Investors, severally and not jointly, in accordance with their Pro Rata Share, unless such audit reveals an underpayment of amounts owed to Investors of more than [***] in the relevant period(s), in which case Opthea will reimburse Investors for the reasonable expenses incurred by Investors in connection with the audit, which shall include, for avoidance of doubt, all fees of the independent public accounting firm engaged for such purpose.

ARTICLE 9

CONFIDENTIAL INFORMATION

9.1Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (each, a "Receiving Party") agrees that, during the Term and for the three (3) year period following the conclusion of the Term (except that the obligations will survive thereafter with respect to any Confidential Information that constitutes a trade secret under Applicable Law) or such longer period for which such Confidential Information may be maintained pursuant to Article 8, will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it by or on behalf of any other Party (each, a "Disclosing Party") or its Affiliates in connection with this Agreement. The foregoing obligations will not apply to any portion of such information or materials that the Receiving Party can demonstrate:

9.1.1 was publicly disclosed by the Disclosing Party before or after such Confidential Information becomes known to the Receiving Party;

9.1.2 was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or non-use, prior to when it was received from the Disclosing Party;

9.1.3 is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof without obligation to keep such Confidential Information confidential;

9.1.4 has been published by a Third Party or otherwise enters the public domain through no fault of the Receiving Party or any of its Affiliates in breach of this Agreement; or

9.1.5 has been independently developed by the Receiving Party or any of its Affiliates, without the aid, application or use of any Confidential Information of any other Party.

9.2Authorized Disclosure. Each Party may disclose Confidential Information belonging to any other Party to the extent such disclosure is reasonably necessary for complying with Applicable Laws, including regulations promulgated by securities exchanges, provided that the Party required to disclose such information promptly notifies the Disclosing Party prior to making any such disclosure and cooperates with the Disclosing Party's efforts to seek confidential treatment or to otherwise limit disclosure and this section does not permit the disclosure of any information under section 275(4) of the Australian PPSA, unless section 275(7) of the Australian PPSA applies. Each Receiving Party may disclose any other Party's Confidential Information to its Representatives (and, in the case of Investors, to the Investor LPs), in each case (a) only to the extent such Persons need to know the Confidential Information solely in connection with the performance of this Agreement, and (b) provided that each Person receiving Confidential Information must be bound by obligations of confidentiality and non-use at least as stringent as an equivalent in scope to those set forth in this Article 9 prior to any such disclosure and the Party making such disclosure to such Person will be liable to such other Party for any breach of such obligations by such disclosee (provided that a Party's Representative or an Investor LP will only be bound by the obligations set forth in this Article 9 to the extent that such Representative or Investor LP actually receives such Confidential Information). Each Party may also disclose the material terms of this Agreement and updates regarding the Development and Commercialization progress of the Product, or a summary of such Party's findings during its due diligence investigation of the Product (if applicable) to any bona fide potential or actual investor, investment banker, acquirer, provider of debt or royalty financing, or other potential or actual financial partner (including, in the case of an Investor, any Investor LP) without the consent of any other Party, and provided that in connection with such disclosure, each disclosee must be bound by obligations of confidentiality and non-use at least as stringent as an equivalent in scope to those set forth in this Article 9 prior to any such disclosure and the Party making such disclosure to such disclosee will be liable to all other Parties for any breach of such obligations by such disclosee. Notwithstanding anything in the foregoing to the contrary, Exhibit K constitutes Opthea's Confidential Information, and Opthea may disclose Exhibit K to Third Parties as determined by Opthea in its sole discretion. In any event, each Party agrees to take all reasonable action to avoid unauthorized use or disclosure of Confidential Information of any other Party hereunder.

9.3Return of Confidential Information. Except as otherwise provided herein, upon expiration or earlier termination of this Agreement, all Confidential Information (including any copies thereof) in written or other tangible form will, at the Disclosing Party's direction, be returned to the Disclosing Party or destroyed by the Receiving Party (with such destruction being confirmed in writing by an authorized officer of the Receiving Party), except (i) to the extent such Confidential Information is necessary to exercise any license or rights hereunder that survive such expiration or earlier termination; and (ii) one (1) copy of each document may be retained by the Receiving Party solely to the extent necessary to permit it to comply with any ongoing rights and responsibilities with respect to such Confidential Information or with Applicable Law. Notwithstanding the foregoing, in the case of Confidential Information of Opthea disclosed by an Investor to Investor LPs, such Investor will request return and/or destruction of such Confidential Information but will not be liable in the event that such Confidential Information is not returned or destroyed.

9.4Confidential Status of the Agreement. Subject to Section 9.2 and Section 9.5, the terms of this Agreement are deemed to be Confidential Information and will be subject to the confidentiality requirements of this Article 9, with each Party being deemed a Receiving Party for such purposes. The Parties each acknowledge that it will be necessary for Opthea to file this Agreement with the U.S. Securities and Exchange Commission and to make other required public disclosures regarding the terms of this Agreement and payments made under this Agreement, and accordingly Opthea will prepare a confidential treatment request in connection with such filing and provide Investors a reasonable opportunity to review and comment on such filing as well as on such other required public disclosures, which comments Opthea will consider and incorporate in good faith, and thereafter use Commercially Reasonable Efforts to obtain confidential treatment as to certain terms of this Agreement; provided that Opthea shall not be required to provide Investors the opportunity to review and comment on any disclosure substantively identical to any disclosure previously reviewed and commented upon by Investors.

9.5Publicity. The Parties recognize that following the Original Effective Date Ocelot SPV LP and Opthea (either individually or jointly) will issue mutually agreed press release(s) announcing the execution of this Agreement, and thereafter each Party may from time to time desire to issue additional press releases and make other public statements or disclosures regarding the subject matter of this Agreement, and hereby agree that such additional press releases, public statements and disclosures regarding the terms of this Agreement will be permitted only with the other Parties' written consent (which will not be unreasonably withheld, conditioned or delayed). Any publication, news release or other public announcement relating to the terms of this Agreement will first be reviewed and approved in writing by all Parties; provided, however, that any disclosure of information that is required by Applicable Law (including U.S. federal securities laws and the rules of a securities exchange), as reasonably advised by the disclosing Party's counsel, may be made without the prior consent of any other Party, although the other Parties will be given prompt notice of any such legally required disclosure and, to the extent practicable, will be provided an opportunity to comment on the proposed disclosure and the disclosing Party will consider in good faith any comments provided by the other Parties on such proposed disclosure. For avoidance of doubt, this Section 9.5 shall not restrict Opthea, without prior disclosure or consent of the Investors, from releasing public statements or disclosures regarding Opthea's development and Commercialization activities with respect to the Product or regarding the subject

matter or terms of this Agreement so long as such disclosure relating to the subject matter or terms of this Agreement is consistent with any prior disclosure by Opthea or Investors in respect thereof.

ARTICLE 10

INTELLECTUAL PROPERTY AND PERSONALLY IDENTIFIABLE INFORMATION

10.1Ownership and Rights.

10.1.1Ownership.

10.1.1.1 For purposes of determining ownership under this Section 10.1, unless otherwise set forth herein, inventorship will be determined in accordance with United States patent laws (regardless of where the applicable activities occurred).

10.1.1.2 Opthea will own and retain all right, title and interest in, to and under all data, results, information, analyses, discoveries, inventions and know-how that are Controlled by Opthea as of the Restatement Effective Date and no such right, title or interest therein, thereto or thereunder is granted to Investors hereunder, except as expressly set forth herein. Each Investor will own and retain all right, title and interest in, to and under all data, results, information, analyses, discoveries, inventions and know-how that are Controlled by such Investor as of the Restatement Effective Date and no such right, title or interest therein, thereto or thereunder is granted to Opthea hereunder, except as set forth herein.

10.1.1.3 Opthea (or its Subsidiary party to the Guaranty and Australian General Security Deed) will be the exclusive and sole owner of and retain all right, title and interest in, to and under (a) the Product, (b) all discoveries and inventions discovered, developed or invented by, or on behalf of, Opthea or Ocelot SPV LP, and any of their Affiliates, and any Permitted Third Party, in performance of the Product Clinical Trials (including the Research Results), (c) all improvements that are discovered, developed or invented by, or on behalf of Opthea under or in performance of this Agreement that relate to Intellectual Property that is Controlled by Opthea as of the Restatement Effective Date and (d) all Intellectual Property in the foregoing subsections (a) through (c) (all of the foregoing (a)-(d), collectively, the "Trial Inventions"). Subject to Section 7.1, each Investor will, and hereby does, assign to Opthea all rights, title and interest of such Investor in, to and under the Trial Inventions, if any. For the avoidance of doubt, any Trial Inventions that are discovered, developed or invented by members of the JSC or the Advisory Committee that are employed by or affiliated with an Investor will be assigned to Opthea.

10.2Patent Prosecution. As between Investors and Opthea, Opthea will have sole and exclusive right to prepare, file, prosecute and maintain all Patents within the Product IP, including

all Patents that cover the Trial Inventions, at its own expense (provided that Opthea will use Commercially Reasonable Efforts to prosecute and maintain such Patents). At Opthea's request and expense (for reasonable out-of-pocket expenses), Investors will reasonably cooperate with Opthea in preparing, filing, prosecuting, and maintaining such Patents. Opthea will provide Investors with copies of all patent applications and other material submissions and correspondence filed with any patent counsel or patent authorities pertaining to the Product IP following reasonable request by any of the Investors. Opthea will promptly provide Investors with copies of all material correspondence sent to or received from any patent counsel or patent authorities pertaining to the Product IP, following reasonable request by any of the Investors.

10.3Intellectual Property Enforcement.

10.3.1Infringement of Product IP. Opthea or its Subsidiary party to the Guaranty and Australian General Security Deed will have the sole and exclusive right, and will use and cause such Subsidiary to use Commercially Reasonable Efforts to enforce the Product IP Controlled by Opthea or such Subsidiary, including Intellectual Property that covers the Trial Inventions, against Third Party Infringement at its sole expense. Each Party shall promptly inform the other Parties of any infringement by a Third Party of any Product IP of which such Party becomes aware. Opthea shall provide to Investors a copy of any written notice delivered by Opthea or its Subsidiary party to the Guaranty and Australian General Security Deed to a Third Party alleging or claiming such Third Party Infringement, as well as copies of material correspondence sent to or received by Opthea or its Subsidiary party to the Guaranty and Australian General Security Deed related thereto, as soon as practicable and in any event not more than five (5) Business Days following such delivery or receipt. Prior to initiating, or permitting a licensee to initiate (if applicable), an enforcement action regarding any suspected Third Party Infringement, Opthea shall provide Investors with written notice of such enforcement action. Opthea will have sole control and responsibility of, and discretion with respect to, such allegations and any related actions or litigation at its sole expense, but will keep Investors reasonably informed (provided that Opthea shall not have sole control and responsibility if an Investor or any of its Affiliates are named in any related actions or litigation, unless the relevant Parties agree separately and specifically in writing).

10.3.2Infringement of Third Party Rights. If any Party learns of Third Party allegations that Opthea or any of its Affiliates or Permitted Third Parties, have infringed, misappropriated or otherwise violated, or are infringing, misappropriating or otherwise violating, any Intellectual Property of a Third Party in connection with either the Product Clinical Trials or performing its obligations or duties hereunder, such Party will promptly notify the other Parties. Opthea shall provide to Investors a copy of any written notice received by Opthea from a Third Party alleging or claiming that the making, having made, using, importing, offering for sale or selling of the Product infringes or misappropriates any Patents or other intellectual property rights of such Third Party, as well as copies of material correspondence sent to or received by Opthea related thereto, as soon as practicable and in any event not more than five (5) Business Days following such delivery or receipt. Opthea will have sole control and responsibility of, and discretion with respect to, such allegations and any related actions or litigation at its sole expense, but will keep Investors reasonably informed (provided that Opthea shall not have sole control and responsibility if an Investor or any of its Affiliates are named in any related actions or litigation, unless the relevant Parties agree separately and specifically in writing). Opthea will not settle or

compromise any allegation, action or litigation in a way that admits fault or liability on the part of any Investor or otherwise results in any cost or liability on the part of any Investor.

10.4Personally Identifiable Information.

10.4.1In conducting the Product Clinical Trials and its other obligations under this Agreement, Opthea will comply, and will use Commercially Reasonable Efforts to require each applicable Permitted Third Party to comply, with Applicable Laws relating to privacy or data protection applicable to Opthea or the Product Clinical Trials being conducted by or on behalf of Opthea, including ensuring that all necessary (a) consents from Clinical Investigators, Subjects and any others from whom Personally Identifiable Information will be received are obtained; (b) regulatory notifications are filed in all countries for which Sites have been selected; and (c) approvals are obtained in all countries for which Sites have been selected, prior to collection or transfer of such Personally Identifiable Information. Without prejudice to the generality of the foregoing, Opthea will comply with the General Data Protection Regulation (2016/679) ("GDPR"), and will ensure the information referred to in Applicable Laws and, if applicable, in particular Articles 13 and 14 of is made available to data subjects (as defined in the GDPR) in relation to the processing of their Personally Identifiable Information by Opthea when acting as a data controller (as defined in the GDPR), and the information is in a concise, transparent, intelligible and easily accessible form, using clear and plain language as required by Article 12 of the GDPR.

10.4.2Opthea will not process, and will use Commercially Reasonable Efforts to require that each applicable Permitted Third Party does not process, any Personally Identifiable Information in a way that is contrary to Applicable Laws.

10.4.3Opthea will maintain, and will use Commercially Reasonable Efforts to require each applicable Permitted Third Party to maintain, appropriate and sufficient technical and organizational security measures to maintain the confidentiality of Personally Identifiable Information and to protect such data against accidental or unlawful destruction or accidental loss, damage, alteration, unauthorized disclosure or access, in particular where such data is transmitted over a network. These technical and organizational security measures will ensure a level of security appropriate to the risk, including, as appropriate, (a) pseudonymisation and encryption; (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services; (c) the ability to restore the availability and access to the Personally Identifiable Information in a timely manner in the event of a physical or technical incident; and (d) a process for regularly testing, assessing and evaluating the effectiveness of those measures.

10.4.4Opthea will promptly notify Investors of: (a) any significant unauthorized use or disclosure or breach of any Personally Identifiable Information promptly upon discovery of such occurrence; and (b) the transmittal of any related breach notification to any affected person, Governmental Authority or the media. Opthea will use Commercially Reasonable Efforts to require each applicable Permitted Third Party to notify Opthea of: (i) any significant unauthorized use or disclosure or breach of any Personally Identifiable Information promptly upon discovery of such occurrence and (ii) the transmittal of any related breach notification to any affected person, Governmental Authority or the media. Opthea shall not disclose any Personally Identifiable

Information to an Investor without prior notice to such Investor and receipt of such Investor's express prior consent.

ARTICLE 11

INDEMNIFICATION AND INSURANCE

11.1 Indemnification by Each Party.

11.1.1 By Investors. Each Investor will, severally and not jointly, indemnify and hold Opthea, its Affiliates and its and their respective officers, directors, employees and agents (the "Opthea Indemnified Parties") harmless from any and all Losses awarded against or incurred or suffered by such Opthea Indemnified Party, whether or not involving a claim or demand made by any Person other than Opthea or an Investor or Collateral Agent against an Opthea Indemnified Party or an Investor Indemnified Party, as applicable (a "Third Party Claim"), arising or resulting from (a) any breach of any of the representations and warranties of such Investor in this Agreement or (b) any breach of any of the covenants or agreements made by such Investor in this Agreement. Any amounts due to any Opthea Indemnified Party hereunder shall be payable by such Investor to such Opthea Indemnified Party upon demand.

11.1.2 By Opthea. Opthea will indemnify and hold each Investor, its Affiliates, its investors and its and their respective officers, directors, employees and agents (the "Investor Indemnified Parties"), harmless from any and all Losses awarded against or incurred or suffered by such Investor Indemnified Party, whether or not involving a Third Party Claim, arising or resulting from (a) any breach of any of the representations and warranties of Opthea in this Agreement or (b) any breach of any of the covenants or agreements made by Opthea in this Agreement (provided that the foregoing shall exclude any indemnification to any Investor Indemnified Party that results from the bad faith, gross negligence or willful misconduct of any Investor Indemnified Party). Any amounts due to any Investor Indemnified Party hereunder shall be payable by Opthea to such Investor Indemnified Party upon demand.

11.2 Indemnification Procedure for Third Party Claims.

11.2.1 Notice of Claim. A Party believing that it is entitled to indemnification in respect of Losses under Section 11.1.1 or Section 11.1.2 (an "Indemnified Party") involving a Third Party Claim will give prompt written notice (an "Indemnification Claim Notice") to the indemnifying Party (the "Indemnifying Party") upon receipt of notice of the commencement of any Third Party Claim for which indemnification may be sought, or if earlier, upon the assertion of any such Third Party Claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 11.2.1 will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Each such notice will contain a description of the Third Party Claim and the nature and amount of the Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party will furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

11.2.2Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party will not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party that is reasonably satisfactory to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of such Third Party Claim.

11.2.3Right to Participate in Defense. Without limiting Section 11.2.2, the Indemnified Party will be entitled to (a) participate in, but not control, the defense of such Third Party Claim and to engage counsel of its choice for such purpose; provided, however, that such engagement will be at the Indemnified Party's own expense unless the engagement thereof has been specifically authorized by the Indemnifying Party in writing, and (b) control its defense of such Third Party Claim and to engage counsel of its choice for such purpose, at the expense of the Indemnifying Party, if the Indemnifying Party has failed to assume the defense and engage counsel in accordance with Section 11.2.2.

11.2.4Settlement. With respect to any Losses related solely to payment of money damages in connection with a Third Party Claim that (a) includes a complete and unconditional release of the Indemnified Party, (b) will not result in the Indemnified Party admitting liability, becoming subject to injunctive or other equitable relief that will otherwise adversely affect the business of the Indemnified Party in any manner, and (c) as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.2.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, only if it obtains the prior written consent of the Indemnified Party (which consent will not be unreasonably withheld, conditioned or delayed). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by the Indemnified Party that is reached without the written consent of the Indemnifying Party (which consent will not be unreasonably withheld, conditioned or delayed). Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld or delayed.

11.2.5Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will reasonably cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

11.2.6A claim by an Indemnified Party under Section 11.1 for any matter not involving a Third Party Claim and in respect of which such Indemnified Party would be entitled to indemnification hereunder may be made by delivering, in good faith, a written notice of demand to the Indemnifying Party, which notice shall contain (a) a description and the amount of any Losses incurred or suffered or a reasonable estimate of Losses reasonably expected to be incurred or suffered by the Indemnified Party, (b) a statement that the Indemnified Party is entitled to indemnification under Section 11.1.1 or 11.1.2, as applicable, for such Losses and a reasonable explanation of the basis therefor, and (c) a demand for payment in the amount of such Losses or a reasonable estimate of such Losses. For all purposes of this Section 11.2.6, Opthea shall be entitled to deliver such notice of demand to the indemnifying Investor on behalf of the Opthea Indemnified Parties, and each Investor shall be entitled to deliver such notice of demand to Opthea on behalf of the such Investor's Investor Indemnified Parties.

11.3Insurance.

11.3.1Generally. Commencing as of the Original Effective Date and thereafter during the Development Term, Opthea will carry and maintain, at its own expense, insurance coverage of the kind and with liability limits that, at a minimum, satisfy the requirements listed below with insurers with a minimum "A-" A.M. Best rating. Any deductibles for such insurance policies will be assumed by Opthea. Such insurance policies will be primary and non-contributing with respect to any other similar insurance policies available to each Investor and its Affiliates. Prior to the Original Effective Date, and annually, at each anniversary of the Original Effective Date (unless, during such year, expiration of the applicable policy occurs first, in which case, on such expiration date), at any of the Investors' written request, Opthea will supply documentation of such insurance coverage via original certificates of insurance, if applicable. Opthea will provide Investors with a minimum of thirty (30) days prior written notice if it is unable to obtain appropriate insurance coverage or if its coverage is canceled, unable to be renewed or materially changed. For clarity, any insurance coverage or the failure to maintain adequate insurance coverage does not limit or reduce Opthea's liability under this Agreement. Opthea will ensure that no subcontractor, including any Permitted Third Party, will continue to perform the work unless such subcontractor is insured as deemed appropriate by Opthea.

11.3.2Minimum Requirements. Commencing on the Original Effective Date and thereafter during the Term (or longer if otherwise stated below), Opthea will maintain the following types of insurance coverage at a minimum level that is the greater of (a) the highest

minimum level required by Applicable Law in the countries in which the Product Clinical Trials and other obligations hereunder are being performed or (b) the following (to the extent different).

11.3.2.1 Commercial General Liability: [***] per occurrence; [***] aggregate, including Premises & Operations, and Personal Injury.

11.3.2.2 Excess Liability: [***] per occurrence; [***] aggregate, including Premises & Operations and Personal Injury.

11.3.2.3 Clinical Trials Liability: [***] per occurrence and in the aggregate. Opthea will obtain such Clinical Trials Liability insurance on a global basis, and, if required, supplemented Clinical Trials Liability insurance in the US, at its expense. Coverage must be maintained for as long as required by Applicable Law in each country after release of the last Subject from the Product Clinical Trials or where there is no legal requirement at least [***] after the termination of the Agreement.

11.3.2.4 Professional Liability: Each clinical research organization who provides professional services to Opthea for a Product Clinical Trial will obtain Professional Liability Insurance in lieu of Clinical Trial Insurance, with a minimum limit of [***] per occurrence. Coverage must be maintained for at least [***] after the later of (i) expiration or early termination of this Agreement and (ii) release of the last Subject from the Product Clinical Trials.

11.3.3 Additional Insured. Opthea will include Investors and their Affiliates as additional insured parties on Opthea's global Clinical Trial Liability insurance policy, as set forth in Section 11.3.2.3, for [***] after the later of termination of this Agreement or release of the last Subject from the Product Clinical Trials.

11.3.4 Product Liability Insurance. Opthea will be responsible for maintaining product liability insurance related to the Development and Commercialization of the Product at its expense.

ARTICLE 12 REPRESENTATIONS AND WARRANTIES; ADDITIONAL COVENANTS

12.1 Representations and Warranties of the Parties.

12.1.1 Each Party hereby represents and warrants that it has the requisite corporate power and authority to enter into this Agreement and that this Agreement constitutes a legal and valid obligation binding upon such Party, enforceable in accordance with its terms.

12.1.2 Each Party hereby represents and warrants that it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement.

12.1.3 [***].

12.2Additional Opthea Representations, and Warranties. Opthea hereby represents and warrants to each Investor that:

12.2.1No Contravention. The execution, delivery and performance by Opthea of this Agreement and each of the other Transaction Agreements, and the execution, delivery and performance by each Subsidiary of Opthea that is party to a Transaction Agreement, have been duly authorized by all necessary corporate or other organizational action, and do not and will not (a) contravene the terms of Opthea's or such Subsidiary's organizational documents; (b) conflict with or result in any breach or contravention of, or the creation of (or the requirement to create) any lien or encumbrance under, or require any payment to be made under (i) any contractual obligation to which Opthea or any of its Subsidiaries is a party or affecting Opthea or the properties of Opthea or any of its Subsidiaries or (ii) any order, injunction, writ or decree of any governmental authority or any arbitral award to which Opthea or its Subsidiaries or their respective property is subject; or (c) violate any Applicable Law, except in the case of this Section 12.2.1, with respect to any conflict, breach, violation, or payment, to the extent that such conflict, breach, violation, or payment would not reasonably be expected to have a material adverse effect on Opthea's ability to satisfy its obligations under this Agreement.

12.2.2Licensure, Registration and Accreditation. Opthea is licensed, registered, or otherwise qualified under all Applicable Laws to do business in each jurisdiction where such licenses, registrations or other qualifications are required.

12.2.3Manufacturing Agreements. As of the Restatement Effective Date, each agreement or arrangement (including any memorandum of understanding regarding a future agreement and any statement of work) between Opthea or any of its Affiliates and any Third Party related to the production, manufacture, supply, process of formulating, processing, filling, finishing, packaging, labeling, shipping, importing and storage of the Product or any active ingredient used in combination with the product, including, but not limited to, aflibercept and ranibizumab (including bulk drug product, bulk drug substance and finished product) (each, together with any amendment, supplement or modification thereto, an "Existing Contract Manufacturing Agreement") is listed on Schedule 12.2.3. A true, correct, and complete copy of Existing Contract Manufacturing Agreement has been made available to each Investor. There is and has been no material breach or default under any provision of any Existing Contract Manufacturing Agreement either by Opthea or by the respective counterparty (or any predecessor thereof) thereto.

12.2.4Debarment. Neither it, nor its Affiliates, nor, to its Knowledge, any Permitted Third Parties engaged by it to perform activities in relation to the Product are debarred or has been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. § 335a or any similar Applicable Laws, and that it has not used and will not knowingly use in any capacity the services of any Person or Permitted Third Party debarred (or otherwise disqualified) to conduct the Product Clinical Trials. Opthea further certifies that neither it, nor any of its Affiliates, are excluded or has been convicted of any crime of engaged in any conduct for which such person or entity could be excluded from any federal health care program, including but not limited to Medicare and Medicaid. No debarment or exclusionary claims, actions, proceedings or investigations are pending or threatened against Opthea or any of its Affiliates, or, to the Knowledge of Opthea, any of their respective representatives. Opthea further

represents and warrants that neither Opthea nor any of its Affiliates, nor any representative of Opthea or any of its Affiliates, has made an untrue statement of a material fact or fraudulent statement to any Regulatory Authority, failed to disclose a material fact required to be disclosed to any Regulatory Authority, or committed an act, made a statement, or failed to make a statement, including with respect to any scientific data or information, that, at the time such disclosure was made or failure to disclose occurred, would reasonably be expected to provide a basis for any Regulatory Authority to invoke the FDA policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991), or any similar policy. Opthea will notify Investors promptly if any of the representations in this Section 12.2.4 become incorrect.

12.2.5Clinical Trial Permits; Certifications; Authorizations. As of the Restatement Effective Date, it and its Permitted Third Parties have, or will have at the required times, such INDs or other filings with all Regulatory Authorities as are required to conduct the Product Clinical Trials and perform any and all of their obligations in connection with the Product Clinical Trials supervised by it. All such INDs and other filings are (i) valid and in full force and effect and no default has occurred, (ii) validly registered and on file with applicable Regulatory Authorities, (iii) in compliance with all formal filing and maintenance requirements, and (iv) in good standing, valid and enforceable. Opthea and its Affiliates have filed (or are in the process of making the filings of) all required notices and responses to notices, supplemental applications, reports (including all adverse event/experience reports) and other required information with the FDA and all other applicable Regulatory Authorities, and all such information is accurate and complete in all material respects. Except as has been made available to Investors, Opthea has not received any notice that the FDA, other Regulatory Authority, institutional review board or independent ethics committee, has initiated, or threatened to initiate, a Clinical Hold or any action to suspend, delay or terminate any IND or otherwise restrict the preclinical or clinical research of either Product.

12.2.6Disclosure of Regulatory Communications. As of the Original Effective Date, the regulatory communications including, if any, meeting minutes, annual reports, notices of inspection, inspection reports, warning or untitled letters, notices of adverse findings, deficiency letters related to the Product, and similar documents made available by Opthea in the Data Room were true and complete copies of such documents. Opthea hereby represents and warrants that such documents comprise all material written regulatory communications related to Opthea or any of its Affiliates, the conduct of the Development Program, or the Product submitted by Opthea or its Affiliates to or received by Opthea or its Affiliates from the FDA and all other applicable Regulatory Authorities as of the Original Effective Date.

12.2.7CRO Inquiry. Up to and as at the Restatement Effective Date, after due inquiry to all applicable CROs responsible for conducting the Product Clinical Trials, Opthea has not received any verbal or written notice of the occurrence of any Serious Safety Issue in the Product Clinical Trials.

12.2.8Compliance. The Product is and has been researched, developed, manufactured, processed, stored, labeled, supplied, promoted, tested, imported, exported, distributed, marketed, licensed, sold or otherwise commercialized by or on behalf of Opthea or any of its Affiliates in compliance in all material respects with all applicable Health Laws. None of Opthea or any of its Affiliates has received any written notice or other communication from any

Regulatory Authority alleging any material violation of any Health Law and there are no investigations, suits, claims, actions or proceedings against or affecting the Product, the Development Program, or Opthea or any of its Affiliates relating to or arising under Health Laws or any Applicable Laws relating to government health care programs, private health care plans or the privacy and confidentiality of patient health information.

12.2.9Preclinical and Clinical Activities. Prior to the Restatement Effective Date, (a) it has conducted all preclinical and clinical activities related to the development of the Product in material compliance with Applicable Laws, including GLP and GCP and applicable regulations and guidance that relate to the proper conduct of clinical studies and requirements relating to the protection of human subjects (including "Informed Consent" as such term is defined under Applicable Laws in the United States and equivalent Applicable Laws in other jurisdictions) and Applicable Laws governing the privacy of patient medical records and other personal information and data, and (b) to Opthea's Knowledge, all Third Parties utilized by Opthea to perform any portion of the preclinical and clinical activities have conducted such portion of such preclinical and clinical activities in material compliance with Applicable Laws. Further, no clinical investigator, researcher, or clinical staff participating in any Product Clinical Trial conducted by or on behalf of Opthea or any of its Affiliates, or in which Opthea or any of its Affiliates have participated, has been disqualified from participating in studies involving the Product, and to Opthea's Knowledge, no such administrative action to disqualify such clinical investigators, researchers or clinical staff has been threatened or is pending.

12.2.10Manufacturing. The manufacture of the Product, including any clinical supplies used in clinical trials, by or on behalf of Opthea and any of its Affiliates has been conducted in material compliance with the applicable specifications and requirements of Good Manufacturing Practices and all other Applicable Laws. No manufacturing site used for the manufacture of the Product is subject to a Regulatory Authority shutdown or import or export prohibitions or has received any Form FDA 483, notice of violation, warning letter, untitled letter or similar correspondence or notice from the FDA or other Regulatory Authority alleging or asserting noncompliance with any Applicable Law, and to Opthea's Knowledge, neither the FDA or any other Regulatory Authority is considering such action. In addition, Opthea and each of its Affiliates are in material compliance with all applicable registration and listing requirements, including those set forth in 21 U.S.C. § 360 and 21 C.F.R. Part 207 and all similar Applicable Laws. To Opthea's Knowledge, no Product has been adulterated or misbranded.

12.2.11Intellectual Property.

12.2.11.1 It, or a wholly-owned Subsidiary of it that is party to the Guaranty and the Australian General Security Deed, owns or possesses sufficient legal rights to all patents, trademarks, service marks, trade names, copyrights, trade secrets, information, proprietary rights and processes necessary for the Development, manufacture and Commercialization of the Product as currently conducted and proposed to be conducted with respect to the Product.

12.2.11.2 Neither Opthea nor any of its Subsidiaries is a party to any past or pending, and neither Opthea nor any of its Subsidiaries has received notice of any, action, suit, proceeding, investigation, or claim that claims

or alleges that the Development, manufacture and Commercialization of the Product by Opthea as currently conducted with respect to the Product infringes, misappropriates, or otherwise violates any patents, trademarks, service marks, trade names, copyrights, trade secrets or other intellectual property rights of any Third Party. To the Knowledge of Opthea, no circumstances have occurred or are occurring that would reasonably be expected to give rise to or serve as a basis for any action, suit, proceeding, investigation, or claim that claims or alleges that the Development, manufacture and Commercialization of the Product by Opthea as currently conducted and proposed to be conducted with respect to the Product infringes or will infringe, misappropriates or will misappropriate, or otherwise violates or will violate any patents, trademarks, service marks, trade names, copyrights, trade secrets or other intellectual property rights of any Third Party. Opthea has not received any communications alleging that Opthea has violated, or that the Development, manufacture or Commercialization of the Product does or will violate, any of the patents, trademarks, service marks, trade names, copyrights, trade secrets or other intellectual property rights of any Third Party. To the Knowledge of Opthea, no Person has infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any of the Product IP.

12.2.11.3 There are no outstanding options, licenses or agreements of any kind granted by or to Opthea relating to the Development, manufacture or Commercialization of the Product, except as set forth on Schedule 12.2.11.3.

12.2.11.4 Opthea, whether directly or through a wholly-owned Subsidiary of Opthea that is party to the Guaranty and the Australian General Security Deed, is the sole and exclusive registered owner of all Product IP. Schedule 12.2.11.4 hereto sets forth an accurate and complete list of all Patents included in the Product IP (the "Product Patents") as of the Restatement Effective Date. For each Product Patent, Opthea has indicated (i) the jurisdiction in which such Patent is pending, allowed, granted or issued, (ii) the patent number or patent serial number, (iii) the owner of such Patent, and (iv) the expiration date of the Patent. All of the patents within the Product Patents that have been issued or granted by the applicable patent office are valid and enforceable and in full force and effect, and have not lapsed, expired or otherwise terminated.

12.2.11.5 Opthea has not received any notice or legal opinion, whether preliminary in nature or qualified in any manner, which concludes that a challenge to the validity or enforceability of any of the issued Product Patents may succeed or otherwise alleges that an issued Product Patent is invalid or unenforceable.

12.2.11.6 Opthea has not received any claim or notice challenging, or threatening to challenge, the ownership of, or rights of Opthea or its Subsidiaries in and to or the validity or enforceability of the Product Patents. Neither Opthea nor any of its Subsidiaries has committed any act, or failed to commit any

required act that would reasonably be expected to cause any Product Patent to expire prematurely, lapse or be declared invalid or unenforceable, or that estops the enforcement of such Product Patent against any Third Party.

12.2.11.7 Opthea has not received any notice that there is any, and, to the Knowledge of Opthea, there is no, Person who is or claims to be an inventor under any of the Product Patents who is not a named inventor thereof.

12.2.11.8 Except as set forth on Schedule 12.2.11.8(a), there are no In-Licenses (any In-License set forth on Schedule 12.2.11.8(a), an "Existing In-License"). A true, correct and complete copy of each Existing In-License has been provided to Investors by Opthea in the Data Room. Neither Opthea nor the respective counterparty thereto have made or entered into any amendment, supplement or modification to, or granted any waiver under any provision of each Existing In-License except as set forth on Schedule 12.2.11.8(b).

12.2.11.9 Each Existing In-License is a valid and binding obligation of Opthea and, to the Knowledge of Opthea, the counterparty thereto. Each Existing In-License is enforceable against Opthea and, to the Knowledge of Opthea, against each counterparty thereto in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law). Opthea has not received any written notice in connection with any Existing In-License challenging the validity, enforceability or interpretation of any provision of such agreement.

12.2.11.10 Opthea has not (A) given notice to a counterparty of the termination of any Existing In-License (whether in whole or in part) or any notice to a counterparty expressing any intention or desire to terminate any Existing In-License or (B) received from a counterparty thereto any written notice of termination of any Existing In-License (whether in whole or in part) or any written notice from a counterparty expressing any intention or desire to terminate any Existing In-License.

12.2.11.11 There is and has been no material breach or default under any provision of any Existing In-License either by Opthea or, to the Knowledge of Opthea, by the respective counterparty (or any predecessor thereof) thereto, and there is no event that upon notice or the passage of time, or both, would reasonably be expected to give rise to any breach or default either by Opthea or, to the Knowledge of Opthea, by the respective counterparty to such agreement. Opthea has not notified the respective counterparty to any Existing In-License or any other Person of any claims for indemnification under any Existing In-License nor has Opthea received any claims for indemnification under any Existing In-License.

12.2.11.12 Opthea has not received any written notice from, or given any written notice to, any counterparty to any Existing In-License regarding any infringement of any of Product Patents licensed thereunder.

12.2.12Opthea Data Provided as of the Original Effective Date. Up to and as of the Original Effective Date, (i) the CMC Information set forth in the Data Room is accurate in all material respects, (ii) the descriptions of, Protocols for, and data and other results of, the Product Clinical Trials conducted by or on behalf of Opthea set forth in the Data Room are accurate and complete and there are no omissions from such documents, data and other results that render such documents, data or other results materially misleading and (iii) the summaries of primary data regarding the Product set forth in the Data Room are accurate and complete in all material respects, and there are no omissions from such summaries as so presented that render such summaries materially misleading.

12.2.13Provision of Information. All information made available by or on behalf of Opthea to Investors or their respective Affiliates with regard to the Product or the Product Clinical Trials in connection with this Agreement was (when provided) and is (as of the Restatement Effective Date) true, accurate and complete in all material respects, and that Opthea has not knowingly or, to Opthea's and its Affiliates' Knowledge (after due inquiry), negligently failed to disclose to Investors any information in its or its Affiliates' control or possession, or of which Opthea is aware, that would be reasonably necessary to make any information that has been disclosed to Investors prior to the Restatement Effective Date with respect to the Product and the Development activities contemplated under this Agreement not misleading in any material respect, including any information regarding any impact on the manufacturing, supply chain, Development or Commercialization of the Product resulting from the coronavirus identified as COVID-19 (and/or variants thereof).

12.2.14Security Interest; Priority. As of the Restatement Effective Date, (a) this Agreement creates a valid security interest in favor of the Collateral Agent in the Collateral and, when properly perfected by filing, will constitute a valid and perfected first priority security interest in the Collateral, to the extent such security interest can be perfected by filing under the UCC, free and clear of all Liens except for Permitted Liens, (b) Opthea has not authenticated any agreement authorizing any secured party thereunder to file a financing statement, except to perfect Permitted Liens, (c) with respect to the Development Costs Account, upon execution and delivery of the Deposit Account Control Agreement, the Collateral Agent will have a valid and perfected, first-priority security interest in the Development Costs Account.

12.2.15Contingent Liabilities. Except as reflected in Opthea's consolidated balance sheet or notes to Opthea's financials for the year ended June 30, 2023 included in its Annual Report on Form 20-F for the year ended June 30, 2023, as of the Restatement Effective Date, Opthea and its Subsidiaries do not have any contingent liabilities that would be required to be reflected on Opthea's balance sheet or in the notes to Opthea's financials in accordance with Accounting Standards except for (i) obligations in connection with this Agreement, and (ii) other contingent liabilities incurred in the ordinary course of business that are not material to the business of Opthea and its Subsidiaries, taken as a whole.

12.2.16Brokers' Fees. Except as set forth on Schedule 12.2.16, there is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Opthea who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

12.2.17National Security Land. Neither Opthea nor any of its Subsidiaries that is party to a Transaction Agreement (i) owns (whether legally or beneficially), or operate, a business that is a "national security business"; or (ii) holds any interest (whether legal or equitable) in Australian land that is "national security land" (with "national security business" and "national security land" having their respective meanings as provided by the Foreign Acquisitions and Takeovers Act 1975 (Cth of Australia).

12.2.18No Illegal and Improper Business Practices. Opthea, its Subsidiaries and its and their respective Representatives (a) have not obtained or induced directly or indirectly through any person and will not attempt to so obtain or induce the procurement of this Agreement or any contract, consent, approval, right, interest, privilege or other obligation or benefit related to this Agreement or a favorable relationship with [***] through any violation of any applicable law or regulation; and (b) have not given or agreed to give and shall not give or agree to give to any person, either directly or indirectly, any placement fee, introductory fee, arrangement fee, finder's fee or any other fee, compensation, monetary benefit or any other benefit, gift, commission, gratuity, bribe or kickback, whether described as a consultation fee or otherwise ("Fees"), with the object of obtaining or inducing the procurement of this Agreement or any contract, right, interest, privilege or other obligation or benefit related to this Agreement, except as may be set out in a separate schedule to this Agreement. For the avoidance of doubt, the following shall not be deemed to be Fees within the meaning of this paragraph: (i) any payments that are legitimate in the normal course of business between each party hereto pursuant to this Agreement, (ii) items, including refreshments, of an inconsequential or immaterial cost or value, and (iii) the regular and customary compensation and benefits received by any party's employees in the ordinary course of business and consistent with past practice.

12.3Investor Representation, Warranty and Covenant. Each Investor hereby represents, warrants and covenants that it will have, as and when needed, sufficient funds to satisfy its obligations hereunder. Such Investor does not assume any obligations to, and will have no rights to engage in, any research, Development, promotion and/or Commercialization of the Product, which remains the sole responsibility of Opthea. Such Investor further represents that it (i) is not organized or operating in a jurisdiction subject to a U.S. government embargo, including Cuba, Iran, North Korea, Syria, the Crimea Region, the Donetsk People's Republic and Luhansk People's Republic located in Ukraine, and (ii) does not appear on and is not otherwise subject to sanctions administered by U.S. or Australian Governmental Authorities, including being designated under the Foreign Sanctions Evaders List or the Specially Designated Nationals and Blocked Persons List administered by the Department of the Treasury's Office of Foreign Assets Control, or (ii) the Entity List, Denied Persons List, or Unverified List maintained by the Department of Commerce's Bureau of Industry and Security (collectively, the "Restricted Party Lists").

12.4Additional Opthea Covenants.

12.4.1Commercialization Licenses.

12.4.1.1 Opthea shall promptly (and in any event within ten (10) Business Days) provide Investors with (i) executed copies of each executed Commercialization License, and (ii) executed copies of each amendment,

supplement, modification or written waiver of any provision of any Commercialization License.

12.4.1.2 Opthea will use Commercially Reasonable Efforts to include in each Commercialization License (i) provisions permitting Opthea to audit the applicable Commercialization Partner on terms and conditions consistent in all material respects with Investors' rights to audit Opthea set forth in Section 8.3 and (ii) provisions requiring the applicable Commercialization Partner to exercise efforts no less stringent, in all material respects, than Commercially Reasonable Efforts in Commercializing the Product and maximizing Net Sales of the Product.

12.4.1.3 Opthea shall provide Investors prompt written notice of any Commercialization Partner's breach or default under the Commercialization License(s) to which it is party, to the extent Opthea gains Knowledge thereof. Opthea shall provide Investors with written notice following the termination of any Commercialization License.

12.4.2Anti-Corruption. Opthea agrees, on behalf of itself and Subsidiaries and its and their respective Representatives, that in the performance of its obligations hereunder:

12.4.2.1 Opthea, its Subsidiaries and its and their respective Representatives will comply with the Anti-Corruption Laws and will not take any action that will, or would reasonably be expected to, cause Investors or its Affiliates to be in violation of any Anti-Corruption Laws; and

12.4.2.2 Opthea will promptly provide Investors with written notice of the following events: (a) upon becoming aware of any breach or violation by Opthea, its Affiliates or any of its or their respective Representatives of any representation, warranty or undertaking set forth in Section 12.4.2.1, or (b) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

12.4.3Required Permits. Opthea covenants that it and its Permitted Third Parties have, or will have at the required times, such INDs or other filings with all Regulatory Authorities as are required to conduct the Product Clinical Trials and perform any and all of their obligations in connection with the Product Clinical Trials supervised by it.

12.4.4Intellectual Property. Opthea covenants that, except as otherwise agreed in writing by the Required Investors, all Product IP owned by Opthea as of the Restatement Effective Date or which Opthea owns in the future will at all times during the Term continue to be owned by Opthea or a wholly owned Subsidiary of Opthea party to the Guaranty and the Australian General Security Deed.

12.4.5In-Licenses. Opthea shall comply in all material respects with its obligations under any In-Licenses and shall not take any action or forego any action that would reasonably be expected to result in a material breach thereof. Promptly, and in any event within five (5) Business Days, after receipt of any (written or oral) notice from a counterparty to any In-License or its Affiliates of an alleged material breach under any In-License, Opthea shall provide Investors a copy thereof. Opthea shall use Commercially Reasonable Efforts to cure any material breaches by it under any In-License and shall give written notice to Investors upon curing any such breach. Opthea shall provide Investors with written notice following becoming aware of a counterparty's material breach of its obligations under any In-License. Opthea shall not terminate any In-License without providing Investors prior written notice. Promptly, and in any event within five (5) Business Days following Opthea's notice to a counterparty to any In-License of an alleged breach by such counterparty under any such In-License, Opthea shall provide Investors a copy thereof.

12.4.6DISCLAIMER OF REPRESENTATIONS AND WARRANTIES. EXCEPT AS OTHERWISE SET FORTH IN THIS ARTICLE 12, NO PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, EITHER ORAL OR WRITTEN, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING THE USE, RESULTS OR EFFICACY OF THE PRODUCT.

ARTICLE 13

TERM; CLOSING CONDITIONS; AND TERMINATION

13.1Term. The term of this Agreement (the "Term") will commence on the Original Effective Date and will expire upon the earliest of (i) termination of this Agreement in accordance with Section 13.4, or (ii) the time that Investors have received Success Payments, in the aggregate, equal to the Fixed Return Cap.

13.2Pre-Signing Conditions.

13.2.1[Reserved].

13.2.2Australian General Security Deed. On or before the Restatement Effective Date, Opthea will execute and deliver to Collateral Agent the Australian General Security Deed, as set forth in Section 7.4.1(a), as such Australian General Security Deed may be amended, to reflect the Collateral Agent and the Investors as secured parties thereunder.

13.2.3Guaranty. On or before the Restatement Effective Date, Opthea will cause to be executed and delivered to Collateral Agent and each Investor the Guaranty, as set forth in Section 7.4.1(a) , as may be amended, to reflect the Collateral Agent and each Investor as beneficiaries thereunder.

13.2.4[Reserved].

13.2.5Opinion. On or before the Restatement Effective Date, Opthea will deliver to each Investor an executed opinion of (i) Cooley LLP in its capacity as U.S. counsel to Opthea, and (ii) DLA Piper Australia in its capacity as Australian counsel to Collateral Agent, each dated as of the date hereof.

13.2.6[Reserved].

13.2.7IRS Withholding Form. On or prior to the Restatement Effective Date, Opthea will execute and deliver to [***] a valid and complete IRS Form W-8BEN-E.

13.2.8[Reserved].

13.3Post-Signing Deliverables.

13.3.1Data Room. No later than five (5) days following the Restatement Effective Date, Opthea (i) shall provide [***] with a copy of the Data Room as it existed as of the Original Effective Date, or (ii) if such a copy is not available, shall provide copies of any documents available in the Data Room as of the Original Effective Date to [***] upon such [***]'s request.

13.4Termination.

13.4.1Mutual Termination. This Agreement may be terminated at any time by mutual written agreement of all of the Investors and Opthea.

13.4.2Fundamental Material Breach. This Agreement may be terminated immediately and in its entirety: (i) by Opthea, in the event of a failure to fund by any Investor as set forth in Section 4.1 and Section 4.2, (ii) by the Required Investors in the event of the failure by Opthea to pay any Success Payment when due, (iii) by the Required Investors, in the event of a breach by Opthea of Section 2.1, Section 3.3, Section 3.7, or Section 10.3.1 ([***]), (iv) by the Required Investors, in the event of a failure by Opthea to complete a Clinical Trial Activity within thirty (30) days (or such longer period as may be agreed to between Opthea and the Required Investors) following the date specified for completion on the applicable Timeline Remediation Plan, pursuant to Section 2.4.3 ([***]), or (v) by the Required Investors, in the event of a failure by Opthea to use Commercially Reasonable Efforts to Develop, Commercialize and maximize Net Sales of the Product as set forth herein ([***]), provided, in each case (i) through (v), that (A) the failing or breaching Party has received written notice from the non-breaching Party of such breach, specifying in reasonable detail the particulars of the alleged breach and (B) solely if the consequences of such failure or breach can be cured, such breach or failure has not been cured within [***] after the date of the relevant notice, in the case of clauses (i) and (ii), or [***] after the date of the relevant notice, in the case of clauses (iii) (except with respect to Section 3.7.2) and (v). The non-breaching Party will have the right to pursue remedies it may have at law or equity for such breach, including the right to seek damages from the breaching Party.

13.4.2.1 By Required Investors. In the event that the Required Investors terminate this Agreement pursuant to clause (iii) or (iv) of Section 13.4.2, Opthea will pay each Investor within [***] of the date of termination, an amount equal to the Development Costs paid by such Investor

prior to the effective date of such termination multiplied by the MoIC, reduced by the amount of any Success Payments or Change of Control Payment previously paid by Opthea to such Investor.

13.4.2.2 By Opthea. In the event that Opthea terminates this Agreement pursuant to clause (i) or (ii) of Section 13.4.2, Opthea will not be required to pay any further Success Payments.

13.4.3Termination for Material Breach. In the event of a material breach of this Agreement not otherwise covered in Section 13.4.2, Opthea (in the case of a breach by Investors) or the Required Investors (in the case of a breach by Opthea) will have the right to terminate this Agreement on [***] written notice to the breaching Party (which notice shall specify in reasonable detail the particulars of the alleged breach), unless (solely if the consequences of such breach can be cured) the breaching Party cures such breach within such [***] period. The non-breaching Party will have the right to pursue remedies it may have at law or equity for such breach, including the right to seek damages from the breaching Party.

13.4.3.1 If the Required Investors terminate this Agreement pursuant to this Section 13.4.3, Opthea will pay each Investor, within [***] following the date of termination, an amount equal to [***] of the Development Costs paid by such Investor prior to the effective date of such termination, reduced by the amount of any Success Payments or Change of Control Payment previously paid by Opthea. In the event that the Required Investors terminate this Agreement pursuant to this Section 13.4.3.1, and Opthea has achieved the Success Payment Trigger prior to such termination or elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to Investors any Success Payments that become due and payable pursuant to Article 6 at the time that such payments become due and payable pursuant to Article 6, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3 and the Fixed Return Cap will be reduced by the amount previously paid to Investor as set forth in this Section 13.4.3.1.

13.4.3.2 If Opthea terminates this Agreement pursuant to this Section 13.4.3.2, and Opthea has achieved the Success Payment Trigger prior to such termination or elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to Investors any Success Payments that become due and payable pursuant to Article 6 at the time that such payments become due and payable pursuant to Article 6, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3.

13.4.3.3 [***].

13.4.4Termination by Investors for Material Adverse Event. If a Material Adverse Event occurs, the Required Investors will have the right to terminate this Agreement on [***] written notice to Opthea, unless (solely if the consequences of such Material Adverse Event can

be cured) the Material Adverse Event is cured by Opthea within such [***] period. If the Required Investors terminate this Agreement pursuant to this Section 13.4.4 and Opthea has achieved the Success Payment Trigger prior to such termination or elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to Investors any Success Payments that become due and payable pursuant to Article 6 at the time that such payments become due and payable pursuant to Article 6, provided that the Fixed Success Payment and the Fixed Return Cap will be adjusted as set forth in Section 6.3.

13.4.5Termination for Failure to Receive Regulatory Approval.

13.4.5.1 Failure to Obtain Regulatory Approval. This Agreement will, upon written notice from either Opthea or the Required Investors to the other Party, terminate in its entirety with no further action from any Party, if the Product has not received Regulatory Approval following conduct and completion of the Product Clinical Trials, Opthea's submission of applications for Regulatory Approval in the U.S., EU or UK in accordance with this Agreement, and Opthea's use of Commercially Reasonable Efforts to obtain such Regulatory Approvals in accordance with this Agreement. For the avoidance of doubt, if Regulatory Approval is received in any jurisdiction, then this Agreement may not thereafter be terminated pursuant to this Section 13.4.5.1.

13.4.5.2 Development Program Failure. The Required Investors will have the right to terminate this Agreement upon written notice to Opthea if the ShORe Trial or the COAST Trial is completed or terminated and either (i) the primary endpoint in such trial is not achieved, or (ii) the Required Investors reasonably determine that the Research Results of such trial do not support Regulatory Approval. For the avoidance of doubt, if an application for Regulatory Approval is accepted for filing by a Regulatory Authority in the U.S, EU or UK then this Agreement may not thereafter be terminated pursuant to this Section 13.4.5.2.

13.4.5.3 If the Required Investors terminate this Agreement pursuant to this Section 13.4.5 and Opthea elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to Investors any Success Payments that become due and payable pursuant to Article 6 at the time that such payments become due and payable pursuant to Article 6, reduced by the amount of any Change of Control Payment previously paid by Opthea, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3.

13.4.6Termination for Bankruptcy. This Agreement may be terminated by the Required Investors if Opthea (a) (i) commences a voluntary case under the U.S. federal or Australian bankruptcy or insolvency laws (as now or hereafter in effect), (ii) files a petition seeking to take advantage of any other Applicable Laws relating to bankruptcy, insolvency, reorganization, winding up or composition for adjustment of debts, (iii) consents to or fails to contest within [***] and in appropriate manner any petition filed against it in an involuntary case under such bankruptcy

laws or other laws, (iv) applies for or consents to, or fails to contest within [***] and in appropriate manner, the appointment of, or the taking of possession by, a receiver, custodian, trustee, administrator, or liquidator of itself or of a substantial part of its property, (v) admits in writing its inability to pay its debts as they become due (or, in respect of Opthea, is presumed or deemed at law to be unable to pay its debts as they fall due), (vi) makes a general assignment for the benefit of creditors, or (vii) takes any corporate action for the purpose of authorizing any of the foregoing; or (b) is subject to a case or other proceeding that is commenced against it in any court of competent jurisdiction seeking (i) relief under the U.S. federal or Australian bankruptcy or insolvency laws (as now or hereafter in effect) or under any other Applicable Laws relating to bankruptcy, insolvency, reorganization, winding up or adjustment of debts, or (ii) the appointment of a trustee, receiver, custodian, liquidator, administrator, or the like for it or all or any substantial part of its assets, and under either clause (i) or (ii), such case or proceeding has continued without dismissal or stay for a period of [***] or an order granting the relief requested in such case or proceeding is entered. This Agreement may be terminated by Opthea if all of the Investors are subject to any of the conditions set forth in limbs (a) and (b) in the foregoing sentence.

13.4.6.1 In the event that the Required Investors terminate this Agreement pursuant to this Section 13.4.6, then Opthea will pay each Investor an amount equal to the Development Costs paid by such Investor as of the effective date of such termination multiplied by the MoIC, reduced by the amount of any Success Payments or Change of Control Payment previously paid by Opthea to such Investor.

13.4.6.2 In the event that Opthea terminates this Agreement pursuant to this Section 13.4.6, if Opthea has achieved the Success Payment Trigger prior to such termination or elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to each Investor any Success Payments that become due and payable pursuant to Article 6 at such time that such payments become due and payable (if ever) pursuant to Article 6, reduced by the amount of any Change of Control Payment previously paid by Opthea to such Investor, provided that such Fixed Success Payments and Fixed Return Cap will be adjusted as set forth in Section 6.3.

13.4.7Termination for Change of Control.

13.4.7.1 Within [***] following a Change of Control, either Opthea (or its successor in such Change of Control) in its sole discretion, or Investors (provided that all Investors unanimously agree to terminate this Agreement pursuant to this Section 13.4.7) may terminate this Agreement (for the avoidance of doubt, whether or not this Agreement is terminated pursuant to this Section 13.4.7, Opthea (or its successor, if applicable) will pay to Investors the Change of Control Payment pursuant to Section 6.7.3). In the event that Opthea or its successor terminates this Agreement pursuant to this Section 13.4.7, then Opthea will pay to Investors, within [***] after the date of termination, a one-time payment, in lieu of the Success Payments (other than Success Payments already paid), calculated based on the remaining Success Payments in the same manner as the

Approval Buy-Out Payment in Section 6.7.1, if Regulatory Approval has previously been obtained, or in the same manner as the General Buy-Out Payment in Section 6.7.2, if Regulatory Approval has not previously been obtained, and in each case as adjusted pursuant to Section 6.3 and reduced by the Change of Control Payment previously paid.

13.4.7.2 If this Agreement is not terminated pursuant to Section 13.4.7.1, this Agreement shall continue in full force and effect, provided that any Fixed Success Payments and the Fixed Return Cap that become due and payable will be adjusted as set forth in Section 6.3 and the Fixed Return Cap will be reduced by the Change of Control Payment previously paid.

13.4.8Termination for Safety Concerns. Either Opthea or the Required Investors may terminate this Agreement upon written notice to the other Party if (a) the IDMC for a Product Clinical Trial recommends termination of such Product Clinical Trial for reasons pertaining to the health or safety of the Subjects or for futility or (b) all of the Parties mutually agree that a material health or safety concern with respect to the Subjects exists. In the event that Opthea or its successor terminates this Agreement pursuant to this Section 13.4.8, then Opthea will not be obligated to make any Success Payments to the Investors following the effective date of such termination, provided that if Opthea elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to each Investor any Success Payments that become due and payable pursuant to Article 6 at such time that such payments become due and payable (if ever) pursuant to Article 6, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3 and be reduced by the amount of any Change of Control Payment previously paid by Opthea to such Investor. Notwithstanding the foregoing, if this Agreement terminates pursuant to this Section 13.4.8 and the reason for such termination (as set forth in the foregoing (a) or (b), as applicable): (i) arose as a result of gross negligence on the part of Opthea; or (ii) is due to (x) the applicable IDMC recommending termination of the applicable Product Clinical Trial or (y) Opthea and Investors mutually agreeing to terminate the applicable Product Clinical Trial, in either case ((x) or (y)), due to a Serious Safety Issue that was previously known, demonstrated or identified by Opthea as being material prior to or as of the Restatement Effective Date and the material data showing, demonstrating, or identifying such Serious Safety Issue were not included in the Data Room, disclosed in writing to Investors or otherwise publicly known prior to the Restatement Effective Date; then, in either case (i) or (ii), Opthea will pay each Investor within [***] following the date of termination, an amount equal to the Development Costs paid by such Investor as of the effective date of such termination multiplied by the MoIC reduced by the amount of any Success Payments or Change of Control Payment previously paid by Opthea.

13.4.9Termination Because of Adverse Patent Impact. The Required Investors may terminate this Agreement if (a) Opthea is prevented, by final and non-appealable judgment of a court of competent jurisdiction, from further Developing or Commercializing the Product in the U.S. or (b) the future value of the Product is materially adversely affected, in the reasonable judgment of the Required Investors, due to (i) Third Party patents that were not publicly disclosed or known to the Required Investors as of the Original Effective Date that would be infringed by the manufacture, use, sale, offer for sale or import of the Product for the Indication in the U.S. or (ii) the invalidity or unenforceability of any claims of any composition-of-matter Patent within the

Product IP covering the Product in the Indication in the U.S. (in either case ((a) or (b)), an "Adverse Patent Impact"), upon written notice to Opthea if Opthea does not cure such Adverse Patent Impact within a period of [***] from the date of the Required Investors' notice to Opthea of an Adverse Patent Impact. If the Required Investors terminates this Agreement pursuant to this Section 13.4.9 and Opthea has achieved the Success Payment Trigger prior to such termination or elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to each Investor any Success Payments that become due and payable pursuant to Article 6 at such time that such payments become due and payable (if ever) pursuant to Article 6, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3 and the Fixed Return Cap will be reduced by the amount of any Change of Control Payment previously paid by Opthea to such Investor.

13.4.10Termination for JSC Decision. The Required Investors may terminate this Agreement in its entirety at any time Opthea exercises its decision-making authority under Section 5.5 to approve a matter set forth in Section 5.2.2 and, after escalation to the Escalation Designees in accordance with Section 5.5, the Required Investors continue in good faith to disagree with such decision. In the event that the Required Investors terminates this Agreement pursuant to this Section 13.4.10, then Opthea will pay to each Investor, within sixty (60) days of the date of termination, an amount equal to [***] of the Development Costs paid by such Investor as of the effective date of such termination reduced by the amount of any Change of Control Payment previously paid by Opthea to such Investor, and, if Opthea elects to continue Development of the Product and achieves the Success Payment Trigger following such termination, then Opthea will remain obligated to pay to each Investor any Success Payments that become due and payable pursuant to Article 6 at such time that such payments become due and payable (if ever) pursuant to Article 6, provided that the Fixed Success Payments and the Fixed Return Cap will be adjusted as set forth in Section 6.3 and the Fixed Return Cap will be reduced by the amount previously paid to such Investor as set forth in this Section 13.4.10 (including, for the avoidance of doubt, the amount of any Change of Control Payment previously paid by Opthea to such Investor).

13.5Termination for Invalidity and Priority of Security Interest. The Required Investors may terminate this Agreement if any provision related to the security interest granted or purported to be granted in the Collateral to the Collateral Agent and Investors hereunder or under the Australian General Security Deed shall for any reason cease to be valid, binding and enforceable in accordance with its terms (or Opthea or any of its Affiliates shall challenge the enforceability of any such provision or assert in writing, or engage in any action or inaction based on any such assertion, that any such provision has ceased to be or otherwise is not valid, binding and enforceable in accordance with its terms), or the security interest granted or purported to be granted in the Collateral to the Collateral Agent and Investors hereunder or under the Australian General Security Deed shall cease to be a valid and perfected first priority security interest to the extent required by this Agreement (subject to Permitted Liens solely to the extent such Permitted Liens have priority by law or statute and such other limitations on perfection and priority as set forth herein), in each case, other than due to a failure by Investors or Collateral Agent to take action to perfect such security interest or due to the release terms hereof and, in each case, after Opthea has failed to cure such failure within [***] following notice thereof where such failure is curable. In the event that the Required Investors terminates this Agreement pursuant to this Section 13.5, then

Opthea will pay to each Investor, within [***] following the date of termination, an amount equal to the Development Costs paid by such Investor as of the effective date of such termination multiplied by the MoIC, reduced by the amount of any Success Payments or Change of Control Payment previously paid by Opthea.

13.6Release of Security Interest. Upon the earlier to occur of (i) any termination of this Agreement and payment by Opthea of all amounts specified in Section 13.4 as being payable upon or following such termination and (ii) the date upon which Investors have received, in the aggregate, equal [***] of the Development Costs paid by Investor hereunder (calculated on the date on which Investors have no further right or obligation under this Agreement to pay Development Costs) (such earlier date, the "Release Date"), Investors' security interest in the Collateral shall be automatically released. Promptly following such date, Investors agrees to sign such further releases and other documents and take such further actions, at the sole cost and expense of Opthea, as may be necessary or desirable, in Opthea's reasonable judgment and at Opthea's request, to more fully give effect to such release. If an Investor does not promptly take such further actions to effect the release of the security interests, and such failure is not cured within [***] after notice of this failure from Opthea, then Opthea, in addition to any other rights or remedies it may seek, shall be entitled to suspend the payment of Success Payments to such Investor until the release has been effected. In connection with any Excluded Licensing Transaction and any other licensing of Intellectual Property permitted pursuant to this Agreement, each Investor shall enter into a customary non-disturbance agreement to the extent requested by Opthea, in each case reasonably satisfactory to such Investor and the counterparty thereto. Notwithstanding anything to the contrary herein, at any time after termination of this Agreement, Opthea shall have the right, but not the obligation, to prepay any remaining Success Payments or other payments in an amount sufficient to cause the release of the security interests under this Section 13.6. Notwithstanding anything to the contrary herein, upon any Permitted Disposition, the Liens granted hereunder in the property thereby disposed will be deemed to be automatically released with no further action on the part of any Person so long as Opthea has delivered a certificate from an officer of Opthea certifying that such disposition was a Permitted Disposition together with evidence reasonably satisfactory to Investors that such disposition was a Permitted Disposition.

13.7Surviving Obligations.

13.7.1Accrued Rights and Obligations. Expiration or termination of this Agreement for any reason will not release any Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to any other Parties or which is attributable to a period prior to such expiration or termination.

13.7.2Surviving Obligations. The following provisions of this Agreement, together with any other provisions that expressly specify that they survive, will survive expiration or earlier termination of this Agreement: Article 1, Article 8, Article 9, Article 11, Section 12.1, Section 12.2, Section 12.3, Article 13, and Article 14.

ARTICLE 14

MISCELLANEOUS

14.1Relationship with Affiliates. Each Party will be responsible for any breach by its Affiliates of its obligations in connection with this Agreement, and each such Party will remain responsible for any responsibilities that it has delegated to an Affiliate as though such Party had performed (or failed to perform) such responsibilities itself.

14.2Notices. Any notice or other communication required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly and sufficiently given only if (a) delivered either personally by hand or by reputable international courier service providing delivery service in [***] to the address set forth below, and, in each case, confirmed by email to the email addresses listed below, or (b) by e-mail (provided that, in respect of notices or other communications to [***], notices or other communications solely by email shall be sufficient only if (i) all email addresses listed in this Agreement for copy are copied, and (ii) a "failed delivery" message is not received by the sender from [***]'s primary email address listed in this Agreement), addressed to the relevant recipient in the manner provided below at the following addresses or such other address as may be designated by notice pursuant to this Section 14.2. Notices shall be deemed effective if given on a Business Day, or, with respect to notices or other communications to [***], if given on a [***] Business Day, in the manners prescribed in the immediately preceding sentence, by 3:30 pm in the place of receipt or on the following Business Day or [***] Business Day (as applicable) if completed after 3:30 pm in the place of receipt.

14.2.1If to Opthea:

Opthea Limited
Suite 0403, Level 4, 650 Chapel Street
South Yarra 3141 Victoria Australia
Attn: [***]
Email: [***]
with a copy, which will not constitute notice, to:

Cooley LLP
3 Embarcadero Center
20th Floor
San Francisco, CA 94111-5800
Attn: [***]
Email: [***]

14.2.2If to Investor:

Ocelot SPV LP
c/o Abingworth LLP
38 Jermyn Street, London, SW1Y 6DN
Attn: [***]
Email: [***]

with another copy to:

[***]
Attn: [***]
Email: [***]

with a copy, which will not constitute notice, to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attn: [***]
Email: [***]

with another copy, which shall not constitute notice, to:

[***]
Attention: [***]
Email: [***]

with another copy, which shall not constitute notice, to:

Cleary Gottlieb Steen & Hamilton LLP
2 London Wall Place
London, EC2Y 5AU
England
Attn: [***]
Email: [***]

14.3Force Majeure. No Party will be liable for any breach or delay in performance of any obligation under this Agreement to the extent caused by any Force Majeure Event. The Party invoking this Section 14.3 must provide prompt written notice and full particulars of such event to the other Parties and will use diligent and commercially reasonable efforts to mitigate the effects of any such force majeure event on such Party's compliance with and performance under this Agreement.

14.4Use of Names. Except as required by Applicable Law, no Party will use any other Parties' nor any of their Affiliates' (including each Investors' securityholders, the limited partners of each Investors' Affiliates (and their respective Affiliates'), Representatives, partners, managers, directors, board members, members, officers, funds, employees or agents) names or trademarks in any press release, public announcement, promotional, publicity or marketing materials, advertising, marketing, endorsement, promotional or sales literature, publicity, public announcement, public relations material, or disclosure in any document employed to obtain funds or financing, in each of the foregoing, whether distributed publicly or to any third party or parties in a non-public communication, without the prior written consent of the relevant Party (which, in the case of [***], may be withheld for any or no reason) except as otherwise expressly permitted

in this Agreement. Notwithstanding the foregoing or any other provision of this Agreement, (i) each Investor and its Affiliates may use the name, logos, and other insignia of Opthea in any "tombstone" or other advertisements, in its publications, marketing or promotional materials to existing and prospective investors and otherwise on the website or in other marketing materials of such Investor and its Affiliates, as applicable, without Opthea prior approval; and (ii) no Party shall disclose the identity of [***], [***], their respective Affiliates or any instrumentalities of [***] or their associates as an investor, or potential investor, in Opthea or any information provided by [***] or any of its Affiliates to Opthea, without [***]'s prior written consent (which may be withheld for any or no reason), except for (A) any information which enters the public domain without breach of any of its confidentiality obligations hereunder; (B) disclosures of any information to the extent required pursuant to applicable law, regulation or legal process (including, without limitation, U.S. federal securities laws and the rules of a securities exchange), in which case the Party required to make such disclosure shall, to the extent not prohibited by any applicable law or regulation, provide [***] with prompt written notice of that fact and, to the extent practicable, provide [***] with an opportunity to promptly comment on such disclosure and consider in good faith any comments promptly provided by [***] on such disclosure; (C) to third-party service providers of Opthea and its Subsidiaries on a "need to know" basis, including legal counsel, accountants, brokers and lenders; and (D) existing or prospective investors, lenders and/or acquirers of Opthea; provided, that, in the case of the foregoing clauses (C) and (D), such service providers, existing investors, prospective investors, lenders and/or acquirers are bound by a duty of confidentiality in relation to such information at least as restrictive as those set forth in this Agreement, and provided further that the disclosing party shall be liable for any breach of the terms of this clause by the recipient.

14.5Assignment. The provisions of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Opthea may not the prior written consent of assign, delegate or otherwise transfer this Agreement or any of its interests, obligations or rights hereunder without the prior written consent of all Investors, and any such purported assignment, delegation or transfer without such consent will be void ab initio and of no effect, provided that Opthea may assign this Agreement to an Affiliate or to any Third Party that acquires all or substantially all of Opthea's business, whether by merger, sale of assets or otherwise, as long as such assignee agrees in a writing to be bound by all the provisions of this Agreement as if such assignee were Opthea under this Agreement. Opthea shall give notice to Investors of any assignment for which consent was not required by Investors promptly after the occurrence thereof, and Opthea shall remain liable to Investors for its obligations to Investors hereunder (and Investors shall be entitled to seek recovery for any breach or default of an obligation hereunder from Opthea or from such Affiliate assignee). [***].

14.6Further Assurances. The Parties will execute such further reasonable documents and perform such further reasonable acts as may be necessary to comply with or more fully effectuate the terms of this Agreement, and any ancillary documents, including security documents. Notwithstanding any provision of the Transaction Agreements otherwise requiring [***] to provide any information or documents to any other Party or any third party, all Parties agree that [***] shall be entitled to withhold, edit, redact and/or otherwise limit disclosure of any such information or documents on the grounds of national security and/or financial or economic

sensitivity, and [***] shall have no liability whatsoever and shall be free and harmless from any claims whatsoever for exercising its rights pursuant to this sentence.

14.7Burdensome Condition. Notwithstanding any provision in any of the Transaction Agreements to the contrary, nothing shall require [***] or any of its Affiliates or direct or indirect equity holders (including any guarantors) or their respective Affiliates or any investment funds advised or managed by one or more Affiliates of [***] (or any related guarantor) or any direct or indirect portfolio companies thereof (excluding, for the avoidance of doubt, Opthea and its Subsidiaries) to (i) agree or commit to any imposition of any condition or restriction with respect to any such person or their respective businesses, product lines or assets or (ii) propose, negotiate, agree, accept, commit to or effect, by consent decree, hold-separate or administrative order or otherwise, the sale, divesture, disposition, or license of any assets, properties, products, rights, services or businesses of any such person, in case of each of (i) and (ii) necessary to secure any requisite approvals and authorizations or expiration of waiting periods for the transactions contemplated by this Agreement (or in connection with any other transactions that Opthea may propose to undertake or complete at any time and from time to time as contemplated by or permitted under any of the Transaction Agreements) under any applicable law or regulation or to obtain the approval, authorization or exemption of any Governmental Authority (the matters described in clauses (i) and (ii) above are each a "Burdensome Condition"). [***]'s obligation to make any payments to Opthea pursuant to this Agreement is subject to the condition, unless waived in writing by [***], that neither [***] nor any of its Affiliates shall have been required to agree or commit to the imposition of any Burdensome Condition.

14.8Fees and Expenses. Each Party to this Agreement will bear its own costs and expenses, including attorneys' fees and expenses, in connection with the closing of the transactions contemplated hereby. Following a breach or default hereunder by Opthea, Opthea shall reimburse Investors and Collateral Agent for their costs and expenses (including legal fees) incurred in collecting the Opthea Obligations, enforcing the Investor Security Interests, or in connection with any bankruptcy or insolvency proceeding commenced by or against Opthea. Following a breach hereunder by an Investor, such Investor shall reimburse Opthea for its costs and expenses (including legal fees) incurred in pursuing any action based on the breach, or in connection with any bankruptcy or insolvency proceeding commenced by or against such Investor.

14.9Governing Law. The construction and validity of this Agreement and the provisions hereof, and the rights and obligations of the Parties hereunder, will be governed by the internal laws of the State of New York, and, to the extent applicable to Patents and Trademarks, the applicable federal laws of the U.S., in each instance without regard to conflict of laws principles.

14.10Dispute Resolution. The Parties recognize that disputes as to certain matters relating to this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation and without resort to litigation. Accordingly, the Parties agree that any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach or termination hereof (and including the scope or applicability of this Section 14.10 or the agreement to arbitrate to any such dispute, controversy or claim) (each a "Dispute") will be resolved as follows:

14.10.1Any of the Parties will have the right to refer such Dispute to the Escalation Designees (provided that if a Dispute affects or otherwise relates to any of the rights or benefits of [***] under this Agreement or otherwise relate to the receipt by [***] of the Success Payments pursuant to this Agreement, then, for the purposes of this Section 14.10, the Escalation Designees shall also include one (1) representative of [***]) for attempted resolution by good faith negotiations for a period of thirty (30) days. Any final decision mutually agreed to by the Escalation Designees (including, where applicable, the representative of [***]) in writing will be conclusive and binding on the Parties. With respect to any Dispute that remains unresolved after the expiration of thirty (30) days after a Dispute is referred to the Escalation Designees (including, where applicable, the representative of [***]), then such Dispute will be submitted to the ICDR for final and binding arbitration pursuant to the arbitration clause set forth in Section 14.10.2. Notwithstanding the foregoing, no matters relating to breach or alleged breach of the ownership of intellectual property or rights in intellectual property or the validity or enforceability thereof will be resolved by arbitration, but rather will be determined by a U.S. federal court of appropriate jurisdiction. Notwithstanding anything in this Agreement to the contrary, any Party will be entitled to seek preliminary injunctive relief in any court of competent jurisdiction immediately if necessary to prevent irreparable harm to that Party.

14.10.2Arbitration Process.

14.10.2.1 Any Party will have the right to initiate arbitration at any time after the expiration of thirty (30) days after a Dispute is referred to the Escalation Designees (including, where applicable, the representative of [***]) by written notice to all other Parties. Any Party to this Agreement may intervene in any arbitration proceedings hereunder by providing written notice to all other Parties. Any disputes concerning the arbitrability of any Party's claims or defenses brought in an arbitration pursuant to this Section will be finally settled by the arbitral tribunal.

14.10.2.2 The seat, or legal place, of arbitration will be New York City, New York and the language of the arbitration will be English. The arbitration will be administered by the ICDR pursuant to the ICDR International Dispute Resolution Procedures. References herein to any arbitration rules or procedures mean such rules or procedures as amended from time to time, including any successor rules or procedures, and references herein to the ICDR include any successor thereto. The arbitration will be before a tribunal comprised of three (3) arbitrators. In the event that the notice of arbitration names only one claimant and on respondent, and no party has exercised its right to joinder or intervention in accordance with Section 14.10.2.1, the claimant and the respondent shall each select one arbitrator within fifteen (15) days of the answer to the notice of arbitration, and within fifteen (15) days of the second arbitrator's appointment, the two (2) Party-appointed arbitrators will select the third, who will serve as the tribunal's chair or president. In the event that more than two Parties are named in the notice for arbitration or at least one contracting Party exercises its right to joinder or intervention in accordance with Section 14.10.2.1, the claimant(s) shall jointly appoint one arbitrator and the respondent(s) shall jointly appoint the other arbitrator within fifteen (15) days of the answer to the notice of arbitration, and within fifteen

(15) days of the second arbitrator's appointment, the two (2) Party-appointed arbitrators will select the third, who will serve as the tribunal's chair or president. If any of the arbitrators are not selected within the time period prescribed above, then the ICDR shall appoint the arbitrator(s). All three (3) arbitrators will be professionals with substantial experience in development and Commercialization of biopharmaceutical products. An arbitrator will be deemed to meet these qualifications unless a Party objects within fifteen (15) days after the arbitrator is appointed; objections to an arbitrator's qualifications will be made reasonably and in good faith, not for the purposes of delay or harassment. This arbitration provision, and the arbitration itself, will be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1 *et*. *Seq*.

14.10.2.3 Consistent with the expedited nature of arbitration, each relevant Party will, upon the written request of the other relevant Parties, promptly provide the other with copies of documents on which the producing Party may rely in support of or in opposition to any claim or defense. At the request of a relevant Party, the arbitrators will have the discretion to order examination by deposition of witnesses to the extent the arbitrator deems such additional discovery relevant and appropriate. Depositions will be limited to a maximum of five (5) per relevant Party and will be held within forty-five (45) days after the grant of a request. Additional depositions may be scheduled only with the permission of the arbitrators, and for good cause shown. Each deposition will be limited to a maximum of seven (7) hours' duration on the record. All objections are reserved for the arbitration hearing except for objections based on privilege and proprietary or confidential information. The relevant Parties will not utilize any other discovery mechanisms, including international processes and U.S. federal statutes, to obtain additional evidence for use in the arbitration. Any Dispute regarding discovery, or the relevance or scope thereof, will be determined by the arbitrators, which determination will be conclusive. All discovery will be completed within ninety (90) days following the appointment of the arbitrators. The relevant Parties shall bear their own costs and fees for the production of documents, witnesses for deposition, and any other discovery that may be ordered by the arbitral tribunal.

14.10.2.4 The arbitrators will have no authority to award punitive or other damages not measured by the prevailing Party's (or Parties') actual damages, except as may be required by statute. Each Party expressly waives and foregoes any right to consequential, punitive, special, exemplary or similar damages or lost profits. The cost of the arbitration, including the fees of the arbitrators and reasonable attorney's fees of the prevailing Party (or Parties), will be borne by the Party (or Parties) the arbitrator determines has not prevailed in the arbitration. The arbitral award shall be accompanied by a reasoned opinion.

14.10.2.5 If an arbitral award does not impose an injunction on the losing Party (or Parties) or contain a money damages award in excess of five million dollars USD ($5,000,000), then the arbitral award will be final and binding and will only be subject to such challenges as would otherwise be

permissible under the Federal Arbitration Act, 9 U.S.C. § 1 *et. Seq*. Judgment on such an award may be entered in any court of competent jurisdiction and the relevant Parties undertake to carry out the award without delay. In the event that an arbitral award imposes an injunction or contains a monetary award in excess of five million dollars USD ($5,000,000), the Parties agree that such award may be appealed pursuant to the AAA's Optional Appellate Arbitration Rules (the "Appellate Rules") and should not be considered to be final and binding until after the time for filing the notice of appeal under the Appellate Rules has expired. Appeals must be initiated within thirty (30) days of receipt of the award, as defined by the Appellate Rules, by filing a notice of appeal within any AAA office. The arbitrators to sit on the appellate panel shall be selected according to the same process set forth under Section 14.10.2.2 above. Following the appeal process, the decision rendered by the appeal tribunal will be final and binding and judgment on that award may be entered in any court of competent jurisdiction and the relevant Parties undertake to carry out the award without delay.

14.10.2.6 Except as may be required by law, or to protect or pursue a legal right to enforce or challenge an award in legal proceedings, where needed for the preparation or presentation of a claim or defense in this arbitration, or by order of the arbitral tribunal upon application of a Party, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of all the Parties.

14.11Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED BY LAW AND NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NO PARTY WILL BE LIABLE TO THE OTHER PARTIES FOR ANY INDIRECT, INCIDENTAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCTS LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. THE PARTIES AGREE THAT THE LIMITATIONS SPECIFIED IN THIS SECTION 14.11 WILL APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. FOR THE AVOIDANCE OF DOUBT, THIS SECTION 14.11 WILL NOT LIMIT (A) OPTHEA'S OBLIGATION TO PAY INVESTORS THE AMOUNTS SET FORTH IN ARTICLE 6 OR SECTION 13.3, OR (B) A PARTY'S LIABILITY RESULTING FROM SUCH PARTY'S (I) GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, (II) BREACH OF Article 9, OR (III) INDEMNIFICATION OBLIGATION PURSUANT TO SECTION 11.1.

14.12No Pass-Through Liability. For the avoidance of doubt, [***] is solely liable for its obligations set forth in or arising under this Agreement, and no direct or indirect legal or beneficial owner of [***] shall have any liability in respect of this Agreement except as may be expressly so provided herein.

14.13Cumulative Remedies. Unless expressly set forth in this Agreement, all rights and remedies of the Parties, including all rights to payment, rights of termination, rights to injunctive relief, and other rights provided under this Agreement, will be cumulative and in addition to all other remedies provided for in this Agreement, in law, and in equity.

14.14Relationship of the Parties; Independent Contractors. Nothing contained herein will be deemed to create a partnership, joint venture, or similar relationship between the Parties, including for tax purposes. No Party is the agent, employee, joint venturer, partner, franchisee, or representative of any other Party. Each Party specifically acknowledges that it does not have the authority to, and will not, incur any obligations or responsibilities on behalf of any other Party. Notwithstanding anything to the contrary in this Agreement, each Party (and its officers, directors, agents, employees, and members) will not hold themselves out as employees, agents, representatives, or franchisees of any other Party or enter into any agreements on such other Party's behalf.

14.15Power of Attorney; Proxies. Each Party agrees it shall not, without the prior written consent of [***], use any power of attorney or proxy granted to it by [***] of this Agreement (if any) to (i) make any representations or warranties on behalf of [***] (other than those expressly contemplated to be made by [***] pursuant to the terms of this Agreement (if any)); (ii) impose any new or increase any existing obligations or liabilities on [***] (other than as expressly contemplated by the terms of this Agreement (if any)); or (iii) amend, modify, terminate or waive (on behalf of [***]) any provision in this Agreement. Each Party agrees that copies of any documents signed on [***]'s behalf pursuant to any power of attorney and/or proxy granted as aforesaid by [***] pursuant to this Agreement (if any) will be provided to [***] as soon as reasonably practicable following execution.

14.16Arm's Length Dealings. Neither Opthea nor any of the Investors nor any of their Affiliates will, for the Term of this Agreement, enter into any agreement on non-arm's length terms that adversely affects the rights or benefits of any Investors under this Agreement or otherwise detrimental to the receipt by Investors of the Success Payments pursuant to this Agreement; provided that the foregoing will not prohibit reasonable and customary director, officer and employee compensation arrangements and other customary benefits including retirement, health, stock option and other benefit plans and indemnifications or reimbursement arrangements.

14.17No Third Party Beneficiaries. This Agreement and the provisions herein are for the benefit of the Parties only, and are not intended to confer any rights or benefits to any Third Party.

14.18Rights Reserved. No license or any other right is granted to any Party, by implication or otherwise, except as specifically set forth in this Agreement. All rights not exclusively granted to Investors or Collateral Agent are reserved to Opthea and its Affiliates. Notwithstanding any other provision of this Agreement to the contrary, and for clarity, no Intellectual Property or other proprietary rights Controlled by Opthea or its Affiliates will be assigned or licensed to Investors in connection with this Agreement.

14.19Amendments; No Waiver. No amendment, supplement, or modification of this Agreement will be binding unless it is in writing and signed by Opthea, Collateral Agent and all of the Investors. No delay or failure on the part of a Party in the exercise of any right under this

Agreement or available at law or equity will be construed as a waiver of such right, nor will any single or partial exercise thereof preclude any other exercise thereof. All waivers must be in writing and signed by each Party against whom the waiver is to be effective. Any such waiver will constitute a waiver only with respect to the specific matter described in such writing and will in no way impair (i) the rights of the Party granting such waiver in any other respect or at any other time or (ii) the rights of any other Party (that is not a Party to such waiver). Notwithstanding the foregoing or anything in this Agreement, no amendment or modification and no waiver, discharge or termination shall (A) forgive the amount or extend the final scheduled date of any payment to be made to any Investor hereunder or increase the amount or extend the expiration date of any Investor's Commitment without the written consent of each Investor directly affected thereby; (B) eliminate or reduce the voting rights of any Investor under this Section 14.19, without the written consent of such Investor; (C) reduce any percentage specified in the definition of Required Investors, consent to the assignment or transfer by Opthea of any of its rights and obligations under this Agreement, release all or substantially all of the Collateral or release all or substantially all of the guarantors from their obligations unless otherwise permitted under this Agreement, in each case without the written consent of all Investors; or (D) change the pro rata sharing of payments without the consent of each Investor. Any such waiver and any such amendment, supplement or modification shall apply equally to each of the Investors and shall be binding upon Opthea, the Investors and all future successors and permitted assigns.

14.20Severability. If any provision (or portion thereof) of this Agreement is determined by a court or arbitration to be unenforceable as drafted by virtue of the scope, duration, extent, or character of any obligation contained herein, it is the Parties' intention that such provision (or portion thereof) will be construed in a manner designed to effectuate the purposes of such provision to the maximum extent enforceable under such Applicable Law. The Parties will enter into whatever amendment to this Agreement as may be necessary to effectuate such purposes.

14.21Entire Agreement. This Agreement, including all Exhibits hereto and the Transaction Agreements, contains the entire understanding of the Parties and supersedes, revokes, terminates, and cancels any and all other arrangements, understandings, agreements, term sheets, or representations and warranties, whether oral or written, between the Parties relating to the subject matter of this Agreement.

14.22Covenant Not to Sue. Opthea shall not, and shall cause its Affiliates to not, commence or pursue, or aid any other Person in commencing or pursuing, any action or claim against any Affiliate of an Investor or any Investor LP or any Affiliate of any Investor LP with respect to the transactions contemplated by this Agreement.

14.23Counterparts. This Agreement will be executed in three (3) counterparts, one (1) for each Party, which, taken together, will constitute one and the same agreement. This Agreement will not be binding on the Parties or otherwise effective unless and until executed by all Parties.

14.24Construction. This Agreement has been negotiated by the Parties and their respective counsel. This Agreement will not be construed in favor of or against any Party by reason of the authorship of any provisions hereof.

14.25Australian PPS provisions – exclusions. Where an Investor has a security interest (as defined in the Australian PPSA) under a Transaction Agreement, to the extent the law permits:

a) for the purposes of sections 115(1) and 115(7) of the Australian PPSA:

   a. such Investor need not comply with sections 95, 118, 121(4), 125, 130, 132(3)(d) or 132(4) of the Australian PPSA; and

   b. sections 142 and 143 of the Australian PPSA are excluded;

b) for the purposes of section 115(7) of the Australian PPSA, such Investor need not comply with sections 132 and 137(3);

c) each Party waives its right to receive from such Investor any notice required under the Australian PPSA (including a notice of a verification statement);

d) if such Investor exercises a right, power or remedy in connection with a security interest, that exercise is taken not to be an exercise of a right, power or remedy under the Australian PPSA unless such Investor states otherwise at the time of exercise. However, this section does not apply to a right, power or remedy which can only be exercised under the Australian PPSA; and

e) if the Australian PPSA is amended to permit the Parties to agree not to comply with or to exclude other provisions of the Australian PPSA, such Investor may notify Opthea that any of these provisions is excluded, or that such Investor need not comply with any of these provisions.

This Section 14.25 does not affect any rights a person has or would have other than by reason of the Australian PPSA and applies despite any other section in any Transaction Agreement.

14.26Australian PPS provisions – further assurances. Whenever an Investor requests Opthea to do anything:

a) to ensure any Transaction Agreement (or any security interest (as defined in the Australian PPSA) or other Lien under any Transaction Agreement) is fully effective, enforceable and perfected with the contemplated priority;

b) for more satisfactorily assuring or securing to such Investor the property the subject of any such security interest or other Lien in a manner consistent with the Transaction Agreement; or

c) for aiding the exercise of any power in any Transaction Agreement,

Opthea shall do it promptly at its own cost (or procure that it is done). This may include obtaining consents, signing documents, getting documents completed and signed and supplying information, delivering documents and evidence of title and executed blank transfers, or otherwise giving possession or control with respect to any property the subject of any security interest or Lien.

14.27 Defaulting Investors.

14.27.1[***].

14.27.2[***]

14.28Collateral Agent.

14.28.1 Each Investor irrevocably appoints Ocelot SPV LP as Collateral Agent of such Investor under this Agreement and the other Transaction Agreements and authorizes Collateral Agent to take such action on such Investor's behalf and to exercise such powers hereunder as are specifically delegated to Collateral Agent by the terms hereof and the other Transaction Agreements, together with such powers as are reasonably incidental thereto. Collateral Agent shall have only those duties which are specified in this Agreement and any other Transaction Agreement and it may perform such duties by or through its agents, representatives or employees. Collateral Agent shall have no duties, except those expressly set forth in this Agreement and the other Transaction Agreements, and no implied covenants, responsibilities, duties, obligations or liabilities shall be read into this Agreement or the other Transaction Agreements or otherwise exist against Collateral Agent. Ocelot SPV LP agrees that it is acting in its capacity as Collateral Agent, for the benefit of the Investors (and not in its capacity as an Investor), under each of the Australian General Security Deed, the Deposit Account Control Agreement, the Guaranty and the Intellectual Property Security Agreement.

14.28.2Neither Collateral Agent nor its officers, directors, employees, agents, attorneys-in-fact or affiliates shall be (i) liable for any waiver, consent or approval given or any action taken or omitted to be given or taken by Collateral Agent or by such Person under or in connection with this Agreement or the other the Transaction Agreements or (ii) responsible for the consequences of any oversight or error in judgment by Collateral Agent or such Person whatsoever, except, in the case of **clauses (i)** and **(ii)**, for Collateral Agent's or such Person's own gross negligence or willful misconduct. Collateral Agent shall not be responsible for (v) the execution, validity, enforceability, effectiveness or genuineness of this Agreement or the other Transaction Agreements, (w) the collectability of any amounts owing under this Agreement or the other Transaction Agreements, (x) the value, sufficiency, enforceability or collectability of any collateral security therefor, (y) the failure by Opthea to perform the Opthea Obligations or (z) the truth, accuracy and completeness of the recitals, statements, representations or warranties made by Opthea or any officer or agent thereof contained in this Agreement, the other Transaction Agreements or in any certificate, report, statement or other document referred to or provided for in, or received by Collateral Agent or any Investor in connection with, this Agreement or the other Transaction Agreements, whether delivered by Collateral Agent to any Investor or by or on behalf of Opthea to any Investor. For the avoidance of doubt, this exception from liability applies only to the Collateral Agent, in its capacity as Collateral Agent, and does not apply to Ocelot in its capacity as Investor.

14.28.3The Collateral Agent confirms that it holds all rights to the Australian General Security Deed also as security trustee for the benefit of itself as Collateral Agent and the Investors. These rights are in addition to any rights or powers held by the Collateral Agent in any other capacity. All protections, indemnities and other rights granted in favour of the Collateral Agent, whether at law or under any Transaction Agreement, in respect of its role as security trustee also apply to the Collateral Agent in its capacity as security trustee.

14.29Reliance by Collateral Agent.

14.29.1Collateral Agent may rely, and shall be fully protected in relying, acting, or refraining to act, upon any resolution, statement, certificate, instrument, opinion, report, notice request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of facsimiles or electronic mail, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct in its capacity as Collateral Agent, Collateral Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Collateral Agent and substantially conforming to the requirements of this Agreement or any of the other Transaction Agreements.

14.29.2Collateral Agent shall be entitled to fail or refuse, and shall be fully protected in failing or refusing, to take any action under this Agreement or the other Transaction Agreements, solely in its capacity as Collateral Agent, unless (A) it first shall receive such advice or concurrence of Required Investors, as it deems appropriate, or (B) it first shall be indemnified to its satisfaction by Investors against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. In all cases Collateral Agent shall be fully protected in acting, or in refraining from acting, under this Agreement or the Transaction Agreements in accordance with a request of Required Investors and such request and any action taken or failure to act pursuant thereto shall be binding upon all Investors. Without prejudice to the generality of anything in this Section 14.29.2, no Investor shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under this Agreement or under any of the other Transaction Agreements in accordance with the instructions of Required Investors.

14.29.3Collateral Agent may execute any of the powers hereof and perform any duty hereunder either directly or by or through agents or attorneys-in-fact. Collateral Agent may utilize the services of such agents and attorneys-in-fact as Collateral Agent in its sole discretion reasonably determines, and all fees and expenses of such agents and attorneys-in-fact shall be paid by Opthea on demand. Collateral Agent shall be entitled to advice of counsel concerning all matters pertaining to such powers and duties. Collateral Agent shall not be responsible for the negligence or misconduct of any agents or attorneys-in-fact selected by it, if the selection of such agents or attorneys-in-fact was done without gross negligence or willful misconduct.

14.29.4Unless the officers of Collateral Agent acting in their capacity as officers of Collateral Agent on Opthea's account with respect to the transactions hereunder have actual knowledge thereof or have been notified in writing thereof by Investors, Collateral Agent shall not be required to ascertain or inquire as to the existence or possible existence of any Event of Default. Collateral Agent shall take such action with respect to such Event of Default as shall be directed by Required Investors; provided, that unless and until Collateral Agent shall have received such directions, Collateral Agent may (but shall not be obligated to) take such action, or refrain from taking such action, with respect to such Event of Default as it deems advisable in the best interests of the Investors.

14.29.5Opthea agrees (i) to indemnify and hold Collateral Agent (and any Person acting on behalf of Collateral Agent) harmless from and against and (ii) promptly upon receipt by Opthea of Collateral Agent's statement, to reimburse Collateral Agent for any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses (including the reasonable fees and disbursements of counsel and other advisors actually incurred) or disbursements of any kind of nature whatsoever with respect to Collateral Agent's performance of its duties under this Agreement and the other Transaction Agreements; provided, that Opthea shall not be liable for the payment to Collateral Agent of any portion of such liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements resulting solely from Collateral Agent's willful misconduct, and nothing in the foregoing is intended to limit the obligation of Opthea to reimburse Collateral Agent for any amounts incurred by Collateral Agent; provided further that Opthea shall not be responsible for reimbursement of any attorneys' and advisors' fees, expenses and costs incurred by the Collateral Agent in connection with the negotiation, documentation and closing of this Agreement and the other Transaction Agreements in excess of $25,000. In the event that Opthea does not have sufficient funds to pay any amount required under this Section 14.29.5 or with respect to any excess amount Opthea is not responsible for reimbursement, each Investor severally, but not jointly, agrees to perform the actions set forth in (i) and (ii) above, according to such Investor's Pro Rata Share, to the extent Collateral Agent shall not have already have been reimbursed by Opthea; provided, that no Investor shall be liable for the payment to Collateral Agent of any portion of such liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements resulting solely from Collateral Agent's gross negligence or willful misconduct. Collateral Agent's right to indemnification shall survive termination of this Agreement.

14.29.6Collateral Agent may resign at any time by giving 30 days' prior written notice thereof to the Investors and Opthea. Upon any such resignation, the Required Investors shall have the right to appoint a successor Collateral Agent (provided that such successor Collateral Agent is not an Affiliate or related party of the Required Investors, which, for the avoidance of doubt, include Launch for so long as Ocelot SPV LP forms part of the Required Investors). If no successor Collateral Agent shall have been so appointed by the Required Investors and accepted such appointment within 30 days after the retiring Collateral Agent's giving of notice of resignation, then the retiring Collateral Agent may, on behalf of the Investors, appoint a successor Collateral Agent, and which successor Collateral Agent, if no Event of Default shall have occurred and be continuing, shall be reasonably satisfactory to Opthea. Upon the acceptance of any appointment as Collateral Agent hereunder by a successor Collateral Agent, such successor Collateral Agent shall thereupon succeed to and become vested with all the rights, powers, privileges and duties of the retiring Collateral Agent, and the retiring Collateral Agent shall be discharged from its duties and obligations under this Agreement. After any retiring Collateral Agent's resignation hereunder as Collateral Agent, the provisions of this Agreement shall inure to its benefit as to any actions taken or omitted to be taken by it while it was Collateral Agent under this Agreement.

14.30Amendment and Restatement; Termination of Letter Agreements.

14.30.1Each Party agrees that, upon the execution and delivery of this Agreement by each of the parties hereto, the terms and provisions of the Existing Agreement shall be and hereby are amended, superseded and restated in their entirety by the terms and provisions of this Agreement. This Agreement is not intended to and shall not constitute a novation, payment and reborrowing or termination of the Opthea Obligations under the Existing Agreement and the other Transaction Agreements as in effect prior to the date hereof. All payments made, and "Opthea Obligations" incurred under (and defined in) the Existing Agreement which are outstanding on the Restatement Effective Date, shall constitute payments made and Opthea Obligations, respectively, under (and shall be governed by the terms of) this Agreement and the other Transaction Agreements. The Commitment of each Investor that is a party to the Existing Agreement shall, on the date hereof, automatically be deemed amended and the only Commitments shall be those hereunder. Without limiting the foregoing, upon the effectiveness hereof: (a) all references in the "Transaction Agreements" (as defined in the Existing Agreement) to the "Funding Agreement" and the "Transaction Agreements" shall be deemed to refer to this Agreement and the Transaction Agreements, and (b) all obligations constituting "Opthea Obligations" under the Existing Agreement with any Investor or any Affiliate of any Investor which are outstanding on the date hereof shall continue as Opthea Obligations under this Agreement and the other Transaction Agreements.

14.30.2Opthea and Ocelot SPV LP hereby acknowledge and agree that any letter agreements or other agreements amending or modifying the Existing Agreement (including the Letter Agreement dated June 5, 2023 between Opthea and Ocelot SPV LP) are hereby terminated in its entirety as of the Restatement Effective Date.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the Restatement Effective Date.

Executed by **OPTHEA LIMITED ACN 006 340 567** acting by the following persons or, if the seal is affixed, witnessed by the following persons in accordance with s127 of the Corporations Act 2001:

./s/ Megan Baldwin	./s/ Karen Adams. . . . .
Signature of director	Signature of director/company secretary
Megan Baldwin	Karen Adams. . . . .
Name of director (print)	Name of director/company secretary (print)

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the Restatement Effective Date.

OCELOT SPV LP, a Delaware limited partnership

By: OCELOT GP LLC, a Delaware limited liability company

Its: General Partner

By: /s/ Neil Cooper
Name: Neil Cooper
Title: Managing Director

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the Restatement Effective Date.

[***]

By: /s/ [***]
Name: [***]
Title: [***]

EXHIBIT LIST

Exhibit A	Form of DACA
Exhibit B	Development Plan
Exhibit C	Escalation Designees
Exhibit D	Form of Intellectual Property Security Agreement
Exhibit E	The Product
Exhibit F-1	OPT-302-1004 (ShORe) Timeline
Exhibit F-2	OPT-302-1005 (COAST) Timeline
Exhibit G	Approved Contract Research Organizations (CROs)
Exhibit H	Approved Vendors
Exhibit I-1	OPT-302-1004 (ShORe) Phase 3 Trial Endpoints
Exhibit I-2	OPT-302-1005 (COAST) Phase 3 Trial Endpoints
Exhibit J-1	ShORe Statistical Analysis Plan
Exhibit J-2	COAST Statistical Analysis Plan
Exhibit K	Confidential Information
Exhibit L	Form of Note
Exhibit M	Australian General Security Deed
Exhibit N	Form of Guaranty
Schedule 1.1.150	Permitted Indebtedness
Schedule 1.1.151	Permitted Liens
Schedule 1.1.163	Prohibited Investments

Schedule 2.2.1(a)	ShORe Protocol
Schedule 2.2.1(b)	COAST Protocol
Schedule 6.7.1	Variable Success Payments
Schedule 7.3.2.2	Restrictive Agreements
Schedule 12.2.3	Manufacturing Agreements
Schedule 12.2.11.3	Product Options, Licenses or Agreements
Schedule 12.2.11.4	Product IP
Schedule 12.2.11.8(a)	In-Licenses
Schedule 12.2.11.8(b)	In-Licenses
Schedule 12.2.16	Broker’s Fees

[***]

Exhibit 11.1

SECURITIES TRADING POLICY

1. Introduction

1.1 Securities of Opthea Limited (the "Company") are listed on ASX and Nasdaq.

1.2 This policy outlines:

(a) when directors, senior management and other employees may deal in Company Securities; and

(b) procedures to reduce the risk of insider trading.

1.3 The requirements imposed by this policy are separate from, and in addition to, the legal prohibitions on insider trading in Australia and any other country where financial products may be quoted. This policy is in addition to all laws prohibiting insider trading.

2. Defined terms

In this policy:

Approving Officer means:

(a) for an Employee who is not a Designated Officer, the Chief Executive Officer ("CEO");

(b) for a Designated Officer who is not a director, the CEO;

(c) for the CEO who is not a director, the chairperson of the Audit & Risk Committee;

(d) for a director (except the chairperson of the board), the chairperson of the board and the CEO, or, in the case where the CEO is also a director, the chairperson of the board and the chairperson of the Audit & Risk Committee; and

(e) for the chairperson of the board, the chairperson of the Audit & Risk Committee and the CEO.

ASX means ASX Limited.

Company Securities includes shares in the Company, options over those shares and any other financial products of the Company traded on ASX and American Depositary Shares ("ADSs") representing ordinary shares traded on Nasdaq.

Designated Officer means a director or person engaged in the senior management of the Company and the Group, whether as an employee or consultant, any person in the accounting and finance department of the Company and any other person that may be designated as such from time to time by the CEO or the chairperson of the Company.

Employee includes full-time, part-time, or temporary employees or consultants and extends to all of such person's activities within and outside their duties at the Group.

Group means the Company and its subsidiaries.

Investment Manager includes a stockbroker or other investment adviser who acts on behalf of an Employee (including, for the avoidance of doubt, a Designated Officer). For the avoidance of doubt, an arm's length superannuation fund that is not a self-managed superannuation fund of an Employee does not fall within the definition of Investment Manager.

Nasdaq means the Nasdaq Stock Market.

Related Party has the meaning given to that term in Chapter 19 (Interpretation and Definitions) of the ASX Listing Rules and includes US Related Persons as set forth in the Company's Related Persons Transaction Policy and shall also include any member of the Employee's family who resides with the Employee, any other persons with whom the Employee shares a household, any family members who do not live in the Employee's household but whose transactions in Company Securities are directed by the Employee or are subject to the Employee's influence or control and any other individuals or entities whose transactions in securities the Employee influences, directs or controls (including, e.g., a venture or other investment fund, if the Employee influences, directs or controls transactions by the fund).

Trading Day means a day on which the Nasdaq or the ASX is open for trading.

3. Insider trading

3.1 If a person has information about securities and the person knows, or ought reasonably to know, that the information is "inside information," it is likely to be illegal for the person to:

(a) deal in the securities;

(b) procure another person to deal in the securities; or

(c) give the information to another person who the person knows, or ought reasonably to know, is likely to:

(i) deal in the securities; or

(ii) procure someone else to deal in the securities.

3.2 See Appendix A for an explanation of "inside information" and "insider trading" under the US securities law framework. The description in Appendix A is intended to be a summary for reference only and does not purport to be complete.

3.3 Insider trading is a criminal offence. It is punishable by substantial fines or imprisonment or both. A company may also be liable if an employee or director engages in insider trading.

3.4 Insider trading may also attract civil penalties. A court may impose substantial pecuniary penalties for insider trading and order payment of compensation to persons who suffer loss or damage because of insider trading.

3.5 The prohibition against insider trading is absolute. It applies even if the decision to trade is not based on material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. In addition, even the appearance of an improper transaction must be avoided to preserve Opthea's reputation for adhering to the highest standards of conduct. It is not an excuse that you did not "use" the information in deciding whether or not to engage in a transaction in Company Securities.

3.6 Similarly, you may not engage in transactions involving the securities of any other company if you are aware of material nonpublic information about that company. For example, you may be involved in a proposed transaction involving a prospective business relationship or transaction with another company. If information about that transaction constitutes material nonpublic information for that other company, you are prohibited from engaging in transactions involving the securities of that other company. It is important to note that "materiality" is different for different companies. Information that is not material to Opthea may be material to another company.

4. What is inside information?

4.1 Inside information is information that:

(a) is not generally available; and

(b) if it were generally available, would, or would be likely to, influence persons who commonly invest in securities in deciding whether to acquire or dispose of the relevant securities.

4.2 Information is generally available if it:

(a) is readily observable;

(b) has been made known in a manner likely to bring it to the attention of persons who commonly invest in securities of the relevant type and a reasonable period for that information to be disseminated has elapsed since it was made known; or

(c) consists of deductions, conclusions or inferences made or drawn from information falling under paragraphs 4.2(a) or 4.2(b).

5. What is dealing in securities?

5.1 Dealing in securities includes:

(a) applying for, acquiring or disposing of, securities;

(b) entering into an agreement to apply for, acquire or dispose of, securities;

(c) gifts involving securities or transfers for tax planning purposes in which the beneficial ownership and pecuniary interest in the transferred securities does

not change; and

(d) granting, accepting, acquiring, disposing, exercising or discharging an option or other right or obligation to acquire or dispose of securities.

6. Trading is prohibited during a Blackout Period

6.1 In addition to the general prohibition on insider trading at any time, an Employee (which, for the avoidance of doubt, includes a Designated Officer) must not deal or procure another person to deal in Company Securities during the following periods:

(a) the period commencing on 31 December and ending at the beginning of the second full trading day following the public announcement of Opthea's half year results;

(b) the period commencing on 30 June and ending at the beginning of the second full trading day following the public announcement of Opthea's full year results; and

(c) only in the event Opthea expects to publicly announce quarterly results, the period commencing on 31 March and 30 September and ending at the beginning of the second full trading day following the announcement of the relevant quarterly results.

(each a "Blackout Period").

The CEO or Company Secretary will notify Employees of the Blackout Periods during these times.

Please note that a Blackout Period may commence early or may be extended if, in the judgment of the CEO or Chief Financial Officer ("CFO"), there exists undisclosed information that would make dealing in Company Securities by an Employee inappropriate. It is important to note that the fact that a Blackout Period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

6.2 From time to time, an event may occur that is material to the Company and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the CEO or CFO may not trade in Company Securities. In that situation, the Company will notify the designated Employees that they must not trade in Company Securities. The existence of an event-specific trading blackout period should also be considered material nonpublic information and should not be communicated to any other person. Exceptions to this policy will not be granted to relevant individuals during an event-specific trading blackout period. Event-specific trading blackouts may include:

(a) status of product or product candidate development or regulatory approvals;

(b) clinical data relating to products or product candidates;

(c) timelines for pre-clinical studies or clinical trials;

(d) acquisitions, disposals or licensing of products, assets, divisions or companies;

(e) public or private sales of debt or equity securities;

(f) gain or loss of a significant licensor, licensee or supplier;

(g) notice of issuance or denial of patents; and

(h) other similar material events.

There may be other types of information that would qualify as material information triggering an event-specific trading blackout as well, use this list merely as a non-exhaustive guide.

6.3 Please note that trading in any Company Securities outside a Blackout Period is not a “safe harbor,” and all Employees should strictly comply with all applicable law. When in doubt, do not trade and do not disclose the information to others! Check with the Compliance Officer, as defined in the Company’s Whistleblower policy, first.

6.4 Employees in the U.S. should note that trading plans such as a security trading plan in compliance with Rule 10b5-1 under the U.S. Securities Exchange Act of 1934 are not effective in providing any form of defence to insider trading under Australian law.

7. Pre-clearance from Approving Officer(s)

7.1 In addition to the general restrictions applying to all Employees (including Designated Officers) during Blackout Periods set out in Section 6 above, before dealing in Company Securities, a Designated Officer must first inform the relevant Approving Officer(s) and obtain pre-clearance. The Company Secretary is to be informed of all such pre-clearances either before or immediately after they are provided by the Approving Officer(s). A pre-clearance to trade expires five (5) business days from its date, unless the pre-clearance specifies a different date. From time to time, the CEO or CFO may identify other persons who require pre-clearance by the relevant Approving Officer. The Company Secretary must keep a written record of each such additional persons subject to pre-clearance.

7.2 The Approving Officer(s) must:

(a) keep a written record of:

(i) any information received from a Designated Officer in connection with this policy; and

(ii) any pre-clearance given under this policy; and

(b) send a copy of the written record to the Company Secretary for keeping.

7.3 The Company Secretary must keep a file of any written record referred to in paragraph 7.2.

7.4 Persons subject to pre-clearance must also provide advance notice of their plans to exercise an outstanding option to the relevant Approving Officer(s).

8. Exceptional circumstances and exceptions to this policy

8.1 Where an optionholder and Opthea possess the same inside information, this policy will not apply to the exercise of options or settlement of other equity awards granted under Opthea's equity compensation plans, for cash or otherwise, including pursuant to any "cashless" or "net" exercise or settlement, as applicable, with Opthea. This policy does, however, apply to any sale of shares as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

9. Dealings by associated persons and Investment Managers

9.1 If an Employee may not deal in the Company Securities, he or she must prohibit any dealing in the Company Securities by:

(a) any Related Party (including nominee companies and family trusts); or

(b) any Investment Manager on their behalf or on behalf of any associated person.

9.2 For the purposes of paragraph 9.1, an Employee must:

(a) inform any Investment Manager or associated person of the periods during which the Employee may and may not deal in Company Securities;

(b) request any Investment Manager or associated person to inform the Employee immediately after they have dealt in Company Securities; and

9.3 Each Employee is responsible for ensuring compliance by any Related Party with this policy, as this policy applies equally to all Related Parties.

10. Prohibited transactions

10.1 Anti-hedging policy. Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited. Since such hedging transactions allow the Employee to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, Employees may no longer have the same objectives as the Company's other shareholders. Therefore, Employees are prohibited from engaging in any such transactions.

10.2 Anti-pledging policy. Pledging shares as collateral for a personal loan could cause the pledgee to transfer shares during a trading blackout period or when the Employee is otherwise aware of material nonpublic information. As a result, Employees may not pledge shares as collateral for a loan. Similarly, you may not hold Company Securities in margin accounts because your broker may sell securities held in the margin account during a blackout period.

10.3 **Short sales**. You may not engage in short sales (i.e., the sale of a security that must be borrowed to make delivery) or "sell short against the box" (i.e., sell with a delayed delivery) if such sales involve Company Securities. Short sales may signal to the market possible bad news about Opthea or a general lack of confidence in its prospects and an expectation that the value of its securities will decline.

10.4 Standing and limit orders. Standing and limit orders (except standing and limit orders under approved trading plans) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an insider is in possession of material nonpublic information. We therefore discourage placing standing or limit orders on Company Securities. You should exercise caution when placing open orders, such as limit orders or stop orders, with brokers, particularly where the order is likely to remain outstanding for an extended period of time. Open orders may result in the execution of a trade during a blackout period, which may result in inadvertent insider trading in violation of this policy.

11. Communicating inside information

11.1 If an Employee (which, for the avoidance of doubt, includes a Designated Officer) has information that he or she knows, or ought reasonably to know, is inside information in relation to Company Securities (or the listed securities of another entity), the Employee must not directly or indirectly communicate that information to another person. An Employee must not inform colleagues (except the relevant Approving Officer(s)) about inside information or its details.

11.2 Even if you do not buy or sell anything, if you pass to another person inside information, you may be liable under Australian and US securities laws for “tipping”. You are the “tipper” and the other person is called the “tippee”. If the tippee buys or sells based on that inside information, or if you know or ought reasonably to have known that the tippee would trade, you might still be guilty of insider trading. For example, if you tell family members who tell others and those people then trade on the information, those family members might be guilty of insider trading too. As a result, you must not discuss material, non-public information about the Company with anyone outside the Company, including spouses, family members, friends, or business associates. This includes anonymous discussion on the internet about the Company or telling another person whether to buy or sell securities of the Company. Even if you are not directly disclosing material nonpublic information, you may not make recommendations or express opinions about securities of another company, Opthea or otherwise, based on material nonpublic information.

12. Breach of policy

12.1 A breach of this policy by an Employee is serious and may lead to disciplinary action, including dismissal in serious cases. It may also be a breach of the law.

12.2 If you become aware that any potential inside information has been or may have been inadvertently disclosed, you must notify the CFO or CEO immediately so that the Company can determine whether or not corrective action, such as general disclosure to the public, is warranted.

12.3 If you are aware of inside information when your employment or service relationship with the Company ends, you still may not trade Company Securities until such information has become public or is no longer material.

12.4 The ultimate responsibility for complying with this policy and applicable laws rests with you. As Opthea requests you do in all aspects of your work, please use your best judgment at all times and consult with an Approving Officer and/or your legal and financial advisors, in confidence, if you have questions.

13. Distribution of policy

13.1 This policy must be distributed to all Employees (including Designated Officers).

14. Assistance and additional information

14.1 Employees who are unsure about any information they may have in their possession, and whether they can use that information for dealing in securities, should contact the CEO.

15. Approved and adopted

15.1 This policy was approved and adopted by the board on August 20, 2024.

Appendix A

Explanation of Insider Trading under the US Federal Securities Laws

As noted above, "**insider trading**" refers to the purchase or sale of a security while in possession of "**material**" "**non-public**" information relating to the security (referred to as "**inside information**" in this policy). "**Securities**" include not only stocks, bonds, notes and debentures, but also options, warrants and similar instruments. "**Purchase**" and "**sale**" are defined broadly under the U.S. federal securities laws. "**Purchase**" includes not only the actual purchase of a security, but any contract to purchase or otherwise acquire a security. "**Sale**" includes not only the actual sale of a security, but any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-stock transactions, the grant and exercise of stock options and acquisitions and exercises of warrants or puts, calls or other options related to a security. It is generally understood that "**insider trading**" includes the following:

- trading by insiders while in possession of material non-public information;
- trading by persons other than insiders while in possession of material non-public information where the information either was given in breach of an insider's fiduciary duty to keep it confidential or was acquired inappropriately; and
- communicating or tipping material non-public information to others, including recommending the purchase or sale of a security while in possession of material non-public information.

As noted above, for purposes of this Statement, the terms "**purchase**" and "**sell**" securities include the acceptance of options or other share-based awards granted by the Company.

What Facts are Material?

The materiality of a fact depends upon the circumstances. A fact is considered "**material**" if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell or hold a security or where the fact is likely to have a significant effect on the market price of the security. Material information can be positive or negative and can relate to virtually any aspect of a company's business or to any type of security, debt or equity.

Examples of material information include (but are not limited to) information concerning:

- dividends;
- corporate earnings or earnings forecasts;
- changes in financial condition or asset value;
- status of and new developments related to product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;

- detailed regarding timelines, progress or results for preclinical studies or clinical trials;
- communications with the U.S. Food and Drug Administration or any comparable foreign government agencies;
- negotiations for the mergers or acquisitions or dispositions of significant subsidiaries or assets;
- notice of issuance or denial of patents, the acquisition of other material intellectual property rights or notice of a material adverse change in intellectual property or patents owned by Company;
- regulatory developments;
- significant new contracts or the loss of a significant contract;
- significant new products or services;
- significant marketing plans or changes in such plans;
- capital investment plans or changes in such plans;
- material litigation, administrative action or governmental investigations or inquiries about the Company or any of its officers or directors;
- significant borrowings or financings;
- defaults on borrowings;
- new equity or debt offerings;
- significant personnel changes;
- material cybersecurity incidents;
- changes in accounting methods and write-offs; and
- any substantial change in industry circumstances or competitive conditions which could significantly affect the Company's earnings or prospects for expansion.

A good general rule of thumb: **when in doubt, do not trade**, and **do not disclose such information to others**.

What is Non-public?

Information is "**non-public**" if it is not available to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors through such media as Dow Jones, Reuters Economic Services, The Wall Street Journal, Bloomberg, Associated Press, PR Newswire or United Press International. Circulation of rumors, even if accurate and reported in the media, does not constitute effective public dissemination.

In addition, even after a public announcement, a reasonable period of time must lapse in order for the market to react to the information. Generally, one should allow approximately forty-eight (48) hours following publication as a reasonable waiting period before such information is deemed to be public.

Who is an Insider?

"**Insiders**" include directors, officers and employees of a company. Insiders have independent fiduciary duties to their company and its shareholders not to trade on material non-public information relating to a company's securities. All directors, officers and employees of the Company are considered insiders with respect to material non-public information about business, activities and securities of the Company. The directors, officers and employees of the Company may not trade the Company's securities or any other securities to which such material non-public information relates while in possession of material non-public information relating to the Company or such other company as the material non-public information relates or tip (or communicate except on a need-to-know basis) such information to others.

It should be noted that trading by any member of the Insider's family who resides with the Insider, any other persons with whom the Insider shares a household, any family members who do not live in the Insider's household but whose transactions in Company Securities are directed by the Insider or are subject to the Insider's influence or control and any other individuals or entities whose transactions in securities the Insider influences, directs or controls (including, e.g., a venture or other investment fund, if the Insider influences, directs or controls transactions by the fund) can be the responsibility of such Insider under certain circumstances and could give rise to legal and Company-imposed sanctions.

Trading by Persons Other than Insiders

Insiders may be liable for communicating or tipping material non-public information to a third party (a "**tippee**"), and insider trading violations are not limited to trading or tipping by insiders. Persons other than insiders also can be liable for insider trading, including tippees who trade on material non-public information tipped to them or individuals who trade on material non- public information which has been unlawfully used.

Tippees inherit an insider's duties and are liable for trading on material non-public information tipped to them by an insider. Similarly, just as insiders are liable for the insider trading of their tippees, so are tippees who pass the material non-public information along to others who trade on such information. In other words, a tippee's liability for insider trading is no different from that of an insider. Tippees can obtain material non-public information by receiving overt tips from others or through, among other things, conversations at social, business, or other gatherings.

Penalties for Engaging in Insider Trading

Penalties for trading on or tipping material non-public information can extend significantly beyond any profits made or losses avoided, both for individuals engaging in the unlawful conduct and their employers. The United States Securities and Exchange Commission and the United States Department of Justice have made the civil and criminal prosecution of insider trading violations a top priority. Enforcement remedies available to the government or private plaintiffs under the U.S. federal securities laws include:

- administrative sanctions;
- sanctions by self-regulatory organizations in the securities industry;
- civil injunctions;
- damage awards to private plaintiffs;
- disgorgement of profits gained by the violator;
- civil fines for the violator of up to three times the amount of profit gained or loss avoided by the violator;

- civil fines for the employer or other controlling person of a violator (i.e., where the violator is an employee or other controlled person) of up to the greater of US$1,000,000 or three times the amount of profit gained or loss avoided by the violator;
- criminal fines for individual violators of up to US$5,000,000 (US$25,000,000 for an entity); and
- jail sentences of up to 20 years.

In addition, insider trading could result in serious sanctions by the Company, including immediate dismissal. Insider trading violations are not limited to violations of the U.S. federal securities laws. Other U.S. federal and state civil or criminal laws, such as the laws prohibiting mail and wire fraud and the Racketeer Influenced and Corrupt Organizations Act (RICO), and equivalent non-U.S. laws also may be violated upon the occurrence of insider trading.

Inside Information Regarding Other Companies

This policy and the guidelines described herein also apply to material and non-public information relating to other companies, including the Company's customers, vendors, suppliers and other business partners ("**Business Partners**"), particularly when that information is obtained in the course of employment with, or other services performed by, or on behalf of, the Company. Civil and criminal penalties, and discipline, including termination of employment for cause, may result from trading on inside information regarding the Company's Business Partners. Each individual should treat material nonpublic information about the Company's Business Partners with the same care required with respect to information related directly to the Company.

Exhibit 12.1

CERTIFICATIONS

I, Frederic Guerard, certify that:

1. I have reviewed this annual report on Form 20-F of Opthea Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 30, 2024

By: /s/ Frederic Guerard

Frederic Guerard
Principal Executive Officer

Exhibit 12.2

CERTIFICATIONS

I, Peter Lang, certify that:

1. I have reviewed this annual report on Form 20-F of Opthea Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 30, 2024

By: /s/ Peter Lang

Peter Lang
Principal Financial Officer

Exhibit 13.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Frederic Guerard, Chief Executive Officer of Opthea Limited (the "Company"), and Peter Lang, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 20-F for the fiscal year ended June 30, 2024, to which this Certification is attached as Exhibit 13.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 30, 2024

In Witness Whereof, the undersigned have set their hands hereto as of the 30th of August, 2024.

/s/ Frederic Guerard	/s/ Peter Lang
Frederic Guerard	Peter Lang
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-251052 on Form S-8 and Registration Statement No. 333-262444 on Form F-3 of our report dated August 30, 2024, relating to the financial statements of Opthea Limited appearing in this Annual Report on Form 20-F for the year ended June 30, 2024.

Melbourne, Australia

August 30, 2024

Exhibit 97.1

OPTHEA LIMITED

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Remuneration Committee (the "***Remuneration Committee***") of the Board of Directors (the "***Board***") of Opthea Limited, an Australian corporation (the "***Company***"), has determined that it is in the best interests of the Company and its shareholders including holders of its American Depository Shares to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement

"***Administrator***" means the Remuneration Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Remuneration Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's chief executive officer, principal financial officer, secretary, principal accounting officer (or if there is no such accounting officer, the controller), chief commercial officer, chief medical officer, any vice-president of the Company in charge of a principal business unit, division, or function (such as clinical, medical affairs, regulatory, quality, chemistry manufacturing and controls, supply chain, commercial, sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's external financial statements, and any measures derived wholly or in part from such measures, including Company share price and total shareholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation (including cash and equity-based) that is granted, earned or vested based upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on share price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a U.S. national securities exchange or a U.S. national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Remuneration Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party including legal and related fees to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation, and shall provide such opinion to the Exchange in accordance with the Listing Standards; or

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling or reducing prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling, reducing or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's organizational documents to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any actions by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002("SOX 304") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time provided however that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment

policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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OPTHEA LIMITED

INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Opthea Limited Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Opthea Limited (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

This deed poll is executed in favour of the Company. The Company has the benefit of, and is entitled to enforce this deed poll, even though it is not a party to this deed poll. This deed poll is irrevocable and may only be varied if the Company and the undersigned agree in writing.

Agreed, acknowledged and executed as a deed poll:

Signed, sealed and delivered by **#name#** in the presence of:

Signature of witness

Signature of **#name#**

Name of witness (print)