Actinogen

ASX ANNOUNCEMENT

ACW H1 FY2023 result – rapidly advancing Phase 2 clinical trial program

Sydney, 22 February 2023. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce the release of its interim financial report for the six months ended 31 December 2022.

The first half of the 2023 financial year marked significant milestones and events for Actinogen.

The major highlights were:

- **US Food and Drug Administration (FDA) approval to proceed with XanaMIA Phase 2b Alzheimer's Disease (AD) six-month trial**
- **Xanamem® program validated by Phase 2a Clinical Biomarker Study results showing large clinical benefit**
- **First patients randomized and treated in XanaCIDD Phase 2a Depression clinical trial**
- **Eminent neurologist Dr Dana Hilt MD appointed as new Chief Medical Officer[1]**
- **Initiated *Clinical Trials Science Forum* webinar with more than 110 registrants for the livestream.**

For further details on these and other milestones and events for the December half, please refer to the interim financial report attached.

Dr Steven Gourlay, Actinogen's CEO and MD, said:

"We continued to add tremendous value to the Xanamem program in the December half year and we are delighted to have two major Phase 2 trials in progress.

"Xanamem has the potential to be an effective low-dose daily oral therapy for the treatment of Alzheimer's disease, depression, and many other neurological conditions where it may be used alone or in combination with other treatments.

"We continue to proactively manage all aspects of our business including actively evaluating potential value-add regional and global business development opportunities with key prospective partners."

Statutory financial result

The statutory result for the first half of the 2023 financial year reflects the Company's ongoing investment in developing and advancing its clinical trial program using its lead molecule Xanamem for the treatment of Alzheimer's disease and major depressive disorder.

® Xanamem is a registered trademark of Actinogen Medical Limited

[1] Post balance date appointment announced 1 February 2023

The net after tax loss for the half year ended 31 December 2022 was $7.439 million (2021: $5.795 million loss).

The major expenditure item for the period was Research and Development costs of $5.384 million (2021: $3.747 million), primarily relating to the commencement of the XanaCIDD Phase 2a trial as well as the in-depth analysis associated with the biomarker study and planning and design of the XanaMIA Phase 2b trial.

Financial position

At 31 December 2022 the Company had a cash and cash equivalents balance of $14.484 million (30 June 2022: $16.370 million) and net assets of $16.073 million (30 June 2022: $21.740 million).

The Company continues to manage its capital requirements efficiently with the implementation of its strategic 'hands-on' hybrid clinical trial management model. This model strikes a highly cost-effective balance between in-house and externally supplied resources for clinical trials while maintaining the highest standards of scientific and clinical experience and expertise.

ENDS

Investors

Dr. Steven Gourlay
CEO & Managing Director
P: +61 2 8964 7401
E. steven.gourlay@actinogen.com.au

Michael Roberts
Investor Relations
M: +61 423 866 231
E. michael.roberts@actinogen.com.au

Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem,® as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11β-HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease, and Xanamem has shown the ability to enhance cognition in healthy, older volunteers. Cognitive impairment is also a feature in Depression and many

® Xanamem is a registered trademark of Actinogen Medical Limited

other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials and clinically significant improvements in patients with biomarker-positive mild AD. Previously, high levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize Xanamem's therapeutic potential.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem® is a trademark of Actinogen Medical.

Disclaimer

This announcement and attachments 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.

ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.

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 2022 to 31 December 2022
(Previous corresponding period: 1 July 2021 to 31 December 2021)

RESULTS FOR ANNOUNCEMENT TO THE MARKET

	31/12/2022 $	31/12/2021 $	Change $	Amount change $
Revenue from ordinary activities	135,912	14,872	814%	121,040
Loss from ordinary activities after tax attributable to members	7,438,708	5,794,920	28%	1,643,788
Net loss for the period attributable to members	7,438,708	5,794,920	28%	1,643,788
Net tangible asset per share	0.007	0.012		

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 increased due primarily to an increase in Research & Development expenditure. 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 2022, in the previous financial year ended 30 June 2022 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 2022.

Foreign Entities
Not applicable.

Review Conclusion
This Report is based on the Interim Financial Report for the half year ended 31 December 2022. The financial report has been subject to a review by an independent auditor and the review is not subject to qualification.

Dr Steven Gourlay
Managing Director
Wednesday, 22 February 2023
Sydney, New South Wales

Actinogen

Interim Financial Report
31 December 2022

Contents

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 half year focused on the ongoing development of Xanamem,® a unique inhibitor of the 11β-HSD1 enzyme that achieves target engagement in the central nervous system. It is an oral medication for neurological diseases amenable to its mechanism of lowering cortisol in brain cells. Elevated brain cortisol is associated with a number of neurological diseases, including neurodegenerative disease such as Alzheimer's disease (AD), neuropsychiatric diseases such as major depressive disorder (MDD or depression), and Fragile X syndrome (FXS).

2. OPERATIONS REVIEW

Major highlights

US Food and Drug Administration (FDA) approval to proceed with XanaMIA Phase 2b Alzheimer's Disease (AD) six-month trial

Xanamem program validated by Phase 2a Clinical Biomarker Study results showing large clinical benefit

First patients randomized and treated in XanaCIDD Phase 2a Depression clinical trial

Eminent neurologist Dr Dana Hilt MD appointed as new Chief Medical Officer[1]

Initiated *Clinical Trials Science Forum* webinar with more than 110 registrants for the livestream

The first half of the 2023 financial year marked significant milestones and events for Actinogen:

Rapidly advanced Phase 2 trial programs:

- Validated the design and outcome measures of the upcoming Phase 2b trial in patients with early AD in the Phase 2a Clinical Biomarker Study by showing clinically significant effects on key endpoints (CDR-SB and cognition)[2] in patients with biomarker-positive AD
- Following review of updated clinical and nonclinical information, received approval from the US Food and Drug Administration (FDA) to proceed with a six-month Phase 2b clinical trial of Xanamem in patients with biomarker-positive AD
- Commenced the XanaCIDD Phase 2a Depression trial in patients who are inadequately treated by their anti- depressant medication and have on-going depression associated with cognitive impairment
- Signed contracts with suppliers worth approximately US$3 million to provide clinical research services for the XanaCIDD Phase 2a Depression trial.

Completed initial development of the to-be-marketed tablet formulation that will be used in the XanaMIA Phase 2b AD trial and future Phase 3 clinical trials

Strengthened the team with key executive and advisory board appointments:

- Eminent US-based neurologist Dr Dana Hilt appointed CMO effective 1 February 2023. Dr Hilt will chair the Company's clinical advisory boards as part of his role
- Former CMO Professor Paul Rolan continues with the Company as Head of Clinical Pharmacology and Lead Physician, Depression
- Esteemed Singapore-based clinical expert in dementia, Associate Professor Christopher Chen appointed to the Company's Depression & Cognition Advisory Board.

Presented an academic poster in December at the Clinical Trials on Alzheimer's Disease (CTAD) conference in San Francisco of the XanaMIA Phase 1b trial results[3]

® Xanamem is a registered trademark of Actinogen Medical Limited.
[1] Post balance date appointment announced 1 February 2023
[2] Clinical Dementia Rating Scale – Sum of Boxes (CDR-SB) is a measure of patient functional abilities and a composite of cognitive tests of mental abilities considered a measure of "executive function".
[3] XanaMIA Phase 1b (Part A) trial results announced 27 April 2022

Operating and Financial Review (continued)

2. OPERATIONS REVIEW (continued)

Initiated the *Actinogen Clinical Trials Science Forum* in August to inform and educate a broad audience, including those from non-technical backgrounds, on the science behind Xanamem and the Company's clinical trials program

CEO, Dr Steven Gourlay presented to the Sachs Neuroscience Innovation Forum in San Francisco in early January and participated in industry meetings at conferences that ran concurrently with the J.P. Morgan Healthcare Conference week. The company continues to evaluate potential value-add regional and global business development opportunities with key prospective partners.

Additional detail on selected major highlights for the Half Year:

FDA approval received to proceed with XanaMIA Phase 2b AD clinical trial

On 22 December 2022, the Company announced receipt of US FDA approval to proceed with its six-month, Phase 2b, placebo-controlled clinical trial of Xanamem in patients with early stages of Alzheimer's disease.

The approval was granted in the context of the Company updating its FDA Investigational New Drug (IND) dossier with new nonclinical and clinical information to support the trial protocol.

The planned Phase 2b trial will enrol 330 patients with mild AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of pTau181 protein in the blood. Use of pTau181 replaces the need to use expensive amyloid brain scans to confirm the diagnosis of AD and the likelihood of progressive disease. Patients will be randomized to treatment over six months with 5 mg, 10 mg or placebo once a day. A follow-on trial will allow participants to continue on Xanamem and provide valuable long-term safety and efficacy data.

Key efficacy endpoints will be those that have shown Xanamem effect in prior trials: CDR-SB and a cognitive test battery measuring attention and working memory.

The trial will use to-be-marketed tablets and is expected to have results in late 2024 or early 2025.

Large clinical benefit shown in AD biomarker study - validates Xanamem program

On 10 October 2022, the Company announced positive Phase 2a clinical data from its Alzheimer's disease biomarker study.

The prospectively conducted, double-blind analysis using new biomarker data was effectively a simulation of the upcoming Phase 2b trial and validated and de-risked Actinogen's AD program by showing:

- Clinical activity in a third clinical trial
- Large clinical effect size in patients with mild AD and elevated blood pTau on the CDR-SB endpoint used to approve anti-amyloid antibodies by the FDA
- Utility of blood pTau levels to select suitable patients with early-stage AD for the XanaMIA Phase 2b trial.

The biomarker study was conducted in 72 patients with available blood biomarker samples from the prior Phase 2a placebo controlled XanADu study of 185 patients. Patients in the original trial had a clinical diagnosis of mild AD,[4] and were treated with Xanamem 10 mg or placebo once daily for 12 weeks.

The biomarker analysis was 'double-blind' and 'pre-specified' meaning the results were generated according to an analysis plan where the biomarker laboratory and company personnel were unaware of which treatment patients had used. This method is standard in the biopharmaceutical industry to avoid bias in the results. Key blood biomarkers studied were phosphorylated tau (pTau) and amyloid levels.

First patient randomized and treated in XanaCIDD clinical trial

On 8 December 2022, the first patient was randomized and treated in the XanaCIDD Phase 2a Depression clinical trial that will measure the effects of Xanamem on safety, cognitive performance and depression in patients who are inadequately treated by their anti-depressant medication and have both depressive symptoms and cognitive impairment.

The XanaCIDD Phase 2a trial is a six-week proof-of-concept, placebo-controlled, parallel group design trial in approximately 160 patients with persistent major depressive disorder (MDD) and cognitive impairment despite a standard course of anti-depressant therapy. Xanamem 10 mg daily or placebo will be added to the existing anti-depressant therapy and effects on cognition, using the Cogstate Cognitive Test Battery, and depression, using the Montgomery Asberg Depression Rating Scale, will be assessed. Results are expected in late 2023 or early 2024.

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

[4] Measured by a Mini Mental State Examination (MMSE) score of 20 to 26. MMSE is a 30-point scale of simple questions to assess mental abilities.

Operating and Financial Review (continued)

3. FINANCIAL REVIEW

Financial position

At 31 December 2022 the Company had a cash and cash equivalents balance of $14,483,827 (30 June 2022: $16,370,283). Cash receipts for the period included:

- $0.90 million from the exercise of options by Non-Executive Director Dr George Morstyn (1.5 million shares at an exercise price of 10 cents per share (cps)) and the former CEO and Managing Director Dr Bill Ketelbey (8.8 million shares at an exercise price 8.5 cps)
- A $4.17 million R&D tax incentive cash rebate received during the December quarter relating to the 2022 financial year.

Net Assets at 31 December 2022 stood at $16,072,902 (30 June 2022: $21,739,877).

The Company continues to manage its capital requirements efficiently with the implementation of its strategic 'hands-on' hybrid clinical trial management model. This model strikes a highly cost-effective balance between in-house and externally supplied resources for clinical trials while maintaining the highest standards of scientific and clinical experience and expertise.

Statutory financial result

The statutory result for the first half of the 2023 financial year reflects the Company's ongoing investment in developing and advancing its clinical trial program using its lead molecule Xanamem for the treatment of Alzheimer's disease and major depressive disorder.

The net after tax loss for the half year ended 31 December 2022 was $7,438,708 (2021: loss of $5,794, 920).

The major expenditure item for the period was Research and Development costs of $5,384,406 (2021: $3,747,128), primarily relating to the commencement of the XanaCIDD Phase 2a trial as well as the in-depth analysis associated with the biomarker study and planning and design of the XanaMIA Phase 2b trial.

Directors' Report

Your Directors present their report pertaining to Actinogen Medical Limited ('Actinogen Medical' or 'the Company') for the half year ended 31 December 2022.

1. BOARD OF DIRECTORS

The names and details of the Company's Directors in office during the 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

2. OPERATING AND FINANCIAL REVIEW

Please refer to pages 3 to 5 of this interim report for information on the Company's principal activities and operating review.

3. 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 2022 forms a part of the Directors' Report and can be found on page 7. Signed in accordance with a resolution of the Board of Directors.

Steven J Gourlay

Dr Steven Gourlay
Managing Director
Sydney, New South Wales
22 February 2023

Auditor's Independence Declaration

Ernst & Young
11 Mounts Bay Road
Perth WA 6000 Australia
GPO Box M939 Perth WA 6843

Tel: +61 8 9429 2222
Fax: +61 8 9429 2436
ey.com/au

Building a better working world

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 2022, 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

Pierre Dreyer
Partner
22 February 2023

Statement of Comprehensive Income

For the half year ended 31 December 2022

	Note	Half year ended 31/12/2022 $	Half year ended 31/12/2021 $
Interest revenue		135,912	14,872
Other income		1,004,101	-
Total revenue & other income	5	**1,140,013**	**14,872**
Research & development costs	5	(5,384,406)	(3,747,128)
Employment costs		(1,295,899)	(720,594)
Corporate & administration costs		(734,739)	(624,568)
Finance costs		(10,061)	(8,443)
Unrealised foreign currency gain / (loss)		(83,786)	-
Share-based payment expenses		(868,775)	(508,853)
Amortisation expense	10	(156,373)	(156,373)
Depreciation expense (right-of-use asset)	9	(40,504)	(40,504)
Depreciation expense (office equipment)	8	(4,178)	(3,329)
Total expenses		**(8,578,721)**	**(5,809,792)**
Loss before income tax		(7,438,708)	(5,794,920)
Income tax expense		-	-
Loss for the half year		**(7,438,708)**	**(5,794,920)**
Other comprehensive income			
Items that may be reclassified subsequently to profit and loss:			
Other comprehensive income		-	-
Total comprehensive loss for the half year		**(7,438,708)**	**(5,794,920)**
Loss per share for attributable to the ordinary equity holders of the Company			
Basic and diluted loss per share in cents		**(0.41)**	**(0.35)**

The above Statement of Comprehensive Income should be read in conjunction with the accompanying Notes.

Statement of Financial Position

As at 31 December 2022

	Note	As at 31/12/2022 $	As at 30/06/2022 $
Current Assets			
Cash and cash equivalents	6	14,483,827	16,370,283
Other receivables and prepayments	7	632,897	4,046,639
Total Current Assets		15,116,724	20,416,922
Non-Current Assets			
Property, plant and equipment	8	21,888	12,531
Intangible assets	10	2,564,085	2,720,458
Right-of-use assets	9	115,936	156,440
Total Non-Current Assets		2,701,909	2,889,429
TOTAL ASSETS		**17,818,633**	**23,306,351**
Current Liabilities			
Trade and other payables	11	1,491,202	1,308,381
Provision for employee entitlements		127,777	92,823
Lease liability	9(b)	89,194	78,337
Total Current Liabilities		1,708,173	1,479,541
Non-Current Liabilities			
Lease liability	9(b)	37,558	86,933
Total Non-Current Liabilities		37,558	86,933
TOTAL LIABILITIES		**1,745,731**	**1,566,474**
NET ASSETS		**16,072,902**	**21,739,877**
Equity			
Contributed equity	12(a)	77,862,128	76,942,670
Reserve shares	12(b)	(6,347,992)	(6,331,492)
Reserves	13	9,936,757	9,067,982
Accumulated losses		(65,377,991)	(57,939,283)
TOTAL EQUITY		**16,072,902**	**21,739,877**

The above Statement of Financial Position should be read in conjunction with the accompanying Notes.

Statement in Changes of Equity

For the half year ended as at 31 December 2022

Half year ended 31 December 2022	Contributed Equity $	Accumulated Losses $	Option Reserve $	Reserve Shares $	Total $
Balance as at 1 July 2022	76,942,670	(57,939,283)	9,067,982	(6,331,492)	21,739,877
Loss for the half year	-	(7,438,708)	-	-	(7,438,708)
Other comprehensive income	-	-	-	-	-
Total comprehensive loss for the half year	-	(7,438,708)	-	-	(7,438,708)
Transactions with equity holders in their capacity as equity holders:					
Shares issued during the half year	919,458	-	-	(16,500)	902,958
Capital raising costs	-	-	-	-	-
Share-based payments	-	-	868,775	-	868,775
Balance as at 31 December 2022	**77,862,128**	**(65,377,991)**	**9,936,757**	**(6,347,992)**	**16,072,902**

Half year ended 31 December 2021	Contributed Equity $	Accumulated Losses $	Option Reserve $	Reserve Shares $	Total $
Balance as at 1 July 2021	60,054,459	(48,441,913)	7,780,027	(1,934,492)	17,458,081
Loss for the half year	-	(5,794,920)	-	-	(5,794,920)
Other comprehensive income	-	-	-	-	-
Total comprehensive loss for the half year	-	(5,794,920)	-	-	(5,794,920)
Transactions with equity holders in their capacity as equity holders:					
Shares issued during the half year	15,423,874	-	-	(2,209,000)	13,214,874
Capital raising costs	(811,013)	-	-	-	(811,013)
Share-based payments	-	-	508,853	-	508,853
Balance as at 31 December 2021	**74,667,320**	**(54,236,833)**	**8,288,880**	**(4,143,492)**	**24,575,875**

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 2022

	Note	Half year ended 31/12/2022 $	Half year ended 31/12/2021 $
Cash Flows from Operating Activities			
Interest received		135,912	14,872
Interest paid		(10,061)	(5,804)
Payments to suppliers and employees		(2,135,892)	(1,439,657)
Payments for research and development		(4,813,187)	(3,601,393)
Government R&D tax rebate and grants received		4,165,402	1,434,713
Net cash outflow from operating activities		**(2,657,826)**	**(3,597,269)**
Cash Flows from Investing Activities			
Purchase of property, plant and equipment	8	(13,535)	-
Net cash outflow from investing activities		**(13,535)**	**-**
Cash Flows from Financing Activities			
Proceeds from issue of shares	12	902,958	13,214,874
Transaction costs associated with issue of shares	12	-	(811,013)
Principal repayment on leases	9(a)	(38,518)	(34,987)
Net cash inflow from financing activities		**864,440**	**12,368,874**
Net (decrease)/increase in cash and cash equivalents		(1,806,921)	8,771,605
Cash and cash equivalents at beginning of the half year		16,370,283	13,456,919
Effect of movement in exchange rates on cash held		(79,535)	-
Cash and cash equivalents at the end of the half year	6	**14,483,827**	**22,228,524**

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 2022

1. CORPORATE INFORMATION

The interim financial statements of Actinogen Medical Limited ("Actinogen Medical" or the "Company") for the half year ended 31 December 2022 were authorised in accordance with a resolution of Directors on 22 February 2023.

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 2022.

2.1. Basis of preparation

The interim condensed financial statements for the six months ended 31 December 2022 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 2022.

2.2. 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 2022, except for the adoption of new standards effective as of 1 July 2022, 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.

Notes to the Financial Statements
(continued)

4. FINANCIAL RISK MANAGEMENT

The Company's principal financial liabilities comprise trade, other payables and lease liabilities. The Company's principal financial assets include trade and other 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 2022:

	Cash and cash equivalents $	Financial assets / liabilities at amortised cost $
As at 31 December 2022		
Financial assets		
Cash and cash equivalents	14,483,827	-
Other receivables and prepayments	-	51,109
Total current assets	14,483,827	51,109
Total financial assets	**14,483,827**	**51,109**
Financial liabilities		
Trade and other payables	-	1,491,202
Lease liabilities - current	-	89,194
Total current liabilities	-	1,580,396
Lease liabilities - non-current	-	37,558
Total non-current liabilities	-	37,558
Total financial liabilities	**-**	**1,617,954**
Net exposure	**14,483,827**	**(1,566,845)**

	Cash and cash equivalents $	Financial assets / liabilities at amortised cost $
As at 30 June 2022		
Financial assets		
Cash and cash equivalents	16,370,283	-
Other receivables and prepayments	-	328,261
Total current assets	16,370,283	328,261
Total financial assets	**16,370,283**	**328,261**
Financial liabilities		
Trade and other payables	-	1,308,381
Lease liabilities - current	-	78,337
Total current liabilities	-	1,386,718
Lease liabilities - non-current	-	86,933
Total non-current liabilities	-	86,933
Total financial liabilities	**-**	**1,473,651**
Net exposure	**16,370,283**	**(1,145,390)**

Notes to the Financial Statements
(continued)

5. OTHER INCOME AND EXPENSES

	Half year ended 31/12/2022 $	Half year ended 31/12/2021 $
Income		
Interest income	135,912	14,872
Other income		
Government grants – R&D Tax Incentive	1,004,101	-
Total other income	1,004,101	-
Total income	**1,140,013**	**14,872**
Expenses		
Research and development costs:		
Laboratory & clinical trial expenses	4,681,286	3,285,507
Regulatory & clinical development consultants	684,571	369,951
Other expenses	18,549	91,670
Total research and development costs	**5,384,406**	**3,747,128**

Government grants totalling $1,004,101 is the increased R&D tax incentive portion recognised as income in the interim period in connection with eligible R&D expenditure previously incurred. Of this portion, $525,320 has been received during the interim period, whilst the balance of $478,781 is included in Other Receivables as at 31 December 2022 (refer Note 7).

6. CASH AND CASH EQUIVALENTS

	As at 31/12/2022 $	As at 30/06/2022 $
Cash at bank and on hand	2,388,913	4,270,017
Short term deposits	12,094,914	12,100,266
Total cash and cash equivalents	**14,483,827**	**16,370,283**

7. OTHER RECEIVABLES

	As at 31/12/2022 $	As at 30/06/2022 $
Prepaid insurance	51,109	104,572
Goods and services tax receivable	103,007	78,296
Research and development tax rebate receivable	478,781	3,640,082
Other receivables	-	223,689
Total other receivables and prepayments	**632,897**	**4,046,639**

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

Notes to the Financial Statements
(continued)

8. PROPERTY, PLANT AND EQUIPMENT

	As at 31/12/2022 $	As at 30/06/2022 $
At cost	45,419	31,884
Accumulated depreciation	(23,531)	(19,353)
Total property, plant and equipment	**21,888**	**12,531**

Movements during the year

	Computer Equipment $	Total $
Opening balance at 1 July 2021	16,509	16,509
Acquisitions	2,937	2,937
Depreciation	(6,915)	(6,915)
Closing balance at 30 June 2022	**12,531**	**12,531**
Opening balance at 1 July 2022	12,531	12,531
Acquisitions	13,535	13,535
Depreciation	(4,178)	(4,178)
Closing balance at 31 December 2022	**21,888**	**21,888**

9. RIGHT-OF-USE ASSET & LEASE LIABILITY

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 2022:

	Right-of-use Assets Leased Premises $	Lease Liability Leased Premises $
As at 1 July 2021	237,448	236,441
Depreciation expense	(81,008)	-
Interest expense	-	10,682
Payments	-	(81,853)
As at 30 June 2022	**156,440**	**165,270**
As at 1 July 2022	156,440	165,270
Depreciation expense	(40,504)	-
Interest expense (a)	-	3,904
Payments (a)	-	(42,422)
As at 31 December 2022 (b)	**115,936**	**126,752**

(a) The lease payments made during the half year totalled $42,422 comprising $38,518 which represents the principal component and $3,904 which represents the interest expense component.

(b) Of the total lease liability amounting to $126,752; $89,194 is current and $37,558 is non-current.

Notes to the Financial Statements
(continued)

9. RIGHT-OF-USE ASSET & LEASE LIABILITY (CONTINUED)

Set out below are the amounts recognised in the statement of comprehensive loss for the half year ended 31 December 2022:

	Half year ended 31/12/2022 $	Half year ended 31/12/2021 $
Depreciation expense on right-of-use asset	40,504	40,504
Interest expense on lease liabilities	3,904	5,804
Rent expense - short-term leases	780	780
Total amounts recognised in profit or loss	**45,188**	**47,088**

10. INTANGIBLE ASSETS

	As at 31/12/2022 $	As at 30/06/2022 $
At cost	5,756,743	5,756,743
Accumulated amortisation and impairment loss	(3,192,658)	(3,036,285)
Total intangible assets	**2,564,085**	**2,720,458**

Movement in Intangible Assets

	Intellectual Property $
Opening balance at 1 July 2021	3,033,204
Amortisation expense	(312,746)
Closing balance at 30 June 2022	**2,720,458**
Opening balance at 1 July 2022	2,720,458
Amortisation expense	(156,373)
Closing balance at 31 December 2022	**2,564,085**

11. TRADE AND OTHER PAYABLES

	As at 31/12/2022 $	As at 30/06/2022 $
Trade payables	375,154	898,739
Accruals and other payables	1,025,817	91,395
Provision for payroll tax	-	13,663
Accrued employee bonuses	13	264,291
Employee tax liabilities	90,218	40,293
Total trade and other payables	**1,491,202**	**1,308,381**

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

Notes to the Financial Statements
(continued)

12. CONTRIBUTED EQUITY

(a) Fully paid ordinary shares

	As at 31/12/2022 $	As at 30/06/2022 $
Fully paid ordinary shares	82,802,836	81,883,378
Capital raising costs	(4,940,708)	(4,940,708)
Total contributed equity	**77,862,128**	**76,942,670**

Movement of fully paid ordinary shares

	Date	Quantity	Unit Price $	Total $
Balance at 1 July 2021		**1,660,558,547**		**60,054,459**
Issue of employee loan shares	16/09/2021	11,900,000	0.110	1,309,000
Institutional Placement	1/12/2021	88,091,659	0.135	11,892,374
Issue of director loan shares	18/11/2021	4,500,000	0.200	900,000
Share Purchase Plan	20/12/2021	9,796,389	0.135	1,322,501
Capital raising costs	1/01/2022			(831,289)
Issue of employee loan shares	13/01/2022	4,000,000	0.195	780,000
Share Purchase Plan	6/04/2022	797,222	0.135	107,625
Issue of employee loan shares	24/05/2022	16,000,000	0.088	1,408,000
Balance at 30 June 2022		**1,795,643,817**		**76,942,670**
Issue of employee loan shares	15/07/2022	250,000	0.066	16,500
Proceeds from exercise of options	11/11/2022	1,500,000	0.100	150,000
Proceeds from exercise of options	9/12/2022	8,775,000	0.085	745,875
Proceeds from exercise of options	9/12/2022	83,333	0.085	7,083
Balance at 31 December 2022		**1,806,252,150**		**77,862,128**

(b) Reserve shares

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. As at 31 December 2022, the following reserve shares were on issue.

	Date	Quantity	Unit Price $	Total $
Balance at 1 July 2021		**(48,362,300)**		**(1,934,492)**
Issue of employee loan shares	16/09/2021	(11,900,000)	0.110	(1,309,000)
Issue of non-executive Director loan shares	18/11/2021	(4,500,000)	0.200	(900,000)
Issue of employee loan shares	13/01/2022	(4,000,000)	0.195	(780,000)
Issue of employee loan shares	24/05/2022	(16,000,000)	0.088	(1,408,000)
Balance at 30 June 2022		**(84,762,300)**		**(6,331,492)**
Issue of employee loan shares	15/07/2022	(250,000)	0.066	(16,500)
Balance at 31 December 2022		**(85,012,300)**		**(6,347,992)**

Notes to the Financial Statements
(continued)

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 31/12/2022 $	As at 30/06/2022 $
Option reserve	9,936,757	9,067,982
Total reserves	**9,936,757**	**9,067,982**

Movements during the year:

	Half year ended 31/12/2022 $	Year ended 30/06/2022 $
Balance at the beginning of the period	9,067,982	7,780,027
Share-based payment expense on Director options	-	25,745
Share-based payment expense on employee options	8,105	34,459
Share-based payment expense on employee loan shares	608,592	580,749
Share-based payment expense on Director loan shares	252,078	647,002
Balance at end of period	**9,936,757**	**9,067,982**

Total share-based payment expenses recognised during the half year amounted to $868,775.

14. COMMITMENTS AND CONTINGENCIES

The Directors are not aware of any commitments, contingent liabilities or assets that exist at 31 December 2022 (2021: Nil):

15. RELATED PARTY TRANSACTIONS

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

16. EVENTS OCCURRING AFTER THE REPORTING PERIOD

There are no other matters or circumstances that have arisen since the end of the reporting period which have significantly affected or may significantly affect the operations of the Company, the results of those operations, or the state of the Company in subsequent financial years.

Directors' Declaration

In the Directors' opinion:

In accordance with a resolution of the Directors of Actinogen Medical Limited, I state that:

(a) The Financial Statements and Notes set out on pages 8 to 18 are in accordance with the Corporations Act 2001, including:

i. complying with Accounting Standard AASB 134 Interim Financial Reporting, and the Corporations Regulations 2001; and

ii. giving a true and fair view of the Company's financial position as at 31 December 2022 and its performance for the half year ended on that date, and,

(b) 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.

Steven J Gourlay

Dr Steven Gourlay
Managing Director
Sydney, New South Wales
22 February 2023

Independent Auditor's Report

Ernst & Young
11 Mounts Bay Road
Perth WA 6000 Australia
GPO Box M939 Perth WA 6843

Tel: +61 8 9429 2222
Fax: +61 8 9429 2436
ey.com/au

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 condensed statement of financial position as 31 December 2022, the condensed statement of comprehensive income, condensed statement of changes in equity and condensed 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 2022 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.

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 2022 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*.

Building a better working world

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

Pierre Dreyer
Partner
Perth
22 February 2023

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

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

Auditors

Ernst & Young
Australia

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