
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of October 2024

Commission File No. 001-39621

OPTHEA LIMITED
(Translation of registrant's name into English)

Level 4
650 Chapel Street
South Yarra, Victoria, 3141
Australia
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F Form 40-F

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release - Quarterly Report and Cashflow

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

OPTHEA LIMITED
(Registrant)

By: /s/ Frederic Guerard

Name: Frederic Guerard

Title: Chief Executive Officer

Date: 10/31/2024



ASX, Nasdaq and Media Release

31 October 2024

Quarterly Activity Report Q1 FY25

Highlights

- Leadership appointments to strengthen medical and commercial capabilities –Chief Financial Officer Tom Reilly, Chief Medical Officer Parisa Zamiri MD, PhD, and Chief Commercial Officer Mike Campbell
- Completed drug substance PPQ campaign validating manufacturing process of sozinibercept
- Joined the S&P/ASX 300 Index
- Presented at the 24th EURETINA Congress

Opthea Limited (ASX: OPT, NASDAQ:OPT) (“Opthea” or “the Company”), today released its Quarterly Activity Report and Appendix 4C for the three-month period ended September 30, 2024 (“Q1 FY25”).

Opthea is a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME).

Opthea’s lead product candidate, sozinibercept, is being evaluated in two fully enrolled pivotal Phase 3 clinical trials (COAST and ShORe) for use in combination with standard-of-care anti-VEGF-A therapies to improve overall efficacy and deliver superior vision gains compared to standard-of-care anti-VEGF-A agents alone.

Sozinibercept has the potential to become the first new treatment for wet AMD in 20 years to deliver superior visual gains when administered in combination with any anti-VEGF-A therapy.

Dr. Fred Guerard, Chief Executive Officer of Opthea Limited, commented, “We continue to make progress in positioning Opthea for success. Our recent executive appointments, including Tom Reilly as Chief Financial Officer, Dr. Parisa Zamiri as Chief Medical Officer, and Mike Campbell as Chief Commercial Officer, significantly strengthen our leadership team in anticipation of our Phase 3 topline data readout. The successful completion of the drug substance PPQ campaign is an important step towards de-risking the program and a potential biologics license application (BLA) filing of sozinibercept in wet AMD. Opthea’s inclusion in the S&P/ASX 300 Index helps further diversify our institutional shareholder base, while the Company’s scientific presence at the 24th EURETINA Congress, underscores our commitment to bringing sozinibercept to wet AMD patients, helping them achieve superior vision for greater independence in their lives.”



About Sozinibercept

Sozinibercept is a novel, first-in-class VEGF-C/D ‘trap’ inhibitor designed to be used in combination with standard-of-care anti-VEGF-A therapies to improve vision in wet AMD patients, many of whom respond sub-optimally or become refractory to existing therapies. VEGF-C and VEGF-D are known to independently stimulate retinal angiogenesis and vascular leakage and permeability, while VEGF-A inhibition can also lead to the upregulation of VEGF-C and VEGF-D. Research shows that the targeted inhibition of VEGF-C and VEGF-D with sozinibercept can prevent blood vessel growth and vascular leakage, which both contribute to the pathophysiology of retinal diseases, including wet AMD. Sozinibercept has the potential to become the first therapy in 20 years to improve visual outcomes in patients with wet AMD, enabling them to live more independently and have a better quality of life.

About Opthea’s Clinical Development Program

The Company is currently conducting two fully enrolled, pivotal Phase 3 multicenter, double-masked, randomized clinical trials, COAST (Combination OPT-302 with Aflibercept Study) and ShORe (Study of OPT-302 in combination with Ranibizumab), designed to assess the safety and superior efficacy of sozinibercept combination therapy versus standard-of-care anti-VEGF-A therapies for the treatment of wet AMD. Opthea’s Phase 3 clinical trial program is designed to support a broad label and, if successful, sozinibercept has the potential to be approved for use in combination with any anti-VEGF-A for the treatment of wet AMD patients. Sozinibercept has received Fast Track Designation from the US Food and Drug Administration for the treatment of wet AMD. To learn more about Opthea’s Phase 3 clinical trial program, please visit ClinicalTrials.gov for COAST, [NCT04757636](https://clinicaltrials.gov/ct2/show/study/NCT04757636), and ShORe, [NCT04757610](https://clinicaltrials.gov/ct2/show/study/NCT04757610).

In Opthea’s prospective, randomized, and controlled Phase 2b clinical trial including 366 treatment-naïve wet AMD patients, sozinibercept was administered in combination with standard-of-care ranibizumab for the treatment of wet AMD. Sozinibercept combination therapy met the pre-specified primary efficacy endpoint of a statistically superior gain in visual acuity at 24 weeks, compared to ranibizumab alone. In addition, secondary outcomes were positive with the combination therapy, including more patients gaining vision of 10 or more letters, improved anatomy, with a reduction in swelling and vascular leakage, and a favorable safety profile. The statistically significant results were published in [Ophthalmology](#) in February 2023.

About Wet AMD

Wet AMD remains the leading cause of vision loss in the elderly, impacting about 3.5 million people in the United States and Europe. The unmet medical need in wet AMD is significant, with many patients failing to achieve optimal vision outcomes or losing vision over time, despite treatment with anti-VEGF-A therapies.

Leadership Team

Opthea appointed Tom Reilly as the Chief Financial Officer, effective October 28, 2024. Mr. Reilly has more than 25 years of experience in building and leading finance and administration teams at life sciences companies both in the United States and globally. Before joining Opthea, Mr. Reilly served as Chief Financial Officer and Head of Human Resources of Amarin Corporation, supporting the commercial



expansion of the company's lead asset in cardiovascular disease. Mr. Reilly also served as Chief Financial Officer for Cara Therapeutics and Head of Finance for the Allergan General Medicines business, supporting several commercial launches in neuroscience. Mr. Reilly spent 14 years with Novartis, serving in roles of increasing responsibility, including Finance Head for the Oncology development unit, Chief Financial Officer for Novartis Pharma Austria, and Financial Controller for Novartis Pharmaceuticals US. He earned his bachelor's degree in finance from Manhattan College, a M.B.A from Seton Hall University, and is a certified public accountant. Mr. Reilly succeeds Daniel Geffken who has served as Chief Financial Officer ad interim.

Dr Parisa Zamiri, has been appointed Chief Medical Officer, effective October 7, 2024. She oversees clinical development and operations, regulatory and medical affairs, as well as biometrics. Dr. Zamiri is a physician-scientist with deep expertise in drug discovery and development. She is an ophthalmologist by training, with clinical experience in medical retina, immunology, and inflammation. She most recently served as the Chief Medical Officer at Complement Therapeutics and previously at Graybug Vision. Prior to that, she served as Vice President, Global Head of Clinical Development and Therapeutic Area Head for Ophthalmology at Novartis Pharmaceuticals, leading a group of clinical scientists and ophthalmologists that designed and executed Phase 1 to Phase 4 clinical trials with novel biologics, gene therapies, small molecules, and digital therapeutics for ophthalmic indications, such as wet AMD, geographic atrophy, retinitis pigmentosa and dry eye. Dr. Zamiri received her medical degree from the King's College Hospital, University of London, and did her ophthalmology residency at the North Thames Rotation, affiliated with the Moorfields Eye Hospital in London. She earned her PhD in ocular immunology for her research on the immune privilege of the subretinal space, conducted at the Schepens Eye Research Institute of Massachusetts Eye and Ear, a Harvard Medical School affiliated institute.

Mike Campbell has been appointed Chief Commercial Officer. Effective September 9, 2024. Mr. Campbell brings 30 years of biotechnology and pharmaceutical commercial leadership experience across sales, marketing, market access, patient services, and operations to the Company. Mr. Campbell dedicated most of his career to launching and commercializing innovative treatments for retinal and ocular surface diseases. During his tenure at Genentech, he was a key leader for the commercial build and launch of Lucentis[®], the first anti-VEGF-A treatment approved for wet AMD; he served in commercial leadership roles through the lifecycle of Lucentis[®], including the expansion into Diabetic Macula Edema, and Retinal Vein Occlusion. Mr. Campbell also contributed to the prelaunch commercial planning of Beovu[®] in wet AMD at Novartis, as well as the \$3.4 billion divestiture of Xiidra[®] for Dry Eye Disease to Novartis, during his tenure at Shire. Mr. Campbell most recently served as Senior Vice President and Head of Commercial at Viartis Eye Care who acquired Oyster Point Pharma, where he led the commercial build for the launch of Tyrvaya[®] in Dry Eye Disease. Mr. Campbell holds a Bachelor of Science degree from Auburn University and is an Executive Education graduate from The Wharton School, University of Pennsylvania.

Opthea is strategically and methodically building the company to position it for success. In addition to expanding its leadership team, Opthea continues to add experienced, talented, and dedicated members to support its mission. At the end of September 2024, Opthea employed 41 team members.

First Quarter Financial Performance & Cash Flow



Opthea's cash balance at 30 September 2024 was US\$167.5m, down from US\$172.5m in the prior quarter ending 30 June 2024, primarily reflecting the receipt of the Retail Entitlement finalised in the middle of July 2024 netted against the operational spend for the quarter of US\$39.8m to advance the two pivotal clinical trials towards top-line data readout.

Cash receipts for the quarter were US\$2.2m, which is up 175% from the US\$0.8m in the previous quarter. This is a consequence of the varying interest on cash holdings after the finalisation of the June/July 2024 capital raise. The net operating cash outflow for the period was US\$41.2m. The prior period net operating cash outflow was US\$38.6m.

Research and development cash costs for the quarter were US\$36.8m, 14% above the previous quarter (Q4 FY24: US\$32.2m). Administration cash costs in Q1 FY25 were US\$2.3m and were down 38% from previous quarter (Q4 FY24: US\$3.7m). Personnel costs of US\$4.3m were up 26% on the previous quarter of US\$3.4m. These were in line with expectations with the recent restructure and addition of staff in the quarter.

Use of Funds from Any Future Capital Raise

We intend to use the net proceeds from any current or future offering or capital raise to advance clinical development, chemistry, manufacturing, and controls, regulatory, and potential commercial activities of sozinibercept for wet AMD, and for general corporate purposes.

In accordance with ASX Listing Rule 4.7C.3, cash paid for Directors and Non-Executive Directors in Q1 FY25 amounted to US\$290k in aggregate which includes director fees and customary reimbursement of applicable costs, including costs for traveling to Opthea meetings.

Authorized for release by CEO Fred Guerard, PharmD, CEO.

Enquiries

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About Opthea

Opthea (ASX:OPT; NASDAQ:OPT) is a biopharmaceutical company developing novel therapies to address the unmet need in the treatment of highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME).

Opthea's lead product candidate, sozinibercept, is being evaluated in two fully enrolled pivotal Phase 3 clinical trials (COAST, [NCT04757636](#), and ShORe, [NCT04757610](#)) for use in combination with standard-of-care anti-VEGF-A therapies to improve overall efficacy and deliver superior vision gains compared to the standard-of-care anti-VEGF-A agents alone.

To learn more, visit [our website](http://www.opthea.com) at www.opthea.com and follow us on [X](#) and [LinkedIn](#).



Risk Factors

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the factors, including potential uncertainties described below, as well as the Risk Factors included in our 20-F filing for the fiscal year ending June 30, 2024 as filed with the Securities and Exchange Commission on August 30, 2024, including our condensed consolidated financial statements and related notes included elsewhere in our Half-Year Report for the fiscal period ended December 31, 2023. If any of the risks and uncertainties described under Risk Factors included in our 20-F for the fiscal year ended June 30, 2024, or the following uncertainties occur, it could harm our business, prospects, results of operations and financial condition. In such event, the trading price of the ordinary shares and the ADSs could decline, and you might lose all or part of your investment. You should not interpret our disclosure of any of the risks and uncertainties described under Risk Factors included in our 20-F for the fiscal year ended June 30, 2024, or the following uncertainties to imply that such risks have not already materialized.

Development Funding Agreement, Financial Resources and Timing of Completion of Clinical Trials

The Company had US\$167.5 million in cash at September 30, 2024. Opthea believes that it will be able to fund its operating and research and development expenses into the third calendar quarter of 2025, which is through the anticipated Phase 3 topline data readouts for COAST (Combination OPT-302 with Aflibercept Study), and ShORe (Study of OPT-302 in combination with Ranibizumab). Opthea may raise additional external funding, including through equity financing, prior to or after its reporting of the top-line data. The amount and timing of Opthea's 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 the timing of regulatory submissions, the performance and cost efficiency of contract research organizations ("CROs") and contract manufacturing organisations, and the continuing impacts of the global supply chain and macroeconomic challenges. In particular, delays in patient enrolment have resulted, and may in the future result in increased costs or delays and other impacts on the timing of our Phase 3 clinical trials. Opthea has based this estimate on assumptions that may prove to be wrong, and Opthea could exhaust its available capital resources sooner than it expects. Opthea may also experience future delays in its clinical development or commercialization of sozinibercept for wet AMD, including due to factors and conditions set forth above or other factors that Opthea cannot presently anticipate.

Opthea intends to focus its development efforts on achieving commercialization of sozinibercept for the treatment of wet AMD and will require additional funding to reach commercialization of sozinibercept in any indication, including wet AMD. In addition, Opthea will require additional external funding to meet the minimum cash condition under the Development Funding Agreement ('DFA'), including prior to the readout of top-line results for Phase 3 clinical trials for OPT-302. If Opthea experiences further delays in its Phase 3 clinical trials, Opthea may need to raise additional external funding, including potentially dilutive equity financing.



Opthea does not have any other committed external source of funds and expects to finance future cash needs through public or private equity or debt offerings or collaborations. However, the DFA limits the type of financing Opthea may pursue in the future and Opthea may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all.

If Opthea raises additional capital, this may cause dilution to holders of the Company's ordinary shares and American Depositary Shares.

Forward-Looking Statements

Certain statements made during or in connection with this announcement contain or comprise certain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. The words "expect", "believe," "should", "could", "may", "will", "plan" and other similar expressions are intended to identify forward-looking statements. Forward-looking statements in this ASX announcement include statements regarding the anticipated sozinibercept topline data timing for the two Phase 3 pivotal trials in wet AMD, and the Company's continued efforts to advance its BLA preparations for FDA approval and prepare for commercial readiness. Forward-looking statements, opinions and estimates provided in this ASX announcement are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current conditions. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. They involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Opthea and its directors and management and may involve significant elements of subjective judgment and assumptions as to future events that may or may not be correct. These statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to future capital requirements, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate sozinibercept safety, tolerability and therapeutic efficacy, clinical research organization and labor costs, intellectual property protections, and other factors that are of a general nature which may affect the future operating and financial performance of the Company including risk factors set forth in Opthea's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the "SEC") on August 30, 2024 and other future filings with the SEC. Actual results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Subject to any continuing obligations under applicable law or any relevant ASX listing rules, Opthea disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this ASX announcement to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based, except as otherwise required by applicable law

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

OPTHEA LIMITED.

ABN

ARBN 672254 027

Quarter ended ("current quarter")

September 30 2024

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (3 months) \$US'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(36,821)	(36,821)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(4,264)	(4,264)
(f) administration and corporate costs	(2,287)	(2,287)
1.3 Dividends received (see note 3)		
1.4 Interest received	2,124	2,124
1.5 Interest and other costs of finance paid	(2)	(2)
1.6 Income taxes paid	(-)	(-)
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)	64	64
1.9 Net cash from / (used in) operating activities	(41,186)	(41,186)

2. Cash flows from investing activities

2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments	(11)	(11)
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cashflows		Current quarter \$US'000	Year to date (3 months) \$US'000
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
2.6	Net cash from / (used in) investing activities	(11)	(11)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	34,796	34,796
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings		

3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)	(31)	(31)
3.10	Net cash from / (used in) financing activities	34,765	34,765

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	172,471	172,471
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(41,186)	(41,186)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(11)

Consolidated statement of cashflows		Current quarter \$US'000	Year to date (3 months) \$US'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	34,765	34,765
4.5	Effect of movement in exchange rates on cash held	1,474	1,474
4.6	Cash and cash equivalents at end of period	167,513	167,513

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$US'000	Previous quarter \$US'000
5.1	Bank balances	20,467	91,729
5.2	Call deposits	147,046	80,742
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	167,513	172,471

6. Payments to related parties of the entity and their associates		Current quarter \$US'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	1,541
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Cash Paid for Directors and Non-Executive Directors in quarter 3 amounted to US\$138k which includes salaries, travel and reimbursement of any costs.

7. Financing facilities	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	170,000	170,000
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	170,000	170,000
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
<p>In August 2022, Opthea entered into a Development Funding Agreement (DFA), The last tranche and option of the DFA was drawn in December 2023 for a total capital funding of US\$170m. Only upon regulatory approval is the Company obligated to pay up to 4.0x the investment amount via a 7% royalty on net sales and certain milestone payments. Opthea accounts for the DFA on its balance sheet as the accreted value based on implied non-cash interest, adjusted for fair market changes if required.</p>		

8. Estimated cash available for future operating activities	\$US'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(41,186)
8.2 Cash and cash equivalents at quarter end (item 4.6)	167,513
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2+ item 8.3)	126,327
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.06
<i>Note: if the entity has reported positive net operating cashflows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: n/a

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: n/a

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: n/a

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1. This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
2. This statement gives a true and fair view of the matters disclosed.

Date: October 31, 2024

Authorised by: Frederic Guerard CEO
(Name of body or officer authorising release – see note 4)

Notes

- 2.1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2.2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 2.3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 2.4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".



- 2.5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.
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