

Appendix 4D
Half Year Financial Report

Name of entity:

ACTINOGEN MEDICAL LIMITED

ABN or equivalent company reference:

14 086 778 476

Current Period:

1 July 2024 to 31 December 2024

(Previous corresponding period: 1 July 2023 to 31 December 2023)

RESULTS FOR ANNOUNCEMENT TO THE MARKET

	31/12/2024 \$	31/12/2023 \$	Change \$	Amount change \$
Revenue from ordinary activities	244,406	106,774	129%	137,632
Loss from ordinary activities after tax attributable to members	(8,168,979)	(11,556,659)	-29%	3,387,680
Net loss for the period attributable to members	(8,168,979)	(11,556,659)	-29%	3,387,680
Net tangible asset per share	0.007	0.004		

BRIEF EXPLANATION OF THE ABOVE FIGURES

Revenues from ordinary activities relates to interest revenue from cash held in interest-bearing accounts and short-term deposits.

The total net loss after tax decreased by 29%. The primary expenditure item was Research & Development. Refer to the attached Directors' Report and financial statements for further information.

Details of entities over which control has been gained or lost during the period

Not applicable. There has been no entity over which control has been gained or lost during the period.

Dividend / Distribution Payments or Reinvestment Plans

Not applicable. No dividends have been paid or declared during the half year ended 31 December 2024, in the previous financial year ended 30 June 2024 or in the previous corresponding period. The Company does not propose to pay dividends in the immediate future.

Associates / Joint Ventures

Not applicable. The Company has not engaged in the acquisition of associates, nor has it engaged in any joint ventures in the half year ended 31 December 2024.

Foreign Entities

Not applicable.

Review Conclusion

This Report is based on the Interim Financial Report for the half year ended 31 December 2024. The financial report has been subject to a review by an independent auditor and the review is not subject to qualification.

Authorised for release by the Board.

Dr Steven Gourlay
Managing Director
24 February 2025
Sydney, New South Wales

For personal use only



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Disclaimer

This Interim Report may contain certain "forward-looking statements" that are not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

Operating & financial review

1. PRINCIPAL ACTIVITIES

The principal activity of the company during the year focused on the ongoing clinical development of Xanamem® (emestedastat), a unique inhibitor of the 11 β -HSD1 enzyme that achieves target engagement in the brain. It is an oral medication for neurological diseases amenable to its mechanism of controlling cortisol in brain cells. Brain cortisol is associated with a number of neurological diseases, including neurodegenerative diseases such as Alzheimer's disease (AD) and neuropsychiatric diseases like major depressive disorder (MDD).

2. OPERATIONS REVIEW

Highlights – Advancing to late-stage clinical development

Progressed two major phase 2 clinical trial programs in Alzheimer's disease and depression

World Health Organization (WHO) granted new and unique International Nonproprietary Name (INN) 'emestedastat' to Xanamem

Published an academic manuscript in peer-reviewed journal, *Clinical Pharmacology in Drug Development*

Commenced production of scale-up batch of drug substance from contract manufacturer to create tablet supply for current and future trials, and confirm readiness for future commercial quantity production

Preparing for commercialization in all other major aspects of the business

Received a \$9.0 million Research & Development (R&D) tax incentive rebate in November 2024. Funding secured to mid-late CY 2026

CEO and CMO presented at numerous significant international conferences and conducted meetings at industry gatherings to continue evaluating potential value-add regional and global business development opportunities.

The first half of the company's 2025 financial year was marked by robust clinical pipeline progress and several major milestones and events including the initiation of preparations for the approaching commercialization of Xanamem.

XanaMIA phase 2b/3 AD trial stepping up

The XanaMIA phase 2b/3 clinical trial in patients with biomarker-positive mild to moderate Alzheimer's disease is picking up pace as clinical sites step up activity with 25 sites now actively pre-screening potential trial participants.

The trial is enrolling a total of 220 participants with mild to moderate AD and elevated levels of the blood biomarker pTau181, designed to identify participants with biomarker-positive AD whose disease is likely to progress during the 36-week treatment period. This design augments the ability to detect a Xanamem 10 mg daily treatment benefit versus placebo over the observation period, as suggested by the analysis of pTau-positive patients in a previous phase 2a trial over 12 weeks ([Taylor et. al. 2024](#)). The primary endpoint of the trial is the Clinical Dementia Rating – Sum of Boxes (CDR-SB) scale, universally included in contemporary AD trials. Other measures include the effects of Xanamem on clinical endpoints of cognition and functional ability.

More than 300 people have been pre-screened with a blood pTau test and approximately 40 have entered the 36-week treatment phase of the trial with another 20 in the latter stages of screening. Final results are expected in the second half of 2026 with interim results anticipated in Q4 this year.

Patients or families and carers of those interested in participating in the XanaMIA phase 2b/3 AD trial in the USA or Australia can seek further information and check for eligibility to join the trial by visiting the company's [website](#).

XanaCIDD phase 2a MDD trial completed - seeking partner(s) to conduct phase 2b trial

The XanaCIDD trial was a six-week phase 2a, proof-of-concept, placebo-controlled, parallel group trial in 165 patients with cognitive impairment in major depressive disorder (MDD). Xanamem (10 mg) or placebo was added to the existing anti-depressant therapy (n=134) or, in patients with a previous history of anti-depressant treatment not currently on an anti-depressant, as a stand-alone treatment (n=31). Results were reported in August 2024.

There was a clinically meaningful and persistent improvement in depression measured by the key secondary endpoint of MADRS¹ and in the Patient Global Impression of Severity (PGI-S) measure at multiple timepoints. Improvement in depressive symptoms was statistically significant in the overall population four weeks after the end of 6 weeks of treatment (Week 10), and at both Week 6 and Week 10 in participants taking a background selective serotonin reuptake inhibitor anti-depressant simultaneously. Cognition improved to a similar extent in both Xanamem and placebo groups (p not significant).

This outcome provides further evidence to support Xanamem as a cortisol control mechanism and indicates that the 10 mg daily dose is clinically effective at reducing symptoms of depression, supporting the selection of 10mg as a clinically active dose for the XanaMIA AD trial.

The company has completed its data analysis and is exploring the path forward for larger trials in MDD with regulators, global thought leaders and potential strategic partners.

New and unique name 'emestedastat' granted to Xanamem by WHO

In January 2025, the WHO granted the nonproprietary name 'emestedastat' to Actinogen for Xanamem. An INN is a unique, globally recognized name for a pharmaceutical drug or active ingredient. Each active substance that is to be marketed as a pharmaceutical must be granted a unique name of worldwide acceptability to ensure the clear identification, safe prescription and dispensing of medicines to patients. Nonproprietary names are intended for wide use ranging from labelling and product information to drug regulation and scientific literature.

By granting the INN, the WHO recognized Xanamem (emestedastat) as the first drug to be named for the class of enzyme inhibitors of 11 β -HSD1 by assigning it the unique suffix of '-stedastat' pertaining to its mechanism of action on 11 β -HSD1. Emestedastat is a unique orally administered molecule in its own class as a 'brain tissue cortisol synthesis inhibitor'

Published clinical pharmacology academic manuscript in peer-reviewed journal, *Clinical Pharmacology in Drug Development*

Two academic manuscripts were published in 2024 in the peer-reviewed *Journal of Alzheimer's Disease*.

On 6 February 2025 the company announced the publication of its latest peer-reviewed journal article entitled *Clinical Pharmacology and Approach to Dose Selection of Emestedastat, a Novel Tissue Cortisol Synthesis Inhibitor for the Treatment of Central Nervous System Disease* in the journal associated with the American College of Clinical Pharmacology, *Clinical Pharmacology in Drug Development*. The review confirms the utility of the 10 mg daily dose of Xanamem being used in current clinical trials. The journal article can be accessed [here](#).

Manufacturing

During the period, the company commenced production of a scale-up batch of drug substance from its contract manufacturer which will progressively be manufactured into Xanamem tablets for use in current and future trials. This step will also confirm readiness for eventual commercial quantity production to potential pharma partners and regulators.

Preparing for commercialization

The company has provided clinical 'proof of concept' in two separate clinical indications to date – AD and MDD. These phase 2 trial data add to the validation of the Xanamem program from prior clinical trials in healthy volunteers and the high levels of target engagement in the brain seen with PET imaging. At this stage the company believes Xanamem's action to control tissue production of cortisol in the brain, also known as 'The Cortisol Hypothesis', is now well-established as a new therapeutic mechanism.

With the Xanamem program in late-stage clinical development, the company is actively engaging in an important range of initiatives in addition to those outlined above to prepare for the approaching commercialization phase. These include:

- Appointment of inaugural Chief Commercial Officer (CCO) - In October 2024, the company appointed Mr Andy Udell as CCO. Mr Udell is a commercial leader with demonstrated success taking biotech companies from the clinic through market planning, commercial readiness and full commercial integration and is already proving to be a valuable commercially savvy resource

The company also continues to fill other strategic operational roles to ensure the success of its clinical development program, including those required for the XanaMIA phase 2b/3 Alzheimer's disease trial in Australia and the USA

- Regulatory meetings – the company continues to plan its path forward in both AD and MDD, with the focus for 2025 being the implementation of the XanaMIA phase 2b/3 trial and meetings with regulators for both AD and MDD to understand registrational requirements for marketing approvals

¹ MADRS: The Montgomery-Asberg Depression Rating Scale is a structured psychiatric interview evaluating MDD symptoms

- Partnering – dialogue continues with multiple parties spanning potential regional and/or global partnership arrangements, with an emphasis on those organizations that are interested in both AD and MDD. The company is also investigating Australian and international grant opportunities that could be used to support expansion of the AD and MDD clinical trial programs
- Intellectual property protection from future generic competition – as a new chemical entity and unique class of drug, Xanamem has additional commercial protection from data exclusivity laws independent of protection provided by approved patents. Data exclusivity laws provide protection against generic manufacturers using Actinogen’s clinical or nonclinical data for a substantial period from the date of marketing approval and therefore effectively block generic competition from the market during that time. Data exclusivity periods vary by country, for example, five years in Australia and the US and ten years in the EU

In addition, patents typically have a period of 20 years from the date of grant. Actinogen has key patents granted for the Xanamem molecule’s chemistry and continues to prosecute newer patents in multiple countries covering the treatment of cognitively normal people, manufacturing process and the treatment of patients with depression supporting an overall robust framework of intellectual property protection

- Ancillary nonclinical and clinical studies – clinical pharmacokinetic (measuring blood levels in the body) and nonclinical studies are being conducted in parallel with the XanaMIA trial appropriate to Xanamem’s late-stage clinical development to support the Xanamem development program.

\$9.0 million R&D tax incentive rebate received and strong cash runway

In November 2024, the company announced that it had received a \$9.0 million R&D tax incentive rebate from the Australian Tax Office for the 2024 financial year. The R&D tax incentive is an Australian federal government program under which companies receive cash refunds for eligible research and development expenditure.

Combined with the proceeds of an \$11.1 million capital raising during the half, the company had a closing cash balance of \$22.9 million at 31 December 2024. Based on the current enrolment profile for the Alzheimer’s clinical trial and other committed expenditure, the company is funded to mid-late CY2026.

Presented at numerous international and Australian AD conferences and conducted investment and partnering meetings associated with events and conferences, including as set out below.

CMO Dr Dana Hilt presented an academic poster at the Alzheimer’s Association International Conference (AAIC) in Philadelphia, USA on 29 July 2024 summarizing the comprehensive clinical pharmacology approach used by the company integrating data from multiple clinical trials to determine the target dose range for Xanamem. The AAIC is a leading global forum to advance dementia science.

CEO Dr Steven Gourlay presented to the Pitt Street Research Conference in Sydney on 18 September 2024, discussing Xanamem’s attractive therapeutic profile for the treatment of neurologic conditions by controlling brain cortisol, and the positive outlook for the company as it enters late-phase clinical trials.

Dr Gourlay presented at the Dementia Trials Australia Annual Scientific Meeting in Sydney on 11 October 2024. His presentation included an analysis of the important validation of Xanamem’s mechanism of action to control brain cortisol provided by the anti-depressant activity identified in the XanaCIDD phase 2a depression trial.

Dr Hilt and Senior Clinical Scientist Dr Jack Taylor presented an academic poster at the Clinical Trials on Alzheimer’s Disease (CTAD) conference in Madrid, Spain on 31 October 2024. The poster presented data to show that elevated plasma pTau181 is useful in predicting clinical decline in patients with mild, clinically diagnosed AD.

Dr Hilt and Dr Gourlay presented at the Sachs Associates 8th Annual Neuroscience Innovation Forum in San Francisco on 12 January 2025. Their presentation was titled *Oral emestedastat (Xanamem®/UE2343): Controlling brain cortisol to slow progression in Alzheimer’s disease*. While in San Francisco, members of the ACW leadership team participated in a significant number of partnering, analyst and investor meetings associated with the 43rd Annual J.P. Morgan Healthcare Conference from January 13 to 16, 2025.

For further information on all the above milestones and events, please refer to the ASX announcements section under the Investor Centre tab on the Actinogen website www.actinogen.com.au.

3. FINANCIAL REVIEW

(a) Financial Performance

The financial performance of the company during the half year ended 31 December 2024 is as follows:

	Half year ended 31/12/2024 \$	Half year ended 31/12/2023 \$
Revenue and other income (\$)	244,406	1,015,804
Net loss after tax (\$)	(8,168,979)	(11,556,659)
Loss per share (cents)	(0.28)	(0.56)
Dividend (\$)	-	-

(b) Financial Position

The financial position of the company as at 31 December 2024 is as follows:

	As at 31/12/2024 \$	As at 30/06/2024 \$
Cash and cash equivalents	22,865,981	9,450,735
Net assets / Total equity	23,968,845	19,696,499
Contributed equity	113,814,110	100,023,653
Accumulated losses	(89,904,814)	(81,735,835)

4. MATERIAL RISKS

In addition to risks associated with any business there are specific, material risks that, either individually or in combination, may materially and adversely affect the future operating and financial performance and prospects of Actinogen and the value of its shares. Some of these risks may be mitigated by Actinogen's internal controls and processes but some are outside the control of Actinogen, its directors and management. The material risks identified by management are described below:

Risk	Implication	Mitigation
Research and Development Activities	Actinogen's future success is dependent on the performance of Actinogen's lead molecule, Xanamem, in clinical trials and whether it proves to be a safe and effective treatment. Xanamem is an experimental product in late-stage clinical development. Product commercialization resulting in potential product sales revenues are likely to be some years away without any guarantee that it will be successful. It requires additional research and development, including ongoing clinical evaluation of safety and efficacy in clinical trials and regulatory approval prior to marketing authorization. Until Actinogen is able to provide further clinical evidence of the ability of Xanamem to improve outcomes in patients, the future success of its technology remains speculative. Research and development risks include uncertainty of the outcome of results, difficulties or delays in development and generally the uncertainty that surrounds the scientific development of pharmaceutical products.	Mitigation measures include 'following the science' of the data generated for Xanamem to date, hiring expert clinical development professionals to design, oversee and analyse the trial program, engagement of leading contract research organisations to manage components of the trials and drive recruitment as well as engagement of well-qualified clinical sites experienced in clinical trial execution and in the relevant therapeutic areas.
Regulatory Approvals	Actinogen operates within a highly regulated industry, relating to the manufacture, distribution and supply of pharmaceutical products. There is no guarantee that Actinogen will obtain the required approvals, licenses and registrations from relevant regulatory authorities in jurisdictions in which it operates. The commencement of clinical trials may be delayed and Actinogen may incur further costs if the Food and Drug Administration (FDA) and other regulatory agencies are tardy or observe deficiencies that require resolution or request additional studies be conducted in addition to those that are currently planned. A change in regulation may also adversely affect Actinogen's ability to commercialize and manufacture its treatments.	Mitigation measures include operating under a US FDA Investigational New Drug (IND) process, engagement of suitably qualified and experienced persons with expertise in the regulation of small molecule therapies, establishing relationships with regulators to facilitate feedback and guidance from them, regular review of evolving regulatory requirements and analysis of the company's activities and plans against regulatory expectations in key jurisdictions, and ensuring that the expectations and uncertainties related to regulatory approvals, and the timing of such approvals, are included in business plans.
Intellectual Property	Securing rights in technology and patents is an integral part of securing potential product value in the outcomes of biotechnology research and development. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. Actinogen's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Because the patent position of biotechnology companies can be highly uncertain and frequently involves complex legal and factual questions, neither the breadth of claims allowed in biotechnology patents, nor their enforceability can be predicted. There can be no assurance that any patents which Actinogen may own, access or control will afford Actinogen commercially significant protection of its technology or its products or have commercial application or that access to these patents will mean that Actinogen will be free to commercialize its technology. Competitors may file patents which could limit the company's freedom to operate for its technologies. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid Actinogen's patented technology. Actinogen's current patenting strategies do not cover all countries which may lead to generic competition arising in those markets.	Mitigation measures include use of expert patent attorneys, regular review of the relevant patent landscape, filing of additional patents and maintenance of patents in a broad geography covering major pharmaceutical markets. The company also has significant protection by virtue of data exclusivity regimes, which in most countries afford extensive multi-year protection from the date a marketing approval is obtained in relation to data generated in the clinical and non-clinical trial processes undertaken in the process of obtaining such an approval.

Risk	Implication	Mitigation
<p>Partnership Model</p>	<p>While undertaking its phase 2/3 clinical program the company is actively pursuing value-add partnership(s) to expand the trial program further and secure commercialization pathways in one or more territories. This model, which typically involves entering into commercial arrangements with other companies in which Actinogen would license its Xanamem technology to the partner in one or more indications and/or geographies and the partner assumes some or all responsibility for progressing, and paying for, the clinical trials and eventual commercialization. This strategy involves the risk that the company will lose some or all control of the development timetable of its products to its commercial partner(s), which may give rise to an unanticipated delay in any commercial returns. Further, the company may be unable to enter into arrangements with suitable commercial partners in respect of relevant indications. If either of these outcomes occurred, the company's business and operations may be adversely affected.</p>	<p>Mitigation measures employed by the company include using expert business development professionals to build relationships with potential partners, performing rigorous due diligence, ensuring that the commercial terms negotiated are fair and utilising expert legal advice to ensure that appropriate warranties and commitments are included in contracts, and that the contracts reflect the agreed commercial position. The company also seeks to form partnerships with relevant regulatory agencies including the FDA, EMA, and MHRA.</p>
<p>Manufacturing</p>	<p>The company's products are manufactured using a specialised manufacturing process at an expert third party facility, as is the norm in the industry. An inability of these third-party contract manufacturing organisations to continue to manufacture the company's products in a timely, economical and/or consistent manner, including any scale up of manufacturing processes, or to maintain legally compliant manufacturing to maintain product supply, could adversely impact on the progress of the company's development programs and potentially on the financial performance of the company.</p>	<p>Mitigation measures include performing rigorous due diligence on contract manufacturers, engaging contract manufacturers with strong track records and sufficient capability to meet the company's foreseeable needs, employing senior managers responsible for managing and monitoring the performance of contract manufacturers, gradually scaling up batch production runs to ensure scalability and maintenance of quality systems and related documentation.</p>
<p>Fundraising risk</p>	<p>Actinogen is reliant upon fundraising to fund its operations. Funds may be available in the future from grants, development and commercial partnerships, tax incentives and capital markets but are not guaranteed. Capital market volatility may impact Actinogen's ability to raise future funds. Currency market fluctuations could impact the amount of funding required where expenditure is denominated in currencies other than the Australian dollar.</p>	<p>Mitigation measures include prudent cash flow forecasting, filing of multiple grant applications, key management focus on partnership relationships, use of specialist advisors in tax, business development and investor relations, maintaining high quality analyst coverage, frequent communications to retail and institutional investors and having a presence at many scientific and business conferences.</p>

5. BUSINESS STRATEGY & OUTLOOK

Actinogen's strategic priorities are focused on four key elements:

- **Accelerate clinical development in Alzheimer's disease**
- **Evaluate the optimal phase 2b development pathway in depression**
- **Forward planning and preparing for commercialization**
- **Proactively engage with regulators, prospective development and commercial partners**

Accelerate clinical development in Alzheimer's disease

The phase 2a clinical biomarker trial highlighted the considerable potential benefits of Xanamem in biomarker-positive patients with AD. These results strongly supported the feasibility of using both the CDR-SB and cognitive function endpoints to evaluate the efficacy of Xanamem to slow or halt disease progression in our XanaMIA phase 2b/3 AD trial. These data were used to simulate and design the current phase 2b/3 trial to increase its chances of achieving successful outcomes

Key features of the phase 2b/3 trial are:

- Enrolment of the same patient population where the large Xanamem effect was seen in patients with mild AD and elevated pTau181 protein in the blood (an indication of progressive AD) in Australia and the USA
- Rapidly pre-screen patients for elevated pTau and key clinical criteria to reduce later screening failures which are more costly
- High quality rating training and standardization to minimize 'noise' in subjective endpoints like the CDR-SB
- 'Hands on' clinical operations and management based in Australia supplemented by select use of USA-based contractors to speed timelines and reduce cost.

Evaluate the optimal development pathway in depression

The positive phase 2a XanaCIDD trial in patients with MDD and cognitive dysfunction provided a rich dataset with which to explore potential responder characteristics and design the next phase 2b trial.

Xanamem treatment in the phase 2a trial showed clinically meaningful and persistent improvement in depression measured by the key MADRS endpoint and in the Patient Global Impression of Severity (PGI-S) measure at multiple endpoints. Maximal benefits on depression for all endpoints were evident at Week 10, four weeks after the end of treatment, indicating a durable therapeutic effect resulting from controlling brain cortisol.

Full analysis of the phase 2a clinical trial data has been completed to identify ideal population and endpoints for future trials.

Key upcoming actions of the phase 2b design phase are:

- Finalize discussions and proposed protocol design with key stakeholders, including:
 - Local and global thought leaders in MDD
 - Potential strategic development partners
 - The FDA and possibly the EMA
- Submit protocol to the FDA IND dossier in Q1 2025 and wait 30 days for clearance
- Continue exploring a range of funding options such as grants or potential licensing or partnership arrangements

Forward planning and preparing for commercialization

In addition to conducting high quality clinical trials there are numerous other important activities for successful drug development which form part of the company's forward planning including preparing for the commercialization of Xanamem.

Key actions under this strategic priority are:

- Optimize manufacturing processes for supply of future clinical trials and marketed product
- Use to-be-marketed tablet formulation in all trials
- Leverage regulatory designations such as ILAP (granted for AD) and FDA breakthrough (planned for AD and possibly depression) where possible
- Maximize intellectual property protections through expanded patent protection and capitalizing on extensive data exclusivity laws wherever available
- Integrate global regulatory strategic planning to optimize path to marketing approvals in multiple geographies
- Plan and conduct required regulatory nonclinical studies to the Good Laboratory Practice standard
- Plan and conduct ancillary clinical pharmacology studies required for marketing approvals.

Proactively engage with regulators, prospective development and commercial partners

Our active business development plan maintains and develops relationships with a broad range of potential drug development partners, both large and small, regional and global. The company also seeks to form partnerships with relevant regulatory agencies including the FDA, the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).

Our engagement with partners has been further strengthened with the positive clinical data on depression from the XanaCIDD trial, along with recognition of peer-reviewed publications of our human PET study, the phase 2a biomarker trial and the clinical pharmacology manuscript for Xanamem. These data point to 10 mg daily as a clinically relevant, safe and effective dose level for depression and Alzheimer's disease, which is the dose being used in the XanaMIA phase 2b/3 AD trial.

Currently we have three open Investigational New Drug applications with the US FDA, using the Alzheimer's program as the 'core' dossier. Further collaboration is planned in the coming months with the FDA covering manufacturing, quality, clinical and nonclinical matters for the depression program. We also aim to build and maintain good working relationships with other global regulators such as the EMA and the UK MHRA.

Key actions under this strategic priority are:

- Consider all types of value-add partnerships
- Proactively engage with the universe of potential biopharma partners who could bring co-development synergies to the Xanamem programs
- Maintain close working relationships with key regulators such as the US FDA, UK MHRA and the EMA
- Partner with leading clinical trial implementation providers
- Partner with key community AD and depression organizations in Australia and globally.

Outlook

Our XanaCIDD MDD trial results in 2024 showed that Xanamem's mechanism of action in the brain to inhibit tissue production of cortisol has significant clinical benefits. In addition, positive confirmation of Xanamem's effective mechanism of action at the 10 mg daily dose in the XanaCIDD trial is driving accelerated participant recruitment and treatment in the current XanaMIA phase 2b/3 trial in 220 patients with biomarker-positive AD.

Sites across Australia and the USA have stepped up the active recruitment and treatment of the target patient population to meet the expected interim results timeline of Q4 2025, once around 100 patients have reached six months of treatment. Final results for all 220 patients are expected in H2 2026.

Upcoming news events this calendar year include ongoing academic presentations at major industry conferences and meetings, peer-reviewed publication of the XanaCIDD phase 2a trial results in depression, results of FDA and/or EMA interactions, a Clinical Trials Science Forum webinar focused on preparing for commercialization, clinical trial updates including enrolment of the 100th patient in XanaMIA phase 2b/3 AD trial in Q2, interim data from the XanaMIA trial in Q4 CY2025 (and final results H2 CY2026). A phase 2b trial in depression could commence this year, subject to identification of non-dilutionary sources of funding such as grants, partnership or licensing deals.

Meanwhile manufacturing, regulatory, clinical pharmacology and nonclinical planning and activities continue in high order to enable rapid expansion on successful phase 2 results.

As the company enters late-stage clinical development, we firmly believe based on the results of our science-driven trials in around 400 people so far, that Xanamem has the potential to be a first-in-class drug for the treatment of AD and a first-in-class antidepressant with a novel mechanism unlike any competitors. This provides great hope to patients and their families in diseases where there is significant unmet medical need.

We remain committed to proactive management of all aspects of our business to ensure the best possible outcomes for patients and shareholders. This includes optimizing our current clinical trials program, forward planning for marketing approvals and preparing for commercialization while balancing partnering efforts and building optimal shareholder returns.

Directors' report

Your Directors present their report pertaining to Actinogen Medical Limited ('Actinogen Medical' or 'the Company') for the half year ended 31 December 2024.

1. BOARD OF DIRECTORS

The names and details of the Company's Directors in office during the interim financial year and until the date of this report are as follows. Directors were in office for the entire period, unless otherwise stated.

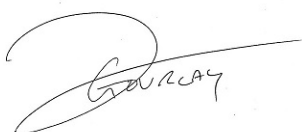
Name	Position	Appointed	Resigned
Dr Geoffrey Brooke	Non-Executive Chairman	1/03/2017	Current
Dr Steven Gourlay	Managing Director / Chief Executive Officer	24/03/2021	Current
Dr George Morstyn	Non-Executive Director	1/12/2017	Current
Mr Malcolm McComas	Non-Executive Director	4/04/2019	Current
Dr Nicki Vasquez	Non-Executive Director	1/03/2023	Current

2. OPERATING AND FINANCIAL REVIEW

Please refer to pages 3 to 10 of this interim report for information on the Company's principal activities, operations, financial position, material risks and business strategy and outlook.

12. AUDITOR'S INDEPENDENCE DECLARATION

The Auditor's Independence Declaration as required under section 307C of the Corporations Act 2001 for the half year ended 31 December 2024 forms a part of the Directors' Report and can be found on page 12. Signed in accordance with a resolution of the Board of Directors.



Dr Steven Gourlay
Managing Director
Sydney, New South Wales
Monday, 24th February 2025



**Shape the future
with confidence**

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Auditor's independence declaration to the directors of Actinogen Medical Limited

As lead auditor for the review of the half-year financial report of Actinogen Medical Limited for the half-year ended 31 December 2024, I declare to the best of my knowledge and belief, there have been:

- a. No contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review;
- b. No contraventions of any applicable code of professional conduct in relation to the review; and
- c. No non-audit services provided that contravene any applicable code of professional conduct in relation to the review.

Ernst & Young

Timothy Dachs
Partner
24 February 2025

Statement of comprehensive income

For the half year ended 31 December 2024

	Note	Half year ended 31/12/2024 \$	Half year ended 31/12/2023 \$
Interest revenue		244,406	106,774
Other income		-	909,030
Total revenue & other income	5	244,406	1,015,804
Research & development costs	5	(4,582,920)	(8,952,776)
Employment costs		(1,867,012)	(1,909,240)
Corporate & administration costs		(975,564)	(907,903)
Finance costs		(20,405)	(11,115)
Realised (loss) / unrealised gain on foreign currency		(31,573)	805
Share-based payment expenses		(733,368)	(580,266)
Amortisation expense	10	(156,373)	(157,658)
Depreciation expense (right-of-use asset)	9	(40,482)	(40,504)
Depreciation expense (office equipment)	8	(5,688)	(13,806)
Total expenses		(8,413,385)	(12,572,463)
Loss before income tax		(8,168,979)	(11,556,659)
Income tax expense		-	-
Loss for the half year		(8,168,979)	(11,556,659)
Other comprehensive income			
Items that may be reclassified subsequently to profit and loss:			
Other comprehensive income		-	-
Total comprehensive loss for the half year		(8,169,979)	(11,556,659)
Loss per share for attributable to the ordinary equity holders of the Company			
Basic and diluted loss per share in cents		(0.28)	(0.56)

The above Statement of comprehensive income should be read in conjunction with the accompanying Notes.

Statement of financial position

As at 31 December 2024

	Note	As at 31/12/2024 \$	As at 30/06/2024 \$
Current Assets			
Cash and cash equivalents	6	22,865,981	9,450,735
Other receivables and prepayments	7	327,520	9,425,548
Total Current Assets		23,193,501	18,876,283
Non-Current Assets			
Property, plant and equipment	8	21,063	24,389
Intangible assets	10	1,937,737	2,094,110
Right-of-use assets	9	276,603	317,085
Total Non-Current Assets		2,235,403	2,435,584
TOTAL ASSETS		25,428,904	21,311,867
Current Liabilities			
Trade and other payables	11	1,062,647	1,179,426
Provision for employee entitlements		107,767	116,873
Lease liability	9(b)	65,758	60,673
Total Current Liabilities		1,236,172	1,356,972
Non-Current Liabilities			
Lease liability	9(b)	223,887	258,396
Total Non-Current Liabilities		223,887	258,396
TOTAL LIABILITIES		1,460,059	1,615,368
NET ASSETS		23,968,845	19,696,499
Equity			
Contributed equity	12(a)	113,814,110	100,023,653
Reserve shares	12(b)	(12,565,867)	(10,483,367)
Reserves	13	12,625,416	11,892,048
Accumulated losses		(89,904,814)	(81,735,835)
TOTAL EQUITY		23,968,845	19,696,499

The above Statement of financial position should be read in conjunction with the accompanying Notes.

Statement of changes in equity

For the year ended 31 December 2024

	Contributed Equity	Accumulated Losses	Option Reserve	Reserve Shares	Total
Half year ended 31 December 2024	\$	\$	\$	\$	\$
Balance as at 1 July 2024	100,023,653	(81,735,835)	11,892,048	(10,483,367)	19,696,499
Loss for the half year	-	(8,168,979)	-	-	(8,168,979)
Other comprehensive income	-	-	-	-	-
Total comprehensive loss for the half year	-	(8,168,979)	-	-	(8,168,979)
<i>Transactions with equity holders in their capacity as equity holders:</i>					
Shares issued during the half year	14,320,303	-	-	(2,082,500)	12,237,803
Capital raising costs	(529,846)	-	-	-	(529,846)
Share-based payments	-	-	733,368	-	733,368
Balance as at 31 December 2024	113,814,110	(89,904,814)	12,625,416	(12,565,867)	23,968,845

	Contributed Equity	Accumulated Losses	Option Reserve	Reserve Shares	Total
Half year ended 31 December 2023	\$	\$	\$	\$	\$
Balance as at 1 July 2023	78,712,128	(68,691,553)	10,584,632	(7,197,992)	13,407,215
Loss for the half year	-	(11,556,659)	-	-	(11,556,659)
Other comprehensive income	-	-	-	-	-
Total comprehensive loss for the half year	-	(11,556,659)	-	-	(11,556,659)
<i>Transactions with equity holders in their capacity as equity holders:</i>					
Shares issued during the half year	12,524,824	-	-	(2,523,375)	10,001,449
Capital raising costs	(453,831)	-	-	-	(453,831)
Share-based payments	-	-	580,266	-	580,266
Balance as at 31 December 2023	90,783,121	(80,248,212)	11,164,898	(9,721,367)	11,978,440

The above Statement of changes in equity should be read in conjunction with the accompanying Notes.

Statement of cash flows

For the half year ended 31 December 2024

	Note	Half year ended 31/12/2024 \$	Half year ended 31/12/2023 \$
Cash Flows from Operating Activities			
Interest received		244,406	106,774
Interest paid		(20,405)	(10,569)
Payments to suppliers and employees		(2,919,843)	(3,181,624)
Payments for research and development		(4,587,557)	(8,198,944)
Government R&D tax rebate and grants received		9,022,474	4,792,865
Net cash inflow/(outflow) from operating activities		1,739,075	(6,491,498)
Cash Flows from Investing Activities			
Purchase of property, plant and equipment	8	(2,363)	(1,500)
Net cash (outflow) from investing activities		(2,363)	(1,500)
Cash Flows from Financing Activities			
Proceeds from issue of shares		11,104,996	10,001,449
Proceeds from exercise of options		1,132,807	-
Transaction costs associated with issue of shares		(529,846)	(453,831)
Principal repayment on leases	9(a)	(29,423)	(42,304)
Net cash inflow from financing activities		11,678,534	9,505,313
Net increase in cash and cash equivalents		13,415,246	3,012,315
Cash and cash equivalents at beginning of the half year		9,450,735	8,460,074
Effect of movement in exchange rates on cash held		-	-
Cash and cash equivalents at the end of the half year	6	22,865,981	11,472,389

The above Statement of cash flows should be read in conjunction with the accompanying Notes.

Notes to the financial statements

For the half year ended 31 December 2024

1. CORPORATE INFORMATION

The interim financial statements of Actinogen Medical Limited (“Actinogen Medical” or the “Company”) for the half year ended 31 December 2024 were authorised in accordance with a resolution of Directors on 24 February 2025.

Actinogen Medical is a for profit company limited by shares incorporated and domiciled in Australia whose shares are publicly traded on the Australian Securities Exchange (ASX). The nature of operations and principal activities of the Company are described in the Directors’ Report. The registered office of the Company is located at Suite 901, Level 9, 109 Pitt Street, Sydney, NSW, Australia.

2. BASIS OF PREPARATION AND CHANGES TO THE COMPANY’S ACCOUNTING POLICIES

The principal accounting policies adopted in the preparation of these financial statements are set out below. These policies have been consistently applied to all the periods presented, unless otherwise stated below. The financial statements of the Company are for the half year ended 31 December 2024.

(a) Basis of preparation

The interim condensed financial statements for the six months ended 31 December 2024 have been prepared in accordance with AASB 134 Interim Financial Reporting. The Company has prepared the financial statements on the basis that it will continue to operate as a going concern. The interim condensed financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company’s annual financial statements as at 30 June 2024.

(b) New standards, interpretations and amendments adopted by the Company

The accounting policies adopted in the preparation of the interim condensed financial statements are consistent with those followed in the preparation of the Company’s annual financial statements for the year ended 30 June 2024, except for the adoption of new standards effective as of 1 July 2024, which did not have a material impact on the Company. The Company has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

3. SEGMENT INFORMATION

The Company’s sole operations are within the biotechnology industry within Australia. Given the nature of the Company, its size and current operations, the Company’s management does not treat any part of the Company as a separate operating segment. Internal financial information used by the Company’s decision makers is presented on a “whole of entity” manner

without dissemination to any separately identifiable segments. Accordingly, the financial information reported elsewhere in this financial report is representative of the nature and financial effects of the business activities in which it engages and the economic environments in which it operates. All non-current assets are held in Australia and all income is derived in Australia.

4. FINANCIAL RISK MANAGEMENT

The Company's principal financial liabilities comprise trade and other payables and lease liabilities. The Company's principal financial assets include receivables, and cash and short-term deposits. The Company is exposed to market risk, credit risk and liquidity risk. The Company's Board and senior management oversees the management of these risks however, the Company's overall risk in these areas is not significant enough to warrant a formalised specific risk management program. Risk management is carried out in their day-to-day functions as the overseers of the business. Set out below is an overview of the financial instruments held by the Company as at 31 December 2024:

As at 31 December 2024	Cash and cash equivalents \$	Financial assets / liabilities at amortised cost \$
Financial assets		
Cash and cash equivalents	22,865,981	-
Other receivables and prepayments	-	196,362
Total current assets	22,865,981	196,362
Total financial assets	22,865,981	196,362
Financial liabilities		
Trade and other payables	-	1,062,647
Lease liabilities - current	-	65,758
Total current liabilities	-	1,128,405
Lease liabilities - non-current	-	223,887
Total non-current liabilities	-	223,887
Total financial liabilities	-	1,352,292
Net exposure	22,865,981	(1,155,930)

Set out below is an overview of the financial instruments held by the Company as at 30 June 2024:

As at 30 June 2024	Cash and cash equivalents \$	Financial assets / liabilities at amortised cost \$
Financial assets		
Cash and cash equivalents	9,450,735	-
Other receivables and prepayments	-	219,483
Total current assets	9,450,735	219,483
Total financial assets	9,450,735	219,483
Financial liabilities		
Trade and other payables	-	1,179,426
Lease liabilities - current	-	60,673
Total current liabilities	-	1,240,099
Lease liabilities - non-current	-	258,396
Total non-current liabilities	-	258,396
Total financial liabilities	-	1,498,495
Net exposure	9,450,735	(1,279,012)

5. OTHER INCOME AND EXPENSES

	Half year ended 31/12/2024 \$	Half year ended 31/12/2023 \$
Income		
Interest income	244,406	106,774
Other income		
R&D tax rebate	-	909,030
Total other income	-	909,030
Total income	244,406	1,015,804
Expenses		
<u>Research and development costs:</u>		
Laboratory & clinical trial expenses	4,360,428	8,756,459
Regulatory & clinical development consultants	131,659	126,811
Other expenses	90,833	69,506
Total research and development costs	4,582,920	8,952,776

6. CASH AND CASH EQUIVALENTS

	As at 31/12/2024 \$	As at 30/06/2024 \$
Cash at bank and on hand	3,850,381	2,235,135
Short term deposits	19,015,600	7,215,600
Total cash and cash equivalents	22,865,981	9,450,735

During the half year ended 31 December 2024, the Company received interest revenue through holding cash and cash equivalents and a research and development tax incentive amounting to \$9,022,474 in connection with R&D expenditure incurred during the prior financial year ended 30 June 2024.

7. OTHER RECEIVABLES AND PREPAYMENTS

None of the other receivables and prepayments are impaired. Due to their short-term nature, carrying amounts approximate their fair value.

	As at 31/12/2024 \$	As at 30/06/2024 \$
Prepaid insurance	43,970	108,829
Goods and services tax receivable	131,158	183,591
Research and development tax rebate receivable	-	9,022,474
Other receivables	152,392	110,654
Total other receivables and prepayments	327,520	9,425,548

8. PROPERTY, PLANT AND EQUIPMENT

	As at 31/12/2024	As at 30/06/2024
	\$	\$
At cost	79,008	76,646
Accumulated depreciation	(57,945)	(52,257)
Total property, plant and equipment	21,063	24,389
Movements during the year:		
	Computer Equipment	Total
	\$	\$
Opening balance at 1 July 2023	37,276	37,276
Acquisitions	8,163	8,163
Depreciation	(21,050)	(21,050)
Closing balance at 30 June 2024	24,389	24,389
Opening balance at 1 July 2024	24,389	24,389
Acquisitions	2,362	2,362
Depreciation	(5,688)	(5,688)
Closing balance at 31 December 2024	21,063	21,063

9. RIGHT-OF-USE ASSET & LEASE LIABILITY

Set out below are the amounts recognised in the statement of comprehensive loss for the half year ended 31 December 2024:

	Half year ended 31/12/2024	Half year ended 31/12/2023
	\$	\$
Depreciation expense on right-of-use asset	40,482	40,504
Interest expense on lease liabilities	15,346	1,815
Rent expense - short-term leases	-	-
Total amounts recognised in profit or loss	55,828	42,319

Set out below are the carrying amounts of the Company's assets and lease liabilities recognised in the statement of financial position and the movements during the half year ended 31 December 2024:

	Right-of-use Assets Leased Premises	Lease Liability Leased Premises
	\$	\$
As at 1 July 2023	75,432	86,933
Recognition of new lease (commencing 1 June 2024)	323,832	323,832
Depreciation expense	(82,179)	-
Interest expense	-	5,172
Payments	-	(96,869)
As at 30 June 2024	317,085	319,069
As at 1 July 2024	317,085	319,068
Depreciation expense	(40,482)	-
Interest expense (a)	-	15,346
Payments (a)	-	(44,769)
As at 31 December 2024 (b)	276,603	289,645

(a) The lease payments made during the half year totalled \$44,769 comprising a principal component of \$29,423 and an interest component of \$15,346.

(b) Of the total lease liability amounting to \$289,645, the amount of \$65,758 is current, and \$223,887 is non-current.

10. INTANGIBLE ASSETS

	As at 31/12/2024	As at 30/06/2024
	\$	\$
At cost	5,756,743	5,756,743
Accumulated amortisation	(3,819,006)	(3,662,633)
Total intangible assets	1,937,737	2,094,110

Movements during the half year:

	Intellectual Property \$
Opening balance at 1 July 2023	2,407,712
Amortisation expense	(313,602)
Closing balance at 30 June 2024	2,094,110
Opening balance at 1 July 2024	2,094,110
Amortisation expense	(156,373)
Closing balance at 31 December 2024	1,937,737

Intellectual property

On 8 December 2014, Actinogen Medical entered into an Assignment of Licence Agreement with Corticrine Limited for the assignment of all of Corticrine's interest in, to and under the Licence Agreement to Actinogen Medical and the assumption by the Company of all of Corticrine's obligations in respect of such Assignment. When the Company acquired the intellectual property from Corticrine, this comprised patents and licences, as well as the value of research performed to date, and the progression of testing to human trials. The intellectual property is supported by several patent families, the most recent of which will expire in 2031, with the composition of matter patents in most key markets extendable up to 2036. The patent useful life has been aligned to the patent term and as a result, those patents are amortised on a straight-line basis over the period of the patent.

As at 31 December 2024, the Company assessed there were no indicators of impairment reversal.

Subsequent patent applications (not included in Intangible Assets)

Actinogen continues to proactively extend its IP portfolio.

During the period, costs associated with this follow-on patent related activity have been expensed. This is consistent with prior years. Only the prime patents on acquisition of Corticrine have been carried forward and amortised over the life of the patents.

11. TRADE AND OTHER PAYABLES

	As at 31/12/2024	As at 30/06/2024
	\$	\$
Trade payables	873,793	597,236
Accruals and other payables	32,934	506,625
Provision for payroll tax	-	25,000
Employee tax liabilities	155,920	50,565
Total trade and other payables	1,062,647	1,179,426

Trade and other payables are non-interest-bearing liabilities stated at amortised cost and settled within 30 days.

12. CONTRIBUTED EQUITY

(a) Fully paid ordinary shares

	As at 31/12/2024 \$	As at 30/06/2024 \$
Fully paid ordinary shares	120,364,209	106,043,906
Capital raising costs	(6,550,099)	(6,020,253)
Total contributed equity	113,814,110	100,023,653

As at 31 December 2024 there were 3,132,813,795 ordinary shares on issue (of which 250,678,965 are Loan Shares, refer 12(b) below for further information). Ordinary shares entitle the holder to participate in dividends and the winding up of the Company in proportion to the number and amount paid on the share held.

Movement of fully paid ordinary shares during the half year were as follows:

	Date	Quantity	Unit Price \$	Total \$
Opening balance at 1 July 2023		1,816,252,150		78,712,128
Issue of rights issue shares	11/09/2023	185,803,027	0.02500	4,645,076
Issue of shortfall shares	15/09/2023	214,254,911	0.02500	5,356,373
Capital raising costs	-	-	-	(453,831)
Cancellation of Employee Loan Plan Shares	16/10/2023	(2,000,000)	-	-
Issue of Employee Loan Plan Shares	8/11/2023	39,750,000	0.02200	874,500
Issue of director Employee Loan Plan Shares	1/12/2023	46,500,000	0.03125	1,453,125
Issue of Employee Loan Plan Shares	1/12/2023	6,750,000	0.02900	195,750
Issue of Employee Loan Plan Shares	9/02/2024	18,000,000	0.03800	684,000
Exercise of unlisted options	15/02/2024	3,430,453	0.03750	128,642
Exercise of unlisted options	21/02/2024	2,431,645	0.03750	91,187
Exercise of unlisted options	7/03/2024	165,198	0.03750	6,195
Issue of Employee Loan Plan Shares	3/04/2024	1,000,000	0.03800	38,000
Cancellation of Employee Loan Plan Shares	12/04/2024	(5,416,673)	-	-
Exercise of unlisted options	8/05/2024	550	0.03750	21
Placement shares	14/05/2024	200,000,000	0.02500	5,000,000
Rights Issue	6/06/2024	155,128,047	0.02500	3,878,201
Capital raising costs	-	-	0.00000	(625,714)
Issue of Employee Loan Plan Shares	17/06/2024	1,000,000	0.04000	40,000
Balance at 30 June 2024		2,683,049,308		100,023,653
Exercise of options	4/07/2024	2,976,534	Various	111,628
Exercise of options	5/07/2024	6,230,920	0.038	233,660
Exercise of options	10/07/2024	2,106,504	Various	86,324
Exercise of options	17/07/2024	162,502	Various	6,719
Exercise of options	18/07/2024	3,841,597	Various	148,330
Exercise of options	19/07/2024	660,144	Various	25,195
Exercise of options	24/07/2024	949,949	Various	41,691
Exercise of options	25/07/2024	7,677,974	Various	292,194
Exercise of options	31/07/2024	3,984,451	Various	151,631
Exercise of options	13/08/2024	138,523	Various	5,199
Exercise of options	5/09/2024	683,001	0.038	25,613
Exercise of options	11/09/2024	40,000	0.038	1,500
Placement shares	24/09/2024	232,500,014	0.030	6,975,000
Share Purchase Plan shares	4/11/2024	99,999,867	0.030	2,999,996
Placement shares to Directors	4/11/2024	37,666,670	0.030	1,130,000
Capital raising costs	-	-	-	(529,846)
Cancellation of Employee Loan Plan Shares	28/11/2024	(5,416,662)	-	-
Cancellation of Employee Loan Plan Shares	3/12/2024	(4,000,000)	-	-
Exercise of options	5/12/2024	62,499	0.050	3,125
Employee Loan Plan Shares	16/12/2024	59,500,000	0.035	2,082,500
Balance at 31 December 2024		3,132,813,795		113,814,110

(b) Reserve shares ("Loan shares")

	Date	Quantity	Unit Price \$	Total \$
Opening balance at 1 July 2023		(95,012,300)		(7,197,992)
Cancellation of Employee Loan Plan Shares	16/10/2023	2,000,000	-	-
Issue of Employee Loan Plan Shares	8/11/2023	(39,750,000)	0.02200	(874,500)
Issue of director Employee Loan Plan Shares	1/12/2023	(46,500,000)	0.03125	(1,453,125)
Issue of Employee Loan Plan Shares	1/12/2023	(6,750,000)	0.02900	(195,750)
Issue of Employee Loan Plan Shares	9/02/2024	(18,000,000)	0.03800	(684,000)
Issue of Employee Loan Plan Shares	3/04/2024	(1,000,000)	0.03800	(38,000)
Cancellation of Employee Loan Plan Shares	12/04/2024	5,416,673	-	-
Issue of Employee Loan Plan Shares	17/06/2024	(1,000,000)	0.04000	(40,000)
Balance at 30 June 2024		(200,595,627)		(10,483,367)
Cancellation of Employee Loan Plan Shares	28/11/2024	5,416,662	-	-
Cancellation of Employee Loan Plan Shares	3/12/2024	4,000,000	-	-
Issue of Employee Loan Plan Shares	16/12/2024	(59,500,000)	0.035	(2,082,500)
Balance at 31 December 2024		(250,678,965)		(12,565,867)

Reserves shares ("Loan shares") are ordinary shares that have historically been accounted for as "in-substance options". No loan amount is recognised in the financial statements. During the half year, 59,500,000 loan shares were issued to employees and contractors of the Company; and 9,416,662 loan shares were cancelled by the Company due to forfeiture by the holders of these loan shares ceasing employment and not repaying the balance payable in accordance with the terms and conditions of the Employee Loan Share Scheme.

13. RESERVES

Reserves are made up of the option reserve. The option reserve records items recognised as share-based payment (SBP) expenses for employee and Director options. Details of the movement in reserves is shown below.

	As at 31/12/2024 \$	As at 30/06/2024 \$
Option reserve	12,625,416	11,892,048
Total reserves	12,625,416	11,892,048
Movements during the half year:	Half year ended 31/12/2024 \$	Year ended 30/06/2024 \$
Balance at the beginning of the period	11,892,048	10,584,632
Share-based payment expense on Employee options	-	100
Share-based payment expense on Employee loan shares	479,738	912,413
Share-based payment expense on Director loan shares	253,630	394,903
Balance at end of period	12,625,416	11,892,048

Total share-based payment expenses recognised during the half year amounted to \$733,368.

14. COMMITMENTS AND CONTINGENCIES

The Directors are not aware of any material commitments, contingent liabilities or assets that exist at 31 December 2024 (2023: \$Nil).

15. EVENTS OCCURRING AFTER THE REPORTING PERIOD

No other matter or circumstance has arisen since the end of the interim financial year which is not otherwise dealt with in this report that has significantly affected or may significantly affect the operations of the Company, the results of those operations or the state of affairs of the Company in subsequent financial years.

16. RELATED PARTY TRANSACTIONS

There were no related party transactions that occurred during the half year.

Directors' declaration

In the Directors' opinion:

1. The Financial Statements and Notes set out on pages 13 to 23, are in accordance with the *Corporations Act 2001* including:
 - (a) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements,
 - (b) giving a true and fair view of the Company's financial position as at 31 December 2024 and of its performance for the year ended on that date, and
2. Subject to the matter set out in Note 2(b) to the financial statements, there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Directors.



Dr Steven Gourlay
Managing Director
Sydney, New South Wales
24 February 2025



**Shape the future
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Independent auditor's review report to the members of Actinogen Medical Limited

Conclusion

We have reviewed the accompanying half-year financial report of Actinogen Medical Limited (the Company), which comprises the statement of financial position as 31 December 2024, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of the Company does not comply with the *Corporations Act 2001*, including:

- a. Giving a true and fair view of the Company's financial position as at 31 December 2024 and of its financial performance for the half-year ended on that date; and
- b. Complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Directors' responsibilities for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.



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Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Company's financial position as at 31 December 2024 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Ernst & Young

Timothy Dachs
Partner
Perth
24 February 2025

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Corporate directory

Board of Directors

Dr Geoffrey Brooke - Non-Executive Chairman
Dr Steven Gourlay - Managing Director & Chief Executive Officer
Dr George Morstyn - Non-Executive Director
Mr Malcolm McComas - Non-Executive Director
Dr Nicki Vasquez - Non-Executive Director

Company Secretary

Mr Peter Webse

Investor Relations

Mr Michael Roberts

Principal Place of Business / Registered Office

Suite 901
Level 9
109 Pitt Street
Sydney NSW 2000

Contact Details

Telephone: 02 8964 7401
info@actinogen.com.au
www.actinogen.com.au
ABN 14 086 778 476

Lawyers

K&L Gates
Level 25 South Tower
525 Collins Street
Melbourne VIC 3000

Share Register

Automic Group
Level 5
126 Phillip Street
Sydney NSW 2000

Auditor

Ernst & Young
Australia

Securities Exchange

Actinogen Medical Limited shares are listed on the Australian Securities Exchange ('ASX').
ASX Code: ACW