



ASX ANNOUNCEMENT

ACW H1 FY2022 result – strong advances in clinical development pipeline

Sydney, 24 February 2022. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to announce the release of its financial report for the half year ended 31 December 2021.

Key Highlights

- **Advanced the Xanamem® clinical development pipeline on multiple fronts:**
 - Selected Major Depressive Disorder (MDD) as third indication for Xanamem based on strong scientific rationale. Planning underway for Phase 2 trial to commence in 2022, with headline results expected in CY2023
 - Received approval to proceed under a US FDA IND for Phase 2 XanaFX trial in adolescent and young adult patients
 - Expanded XanaFX trial to include sites in North America, added 5mg dose group and increased target enrolment from 50 to 75. Signed Letter of Intent and subsequent full work order with Worldwide Clinical Trials to operationalise the trial, which now spans four countries. Headline results expected in CY2023
 - Completed target enrolment of 105 patients for the XanaMIA Part A trial in Mild Cognitive Impairment (MCI) due to Alzheimer’s Disease (AD). Last patient visit completed February 2022 and expected results timeline narrowed from Q2 2022 to April 2022
 - Added a retrospective analysis of the effects of Xanamem on biomarkers of possible disease modification using stored samples from prior Phase 2 XanADu study in mild AD. Results expected in H2 2022 and, together with the XanaMIA Part A trial results expected in April 2022, will inform the design of the XanaMIA Part B trial and subsequent AD trials.
- **Successfully completed a \$13.3 million capital raising to fund expansion of the clinical development pipeline**^{1 2}
- **Established two new Xanamem clinical advisory boards for FXS and Depression programs**
- **Filled key operational and technical positions to drive strategic initiatives including appointment of Chief Medical Officer in February 2022**

® Xanamem is a registered trademark of Actinogen Medical Limited

¹ Including the proposed \$107,625 subscription to the placement by CEO Dr Steven Gourlay that is subject to shareholder approval.

² Unless stated otherwise, all financial information relates to the half year ended 31 December 2021 and all financial data is quoted in Australian dollars.

- Finalised a clinical protocol for a strategic collaboration with Oxford University researchers to investigate the therapeutic potential for Xanamem to control the metabolic effects of excessive cortisol in a disease called Mild Autonomous Cortisol Secretion (MACS)
- Appointed leading global clinical research company Worldwide Clinical Trials to manage XanaFX Phase 2 clinical trial involving 75 participants in four countries
- Updated potential pharmaceutical industry partners on expanded clinical development pipeline and multiple near and medium-term milestones at international industry conferences in January 2022
- Strengthened the balance sheet - cash balance of A\$22.2 million at 31 December 2021, including funds received from the capital raising.

The first half of the 2022 financial year marked significant advances in the execution of Actinogen's strategic action plan, which comprises three key elements:

- Operational excellence to deliver high-quality, timely data in 2022 and 2023
- Strengthening the team and developing strategic and expert partnerships
- Forward planning to optimise timelines to marketing approvals.

The Company continues to successfully execute its primary strategic priority of focusing on operational excellence in its clinical development program, which is designed to deliver timely and high-quality confirmation of clinical efficacy and safety in each of its disease programs. ACW is conducting its lead programs in AD and FXS under US IND oversight to ensure it adheres to a global standard of regulatory compliance for clinical development, non-clinical studies and manufacturing.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"The first half of the 2022 financial year marked significant advances in Actinogen's clinical development pipeline on multiple fronts. We selected Major Depressive Disorder (MDD) as our third disease indication for Xanamem and expanded the scope and size of our Phase 2 XanaFX trial for Fragile X Syndrome. We also completed target enrolment and patient visits for our XanaMIA Part A trial in Mild Cognitive Impairment due to Alzheimer's Disease, with results now expected in April 2022.

"Other achievements included successfully completing a \$13 million capital raising to help support the expanded clinical pipeline, creating two new specialist clinical advisory boards led by world class experts in Fragile X Syndrome, Depression, and Cognition, and striking a strategic collaboration with researchers at Oxford University.

"We look forward to continuing this outstanding momentum through 2022 as we pursue our revolutionary therapy to help make a material difference to the quality of life for people and their families living with serious neurological conditions such as Alzheimer's Disease, Depression, and Fragile X Syndrome."

Statutory Financial Result

The statutory result for the first half of the 2022 financial year reflects the Company's ongoing investment in developing and advancing its lead molecule Xanamem for the treatment of Alzheimer's Disease, Fragile X Syndrome and Mild Depressive Disorder.

The net after-tax loss for the half year ended 31 December 2021 was \$5,794,920 (2020: loss of \$2,357,619).

The major expenditure item for the period was Research and Development costs of \$3,747,128 (2020: \$789,921) primarily relating to clinical trials.

Financial Position

At 31 December 2021 the Company had a cash and cash equivalents balance of \$22,228,524 (30 June 2021: \$13,456,919), and Net Assets of \$24,575,875 (30 June 2021: \$17,458,081).

ENDS

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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 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.

We are currently developing our lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, Depression and other neurological diseases where reducing cortisol inside brain cells could have a positive impact. 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 works by blocking the production of intracellular cortisol 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, potentially linked to cognitive impairment and anxiety in Fragile X Syndrome, and cognitive impairment in Depression and other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterise 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 based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen

Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

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

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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 2021 to 31 December 2021

(Previous corresponding period: 1 July 2020 to 31 December 2020)

RESULTS FOR ANNOUNCEMENT TO THE MARKET

	31/12/2021 \$	31/12/2020 \$	Change \$	Amount change \$
Revenue from ordinary activities	14,872	16,313	-9%	(1,441)
Loss from ordinary activities after tax attributable to members	5,794,920	2,357,619	59%	3,437,301
Net loss for the period attributable to members	5,794,920	2,357,619	59%	3,437,301
Net tangible asset per share	0.012	0.008		

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 2021, in the previous financial year ended 30 June 2021 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 2021.

Foreign Entities

Not applicable.

Review Conclusion

This Report is based on the Interim Financial Report for the half year ended 31 December 2021. 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
Date: 24 February 2022
Sydney, New South Wales

Interim Financial Report 31 December 2021

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Contents

Operating & Financial Review	3
Directors' Report	6
Auditor's Independence Declaration	7
Statement of Comprehensive Income	8
Statement of Financial Position	9
Statement in Changes of Equity	10
Statement of Cash Flows	11
Notes to the Financial Statements	12
Directors' Declaration	19
Independent Auditor's Report	20
Corporate Directory	22

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Operating & Financial Review

1. PRINCIPAL ACTIVITIES

The principal activity of the Company during the year focused on the ongoing development of Xanamem^{®1}, a unique inhibitor of the 11 β -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. Dysregulated brain cortisol is associated with a number of neurological diseases, including Alzheimer's Disease, Fragile X Syndrome and Depression.

2. OPERATIONS REVIEW

The first half of the 2022 financial year marked significant advances in the execution of Actinogen's strategic action plan, which comprises three key elements:

- Operational excellence to deliver high-quality, timely data in 2022 and 2023
- Strengthening the team and developing strategic and expert partnerships
- Forward planning to optimise timelines to marketing approvals.

Highlights

- (i) **Advanced the Xanamem clinical development pipeline on multiple fronts in Alzheimer's Disease (AD) and Fragile X Syndrome (FXS), and selected Major Depressive Disorder (MDD) as the third indication for Xanamem based on strong scientific rationale**
- (ii) **Successfully completed a \$13.3million capital raising to fund expansion of the clinical development pipeline^{2 3}**
- (iii) **Established two new Xanamem clinical advisory boards for FXS and Depression programs**
- (iv) **Filled key operational and technical positions to drive strategic initiatives including appointment of Chief Medical Officer in February 2022**
- (v) **Finalised a clinical protocol for a strategic collaboration with Oxford University researchers to investigate the therapeutic potential for Xanamem to control the metabolic effects of excessive cortisol in a disease called Mild Autonomous Cortisol Secretion (MACS)**
- (vi) **Appointed leading global clinical research company Worldwide Clinical Trials to manage XanaFX Phase 2 clinical trial involving 75 participants in four countries**
- (vii) **Updated potential pharmaceutical industry partners on expanded clinical development pipeline and multiple near and medium-term milestones at international industry conferences in January 2022**
- (viii) **Strengthened the balance sheet - cash balance of \$22.2 million at 31 December 2021, including funds received from the capital raising and a \$1.4 million tax incentive rebate**
- (ix) **Strengthened intellectual property portfolio - received notification from the Brazilian Patent and Trademark Office of grant of patent application for Xanamem.**

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² Including the proposed \$107,625 subscription to the placement by CEO Dr Steven Gourlay that is subject to shareholder approval.

³ Unless otherwise stated, all financial information in this Operations Review relates to the half year ended 31 December 2021 and all financial data is quoted in Australian dollars.

Operating and Financial Review (continued)

2. OPERATIONS REVIEW (continued)

The Half Year in Review

(i) Advancing the Xanamem clinical development pipeline through multiple clinical trials

Actinogen continues to successfully execute its primary strategic priority of focusing on operational excellence in its clinical development program, which is designed to deliver timely and high-quality confirmation of clinical efficacy and safety in each of its disease programs. The Company is conducting its lead programs in AD and FXS under US IND oversight to ensure it adheres to a global standard of regulatory compliance for clinical development, non-clinical studies and manufacturing.

Major developments and milestones in the clinical development pipeline announced during the six months to 31 December 2021 include:

- Selected Major Depressive Disorder (MDD) as third indication for Xanamem based on strong scientific rationale. Planning underway for Phase 2 trial to commence in 2022, with headline results expected in 2023⁴
- Filed Investigational New Drug (IND) submission to the US FDA for the Fragile X Syndrome (FXS) program and received approval to proceed under that IND for Phase 2 XanaFX trial in male adolescent and young adult patients with FXS
- Expanded XanaFX trial to include sites in North America, added 5mg dose group and increased target enrolment from 50 to 75. Signed Letter of Intent with Worldwide Clinical Trials Pty Limited to operationalise the trial, which now spans four countries (also see point (vi) below). Headline results expected in 2023
- Completed target enrolment of 107 patients for the XanaMIA Part A trial in Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD). Last patient visit completed in February 2022 and expected results timeline narrowed from Q2 2022 to April 2022
- Added a retrospective analysis of the effects of Xanamem on biomarkers of possible disease modification using stored samples from the prior Phase 2 XanADu study in mild AD. Results expected in H2 2022 and, together with the XanaMIA Part A trial results expected in April 2022, will inform the design of the XanaMIA Part B trial and subsequent AD trials.

(ii) Capital raising

In December 2021, Actinogen announced the successful completion of a \$13.3 million capital raising, comprising a \$12 million institutional placement of 88,888,881 new, ordinary fully paid Actinogen shares at an offer price of \$0.135 per new share⁵, and a \$1.3 million Share Purchase Plan (SPP) of 9,796,389 new, ordinary fully paid shares to existing shareholders at the same \$0.135 issue price.⁶ The funds raised are primarily being applied to the expanded clinical development pipeline including the addition of the MDD program, the expanded XanaFX trial and the retrospective AD biomarker study.

(iii) New Xanamem clinical advisory boards for FXS and Depression programs

In December 2021, the Company announced the establishment of two new Xanamem clinical advisory boards for its programs in FXS and Depression, and the inaugural expert appointments to those boards comprising five renowned global thought leaders in clinical trials for FXS, Depression and assessment of Cognition:

- **Fragile X Syndrome Clinical Advisory Board**
Dr Elizabeth Berry-Kravis, MD, PhD and Dr Pam Ventola, PhD, both based in the USA
- **Depression and Cognition Clinical Advisory Board**
Professor John Harrison, PhD, based in the UK, Dr Dana C. Hilt, MD based in the USA and Dr Christina Kurre Olsen based in Denmark

The expertise and qualifications of all advisory board members can be found on the Company's website.

(iv) Expansion in key operational and consultant personnel

The Company has continued to fill vital organisational and technical consultant roles to drive strategic initiatives and ensure the success of its clinical development pipeline and other operational requirements. Specialists in pivotal fields such as global regulatory affairs, clinical neurology, clinical pharmacology, pharmacology, biostatistics, toxicology, manufacturing and quality have been appointed as required to maintain operational momentum. The Company also announced the appointment of Professor Paul Rolan to the key Chief Medical Officer post in February 2022.

⁴ Years refer to calendar years unless stated otherwise.

⁵ Including the proposed \$107,625 subscription to the placement by CEO Dr Steven Gourlay that is subject to shareholder approval.

⁶ Total dollar values may not equate to total shares issued at \$0.135 offer price due to rounding up share allocations to the nearest whole share. \$13,322,500 (before costs) was raised in aggregate through the issue of 98,685,270 new, ordinary shares at \$0.135 per share.

Operating and Financial Review (continued)

2. OPERATIONS REVIEW (continued)

(v) Strategic collaboration with Oxford University researchers

The Company announced in December 2021 the finalisation of a clinical protocol as part of its strategic collaboration with researchers at the Radcliffe Department of Medicine, University of Oxford, to investigate Xanamem and a condition called Mild Autonomous Cortisol Secretion (MACS). MACS is associated with over-production of the stress hormone cortisol by non-cancerous growths on the adrenal glands.

The placebo-controlled 12-week clinical trial will enrol approximately 40 participants and is designed to investigate the therapeutic potential for Xanamem in patients with MACS and will evaluate effects of Xanamem on metabolism, bone density, and cognitive function.

The trial is funded by a Medical Research Council (UK) grant, and Actinogen will supply Xanamem to Oxford free-of-charge and provide trial design support. Results are anticipated in 2024.

(vi) Signed Letter of Intent and Work Order with Worldwide Clinical Trials to manage XanaFX Phase 2 clinical trial

In November 2021 Actinogen signed a Letter of Intent with leading global clinical research organisation Worldwide Clinical Trials (Worldwide) to initialise the company's XanaFX Phase 2 trial pending the negotiation of a full service work order, which was signed and announced in February 2022.

Worldwide is a global clinical research organisation specialising in neurological, paediatric, and rare diseases and the agreement appoints Worldwide to manage the XanaFX trial which will study cognition, anxiety, sleep and behavioural problems in male adolescents and young adults possessing the full genetic features associated with FXS. It will be a randomised, placebo-controlled, double-blind, 12-week trial of 5mg and 10mg Xanamem oral doses with 75 participants enrolled in the trial at sites in North America, Great Britain, Australia and New Zealand. Results are anticipated in 2023.

(vii) International industry conferences

In early January 2022 in San Francisco, CEO Dr Steven Gourlay presented at the Biopartnering @JPM associated with the 40th annual JP Morgan HealthCare Conference and at the H.C. Wainwright BioConnect Virtual Conference that ran concurrently with the JP Morgan conference.

Dr Gourlay also used his time in San Francisco to conduct multiple advisor, business development and other stakeholder meetings during the conference week to update potential pharmaceutical industry partners on the Company's expanded clinical development pipeline and its near and medium-term milestones.

(viii) Strong Balance Sheet

Actinogen's cash balance as at 31 December 2021 was \$22.2 million, including funds received from the capital raising concluded in December 2021 and the \$1.4 million tax incentive rebate received in October 2021. The Company remains well positioned to fund its current planned clinical trials and advance the clinical development of Xanamem.

(ix) Strengthened intellectual property portfolio

In August 2021, the Company received official notification from the Brazilian Patent and Trademark Office of grant of its patent application for Xanamem. The grant of the Brazilian patent completed a key part of Actinogen's intellectual property portfolio, with protection across all major pharmaceutical markets including the USA, UK, EU, Japan, China, Canada and Australia. The patents provide exclusive rights in these regions and cover the composition of matter of Xanamem and its use in all diseases.

Globally, this patent encompasses composition of matter protection to 2031 with the possibility to extend by an additional 5 years in markets including Australia, the US, the EU, Korea, Japan, China, and Israel.

Directors' Report

Your Directors present their report pertaining to Actinogen Medical Limited ('Actinogen Medical' or 'the Company') for the half year ended 31 December 2021.

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 2021 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.



Dr Steven Gourlay
Managing Director
Sydney, New South Wales
Thursday, 24 February 2022



**Building a better
working world**

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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 2021, 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
24 February 2022

Statement of Comprehensive Income

For the half year ended 31 December 2021

	Note	Half year ended 31/12/2021 \$	Half year ended 31/12/2020 \$
Interest revenue		14,872	16,313
Other income		-	50,000
Total revenue & other income	5	14,872	66,313
Research & development costs	5	(3,747,128)	(789,921)
Employment costs		(720,594)	(772,865)
Corporate & administration costs		(624,568)	(539,107)
Finance costs		(8,443)	(11,843)
Share-based payment expenses	13	(508,853)	(82,211)
Amortisation expense	10	(156,373)	(176,751)
Depreciation expense (right-of-use asset)	9	(40,504)	(47,556)
Depreciation expense (office equipment)	8	(3,329)	(3,678)
Total expenses		(5,809,792)	(2,423,932)
Loss before income tax		(5,794,920)	(2,357,619)
Income tax expense		-	-
Loss for the half year		(5,794,920)	(2,357,619)
Other comprehensive income			
Items that may be reclassified subsequently to profit and loss:			
Other comprehensive income		-	-
Total comprehensive loss for the half year		(5,794,920)	(2,357,619)
Loss per share for attributable to the ordinary equity holders of the Company			
Basic and diluted loss per share in cents (w weighted average)		(0.35)	(0.16)

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

Statement of Financial Position

As at 31 December 2021

	Note	As at 31/12/2021 \$	As at 30/06/2021 \$
Current Assets			
Cash and cash equivalents	6	22,228,524	13,456,919
Other receivables	7	342,678	1,634,322
Total Current Assets		22,571,202	15,091,241
Non-Current Assets			
Property, plant and equipment	8	13,180	16,509
Intangible assets	10	2,876,831	3,033,204
Right-of-use assets	9	196,944	237,448
Total Non-Current Assets		3,086,955	3,287,161
TOTAL ASSETS		25,658,157	18,378,402
Current Liabilities			
Trade and other payables	11	805,718	619,573
Provision for employee entitlements		75,110	64,307
Lease liability	9	74,702	71,170
Total Current Liabilities		955,530	755,050
Non-Current Liabilities			
Lease liability	9	126,752	165,271
Total Non-Current Liabilities		126,752	165,271
TOTAL LIABILITIES		1,082,282	920,321
NET ASSETS		24,575,875	17,458,081
Equity			
Contributed equity	12	74,667,320	60,054,459
Reserve shares	12	(4,143,492)	(1,934,492)
Reserves	13	8,288,880	7,780,027
Accumulated losses		(54,236,833)	(48,441,913)
TOTAL EQUITY		24,575,875	17,458,081

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 2021

	Contributed Equity	Accumulated Losses	Option Reserve	Reserve Shares	Total
	\$	\$	\$	\$	\$
Half year ended 31 December 2021					
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)
<i>Transactions with equity holders in their capacity as equity holders:</i>					
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
Half year ended 31 December 2020					
Balance as at 1 July 2020	47,924,606	(44,526,846)	7,490,745	-	10,888,505
Loss for the half year	-	(2,357,619)	-	-	(2,357,619)
Other comprehensive income	-	-	-	-	-
Total comprehensive loss for the half year	-	(2,357,619)	-	-	(2,357,619)
<i>Transactions with equity holders in their capacity as equity holders:</i>					
Shares issued during the half year	7,360,230	-	-	-	7,360,230
Capital raising costs	(511,284)	-	-	-	(511,284)
Share-based payments	-	-	82,211	-	82,211
Balance as at 31 December 2020	54,773,552	(46,884,465)	7,572,956	-	15,462,043

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 2021

	Note	Half year ended 31/12/2021 \$	Half year ended 31/12/2020 \$
Cash Flows from Operating Activities			
Interest received		14,872	16,313
Interest paid		(5,804)	(9,737)
Payments to suppliers and employees		(1,439,657)	(488,990)
Payments for research and development		(3,601,393)	(1,385,657)
Government R&D tax rebate and grants received		1,434,713	2,933,544
Net cash (outflow)/inflow from operating activities		(3,597,269)	1,065,473
Cash Flows from Investing Activities			
Purchase of property, plant and equipment		-	-
Net cash outflow from investing activities		-	-
Cash Flows from Financing Activities			
Proceeds from issue of shares		13,214,874	7,360,230
Transaction costs associated with issue of shares		(811,013)	(511,284)
Principal repayment on leases		(34,987)	(42,277)
Net cash inflow from financing activities		12,368,874	6,806,669
Net increase in cash and cash equivalents		8,771,605	7,872,142
Cash and cash equivalents at beginning of the half year		13,456,919	5,040,486
Cash and cash equivalents at the end of the half year	6	22,228,524	12,912,628

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 2021

1. CORPORATE INFORMATION

The interim financial statements of Actinogen Medical Limited (“Actinogen Medical” or the “Company”) for the half year ended 31 December 2021 were authorised in accordance with a resolution of Directors on 24 February 2022.

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 2021.

2.1. Basis of preparation

The interim condensed financial statements for the six months ended 31 December 2021 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 2021.

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 2021, except for the adoption of new standards effective as of 1 July 2021, 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 2021:

	Cash and cash equivalents \$	Financial assets / liabilities at amortised cost \$
As at 31 December 2021		
Financial assets		
Cash and cash equivalents	22,228,524	-
Trade and other receivables	-	35,981
Total current assets	22,228,524	35,981
Total financial assets	22,228,524	35,981
Financial liabilities		
Trade and other payables	-	805,718
Lease liabilities - current	-	74,702
Total current liabilities	-	880,420
Lease liabilities - non-current	-	126,752
Total non-current liabilities	-	126,752
Total financial liabilities	-	1,007,172
Net exposure	22,228,524	(971,191)

	Cash and cash equivalents \$	Financial assets / liabilities at amortised cost \$
As at 30 June 2021		
Financial assets		
Cash and cash equivalents	13,456,919	-
Trade and other receivables	-	89,956
Total current assets	13,456,919	89,956
Total financial assets	13,456,919	89,956
Financial liabilities		
Trade and other payables	-	619,573
Lease liabilities - current	-	71,170
Total current liabilities	-	690,743
Lease liabilities - non-current	-	165,271
Total non-current liabilities	-	165,271
Total financial liabilities	-	856,014
Net exposure	13,456,919	(766,058)

Notes to the Financial Statements

(continued)

5. OTHER INCOME AND EXPENSES

	Half year ended 31/12/2021	Half year ended 31/12/2020
	\$	\$
Income		
Interest income	14,872	16,313
Other income		
Government grants	-	50,000
Total other income	-	50,000
Total income	14,872	66,313
Expenses		
Research and development costs:		
Research consultants	369,951	246,094
Administrative	91,670	157,425
Laboratory expenses	3,285,507	386,402
Total research and development costs	3,747,128	789,921

6. CASH AND CASH EQUIVALENTS

	As at 31/12/2021	As at 30/06/2021
	\$	\$
Cash at bank and on hand	15,128,258	6,391,919
Short term deposits	7,100,266	7,065,000
Total cash and cash equivalents	22,228,524	13,456,919

7. OTHER RECEIVABLES

	As at 31/12/2021	As at 30/06/2021
	\$	\$
Prepaid insurance	35,981	89,956
Goods and services tax receivable	306,697	105,795
Research and development tax rebate receivable	-	1,438,571
Total other receivables	342,678	1,634,322

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 31/12/2021	As at 30/06/2021
	\$	\$
At cost	28,947	28,947
Accumulated depreciation	(15,767)	(12,438)
Total property, plant and equipment	13,180	16,509

Movements during the half year

	Computer Equipment	Total
	\$	\$
Opening balance at 1 July 2020	18,541	18,541
Acquisitions	6,188	6,188
Depreciation	(8,220)	(8,220)
Closing balance at 30 June 2021	16,509	16,509
Opening balance at 1 July 2021	16,509	16,509
Depreciation	(3,329)	(3,329)
Closing balance at 31 December 2021	13,180	13,180

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 2021:

	Right-of-use Assets Property	Lease Liability
	\$	\$
As at 1 July 2020	372,501	389,870
Adjustment to right-of-use asset due to revised lease terms	(69,325)	(69,325)
Depreciation expense	(93,937)	-
Adjustment to depreciation expense due to revised lease terms	28,209	-
Interest expense	-	18,054
Payments	-	(102,158)
As at 30 June 2021	237,448	236,441
As at 1 July 2021	237,448	236,441
Depreciation expense (a)	(40,504)	-
Interest expense (b)	-	5,804
Payments (b)	-	(40,791)
As at 31 December 2021	196,944	201,454

- (a) The lease payments made during the half year totalled \$40,791 comprising \$34,987 which represents the principal component and \$5,804 which represents the interest expense component.
- (b) Of the total lease liability amounting to \$201,454, \$74,702 is current, and \$126,752 is non-current.

Set out below are the amounts recognised in the statement of comprehensive loss for the half year ended 31 December 2021:

	Half year ended 31/12/2021	Half year ended 31/12/2020
	\$	\$
Depreciation expense on right-of-use asset	40,504	47,556
Interest expense on lease liabilities	5,804	9,737
Rent expense - short-term leases	780	780
Total amounts recognised in profit or loss	47,088	58,073

Notes to the Financial Statements

(continued)

10. INTANGIBLE ASSETS

	As at 31/12/2021	As at 30/06/2021
	\$	\$
At cost	5,756,743	5,756,743
Accumulated amortisation and impairment loss	(2,879,912)	(2,723,539)
Total intangible assets	2,876,831	3,033,204

Movement in Intangible Assets

	Intellectual Property \$
Opening balance at 1 July 2020	3,345,951
Amortisation expense	(312,747)
Closing balance at 30 June 2021	3,033,204
Opening balance at 1 July 2021	3,033,204
Amortisation expense	(156,373)
Closing balance at 31 December 2021	2,876,831

11. TRADE AND OTHER PAYABLES

	As at 31/12/2021	As at 30/06/2021
	\$	\$
Trade payables	364,008	392,187
Accruals and other payables	382,732	54,903
Goods and services tax payable	2,500	1,116
Provision for payroll tax	-	10,620
Employee tax liabilities	56,478	160,747
Total trade and other payables	805,718	619,573

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 31/12/2021 \$	As at 30/06/2021 \$
Fully paid ordinary shares	79,587,752	64,163,878
Capital raising costs	(4,920,432)	(4,109,419)
Total contributed equity	74,667,320	60,054,459

Movement of fully paid ordinary shares

	Date	Quantity	Unit Price \$	Total \$
Opening balance at 1 July 2020		1,116,231,320		47,924,606
Proceeds from Placement	22/10/2020	272,727,273	\$ 0.022	6,000,000
Proceeds from Rights Issue	17/11/2020	61,828,576	\$ 0.022	1,360,230
Capital raising costs				(511,284)
Balance as at 31 December 2020		1,450,787,169		54,773,552
Proceeds from Shortfall Placement	10/02/2021	161,409,078	\$ 0.022	3,551,000
Capital raising costs				(204,585)
Loan Shares	15/03/2021	24,181,150	\$ 0.035	846,340
Loan Shares	15/03/2021	24,181,150	\$ 0.045	1,088,152
Balance at 30 June 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	1,322,500
Capital raising costs during the half year				(811,013)
Balance as at 31 December 2021		1,774,846,595		74,667,320

(b) Reserve shares

Reserve 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 2021, the following reserve shares were on issue.

	Date	Quantity	Unit Price \$	Total \$
Issue of CEO/Managing Director loan shares	15/03/2021	(24,181,150)	\$ 0.035	(846,340)
Issue of CEO/Managing Director loan shares	15/03/2021	(24,181,150)	\$ 0.045	(1,088,152)
Balance at 30 June 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)
Balance as at 31 December 2021		(64,762,300)		(4,143,492)

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 31/12/2021	As at 30/06/2021
	\$	\$
Option reserve	8,288,880	7,780,027
Total reserves	8,288,880	7,780,027

Movement in Option Reserve

	Half year ended 31/12/2021	Year ended 30/06/2021
	\$	\$
Balance at the beginning of the period	7,780,027	7,490,745
Share-based payment expense on Director options	49,902	86,685
Share-based payment expense on employee options	25,775	59,688
Share-based payment expense on employee loan shares	145,014	-
Share-based payment expense on Director loan shares	288,162	142,909
Balance at end of period	8,288,880	7,780,027

Total share-based payment expenses recognised during the half year amounted to \$508,803.

14. COMMITMENTS AND CONTINGENCIES

Other than what is mentioned below, the Directors are not aware of any commitments, contingent liabilities or assets that exist at 31 December 2021 (2020: Nil):

- On 9 February 2022, the Company appointed leading clinical research organisation Worldwide Clinical Trials Pty Ltd to manage the recruitment, conduct and general implementation of its XanaFX Phase 2 trial in adolescent boys and young adults with Fragile X Syndrome (FXS). The Work Order is a full-service agreement and totals approximately \$13,600,000. The Work Order will remain in force until study completion unless otherwise terminated by the Company or Worldwide with 30 days' notice at cause or 90 days' notice without cause. In the event of termination, Worldwide will be entitled to receive payment only for services performed up to the effective date of termination, together with any reasonable fees required in connection with an orderly cessation of all services.

15. RELATED PARTY TRANSACTIONS

There were no related party transactions that occurred during the half year other than transactions set out below:

- On 18 November 2021, 4.5 million loan shares were issued, as approved by shareholders, to Non-Executive Directors of Company at an issue price of \$0.20 each.

16. EVENTS OCCURRING AFTER THE REPORTING PERIOD

Other than what is stated below, 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.

- On 9 February 2022, the Company appointed leading clinical research organisation Worldwide Clinical Trials Pty Ltd to manage the recruitment, conduct and general implementation of its XanaFX Phase 2 trial in adolescent boys and young adults with Fragile X Syndrome (FXS). Refer to Note 14 Commitments and Contingencies for more information.

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 2021 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.



Dr Steven Gourlay
Managing Director
Sydney, New South Wales
Thursday, 24 February 2022

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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 at 31 December 2021, 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 statement 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 2021 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 2021 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.

The Ernst & Young logo is a stylized, handwritten-style signature of the words 'Ernst & Young' in black ink.

Ernst & Young

A handwritten signature in black ink, appearing to read 'P. Dreyer', is written over a faint, larger version of the signature.

Pierre Dreyer
Partner
Perth
24 February 2022

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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

Company Secretary

Mr Peter Webse

Principal Place of Business / Registered Office

Suite 901
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109 Pitt Street
Sydney NSW 2000

Contact Details

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ABN 14 086 778 476

Lawyers

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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