

ASX ANNOUNCEMENT**December 2019 Quarterly Update**

- **Impressive results from XanaHES Phase I study, demonstrating a statistically significant improvement in cognition following treatment with 20mg Xanamem daily**
- **Comprehensive review of all Xanamem data, together with new indications, determine optimum strategic direction**
- **Funding options include non-dilutive grant applications submitted to broaden Xanamem portfolio**
- **A\$4.58m R&D Tax Incentive Rebate received – with a further 2019 rebate expected**
- **New Phase II clinical studies expected to initiate during 2020**

Sydney, 28 January 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its Appendix 4C and quarterly update report for the three-month period ended 31 December 2019.

XanaHES Phase I Clinical Trial – statistically significant efficacy results

On 1 October 2019, Actinogen Medical announced impressive results from its XanaHES trial, which assessed the clinical cognitive effect of 20mg Xanamem daily in healthy elderly patients. While the study was primarily designed to investigate the safety of 20mg Xanamem in healthy elderly patients, it also included a number of exploratory efficacy outcome measures. These measures involved six cognitive efficacy assessments using the Cogstate Neuropsychiatric Test Battery (NTB). Most compelling, was the statistically significant improvement in cognition demonstrated for Xanamem over placebo. This was shown in three of the six domains tested after only 4 weeks of treatment, and the response persisted out to the end of treatment at 12 weeks. These results confirmed the expected clinical outcome of treating with Xanamem, and corroborated the previous results seen in animal and human studies, that indicated that the mechanism of action of Xanamem should result in cognitive improvement.

XanaHES also demonstrated a statistically significant reduction in serum cortisol levels for Xanamem over placebo, and a good safety profile was observed, with no treatment-related serious adverse events. These impressive results build on the growing Xanamem dataset by reinforcing the 'cortisol hypothesis' that underpins Xanamem's development.

Ongoing studies progress on track

The Phase I Target Occupancy study is designed to measure the effectiveness of different Xanamem doses on inhibiting the 11 β -HSD1 enzyme in the brain. Results from both Alzheimer's and cognitively normal patients have demonstrated that doses from 5mg to 30mg Xanamem daily effectively occupy the 11 β -HSD1 enzyme binding sites in the brain. This confirms that Xanamem works as designed, to penetrate the brain in concentrations that will adequately inhibit 11 β -HSD1 activity in the brain. Additional subject cohorts dosed at 10mg Xanamem with delayed PET imaging have confirmed the central nervous system pharmacokinetics (CNS PK) of Xanamem, providing a deeper understanding of how Xanamem acts within the brain. This study has been supported and enhanced by a further series of studies (the in-vitro Homogenate Binding studies), and collectively these studies will confirm the optimum Xanamem dosing regimen to take forward into future Phase II studies.

Additionally, the pre-clinical long-term toxicology studies are progressing as planned, with no substantial safety or long-term toxicity issues reported. These studies are required by regulatory authorities to commence

human studies with dosing durations beyond 12 weeks. The Company is confident that human studies of more than 12 weeks dosing with Xanamem should be approved by regulatory authorities.

Comprehensive strategic review - study proposals now well advanced

Actinogen and its advisors are in the final stages of completing a comprehensive review of all Xanamem data, target indications, and potential funding options, to inform Actinogen's optimum strategic direction. An updated Clinical Development Plan is now well advanced, with proposals under discussion to initiate new studies in Alzheimer's disease, and in cognitive impairment in schizophrenia, and type-2 diabetes.

During the quarter, the Company proactively engaged with key opinion leaders and relevant regulatory bodies to further inform on these plans. In addition, the Company has submitted grant applications with the aim of broadening and developing the Xanamem portfolio with non-dilutive funding alternatives.

Ongoing engagement with biotech investors and potential pharma partners

During the period, Actinogen Medical continued discussions with potential collaborators and commercial partners, and presented at numerous investors, biotech and industry conferences, including:

- Clinical Trials on Alzheimer's Disease (CTAD) in San Diego on 4-7 December 2019
- AusBiotech Invest and Partnering Conference in Melbourne on 31 October 2019
- Australian Microcap Investment Conference in Melbourne on 22 October 2019
- AC4R Annual Scientific Meeting in Sydney on 11 October 2019

Additionally, Dr Bill Ketelbey recently presented at the 3rd Annual SACHS Neuroscience Innovation Forum during JP Morgan Week (13-16 Jan) in San Francisco, USA. This was an excellent opportunity for the Company to update international pharmaceutical leaders and major global investors on the compelling results achieved with XanaHES, and the expanded Xanamem dataset generated over the past few months. Following the Forum, Actinogen participated in numerous meetings with potential partners and collaborators during the JP Morgan week.

In recognition of the advances made in the development of Xanamem, Actinogen has been accepted to present all the Xanamem data at the International Advancement in Alzheimer's and Parkinson's Disease Therapies (AD/PD) Focus Meeting in Vienna in April 2020. This specialist Alzheimer's conference includes all the latest breakthroughs in Alzheimer's drug development, translational R&D, early diagnosis, and clinical trials, and we are proud to be invited to add to the global Alzheimer's community knowledge base.

Financials

In October 2019, Actinogen received an R&D Tax Incentive rebate of A\$4.58m, with an expectation to receive an additional A\$0.65m early in 2020.

The Company holds A\$8.5m cash as at 31 December 2019.

Outlook

Actinogen CEO and MD, Dr. Bill Ketelbey, commented "The breakthrough XanaHES results and considerable dataset generated throughout 2019 on Xanamem has received an extremely positive response from both the medical and research communities and the industry, placing us in a strong position going forward. We are particularly pleased with the engagement from potential partners, collaborators and investors that we met with over recent weeks."

"We are now finalising the designs to optimise the clinical studies in Alzheimer's disease and the new target indications. We're advancing the development of trial proposals to align with the Company's strategic plans and expect a number of clinical studies to initiate during the year ahead."

ENDS

Actinogen Medical

Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au

 @BillKetelbey

Investor and Media Enquiries

Arthur Chan
WE Communications
P: +61 2 9237 2805
E: arthurc@we-worldwide.com

Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company developing novel therapies for cognitive impairment associated with chronic neurological and metabolic diseases. The company is currently developing its lead compound Xanamem as a promising new therapy for Alzheimer's disease and cognitive impairment associated with schizophrenia and mood disorders. The cognitive dysfunction associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem™

Xanamem's novel mechanism of action sets it apart from other therapies for Alzheimer's disease. It works by blocking the excess production of intracellular cortisol – the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to changes in the brain, affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, schizophrenia and the mood disorders.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem™ 20mg once daily in healthy elderly volunteers, showed that the drug exhibited a good safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem™ produced a statistically significant improvement in cognition, which, along with other data recently generated, confirms the underlying mechanism of action of Xanamem.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2020, including in Alzheimer's disease, and in cognitive impairment associated with schizophrenia, mood disorders and diabetes.

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.

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) 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, Link Market Services.

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

ACTINOGEN MEDICAL LIMITED

ABN

14 086 778 476

Quarter ended ("current quarter")

31 December 2019

| Consolidated statement of cash flows | Current quarter | Year to date |
|---|------------------------|---------------------|
| | \$A'000 | (6 months) |
| | | \$A'000 |
| 1. Cash flows from operating activities | | |
| 1.1 Receipts from customers | | |
| 1.2 Payments for | | |
| (a) research and development | (2,218) | (4,201) |
| (b) product manufacturing and operating costs | - | - |
| (c) advertising and marketing | (166) | (395) |
| (d) leased assets | - | - |
| (e) staff costs | (32) | (65) |
| (f) administration and corporate costs | (89) | (232) |
| 1.3 Dividends received | - | - |
| 1.4 Interest received | 20 | 58 |
| 1.5 Interest and other costs of finance paid | (1) | (3) |
| 1.6 Income taxes paid | - | - |
| 1.7 Government grants and tax incentives | 4,603 | 4,631 |
| 1.8 Other (provide details if material) | - | - |
| 1.9 Net cash from / (used in) operating activities | 2,801 | 477 |
| 2. Cash flows from investing activities | | |
| 2.1 Payments to acquire: | | |
| (a) property, plant and equipment | (16) | (16) |
| (b) businesses (see item 10) | - | - |
| (c) investments | - | - |

| Consolidated statement of cash flows | Current quarter | Year to date (6 months) |
|---|------------------------|------------------------------------|
| | \$A'000 | \$A'000 |
| (d) intellectual property | - | - |
| (e) other non-current assets | - | - |
| 2.2 Proceeds from disposal of: | | |
| (a) property, plant and equipment | - | - |
| (b) businesses (see item 10) | - | - |
| (c) investments | - | - |
| (d) intellectual property | - | - |
| (e) other non-current assets | - | - |
| 2.3 Cash flows from loans to other entities | - | - |
| 2.4 Dividends received | - | - |
| 2.5 Other (provide details if material) | - | - |
| 2.6 Net cash from / (used in) investing activities | (16) | (16) |
| 3. Cash flows from financing activities | | |
| 3.1 Proceeds from issues of shares | - | - |
| 3.2 Proceeds from issue of convertible notes | - | - |
| 3.3 Proceeds from exercise of share options | - | - |
| 3.4 Transaction costs related to issues of shares, convertible notes or options | - | - |
| 3.5 Proceeds from borrowings | - | - |
| 3.6 Repayment of borrowings | - | - |
| 3.7 Transaction costs related to loans and borrowings | - | - |
| 3.8 Dividends paid | - | - |
| 3.9 Other (repayment of loan shares by Managing Director) | 360 | 360 |
| 3.10 Net cash from / (used in) financing activities | 360 | 360 |
| 4. Net increase / (decrease) in cash and cash equivalents for the period | | |
| 4.1 Cash and cash equivalents at beginning of quarter/year to date | 5,347 | 7,672 |
| 4.2 Net cash from / (used in) operating activities (item 1.9 above) | 2,801 | 477 |
| 4.3 Net cash from / (used in) investing activities (item 2.6 above) | (16) | (16) |
| 4.4 Net cash from / (used in) financing activities (item 3.10 above) | 360 | 360 |

| Consolidated statement of cash flows | | Current quarter | Year to date (6 months) |
|---|--|------------------------|------------------------------------|
| | | \$A'000 | \$A'000 |
| 4.5 | Effect of movement in exchange rates on cash held | 1 | - |
| 4.6 | Cash and cash equivalents at end of quarter | 8,493 | 8,493 |

| 5. Reconciliation of cash and cash equivalents | Current quarter | Previous quarter |
|---|--|-------------------------|
| at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | \$A'000 | \$A'000 |
| 5.1 | Bank balances | 1,247 |
| 5.2 | Call deposits | 4,100 |
| 5.3 | Bank overdrafts | - |
| 5.4 | Other (provide details) | - |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above) | 5,347 |

6. Payments to directors of the entity and their associates

- | | | Current quarter |
|-----|--|------------------------|
| | | \$A'000 |
| 6.1 | Aggregate amount of payments to these parties included in item 1.2 | 135 |
| 6.2 | Aggregate amount of cash flow from loans to these parties included in item 2.3 | - |
| 6.3 | Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2 | |

Directors' fees, salaries including superannuation benefits and professional consultancy fees. All payments are on normal commercial terms.

7. Payments to related entities of the entity and their associates

- | | | Current quarter |
|-----|--|------------------------|
| | | \$A'000 |
| 7.1 | Aggregate amount of payments to these parties included in item 1.2 | - |
| 7.2 | Aggregate amount of cash flow from loans to these parties included in item 2.3 | - |
| 7.3 | Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2 | |

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| 8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i> | Total facility amount at quarter end \$A'000 | Amount drawn at quarter end \$A'000 |
|--|--|---|
| 8.1 Loan facilities | - | - |
| 8.2 Credit standby arrangements | - | - |
| 8.3 Other (please specify) | - | - |
| 8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well. | | |

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| 9. Estimated cash outflows for next quarter | \$A'000 |
|--|--------------|
| 9.1 Research and development | 932 |
| 9.2 Product manufacturing and operating costs | - |
| 9.3 Advertising and marketing | 165 |
| 9.4 Leased assets | - |
| 9.5 Staff costs | 31 |
| 9.6 Administration and corporate costs | 114 |
| 9.7 Other | - |
| 9.8 Total estimated cash outflows | 1,242 |

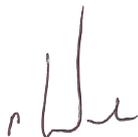
Note: The Company expects to receive approximately \$4.6m in FY2019 R&D Tax rebates in the December 2019 quarter, with a further FY2019 rebate of up to \$0.65m expected thereafter.

| 10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above) | Acquisitions | Disposals |
|--|--------------|-----------|
| 10.1 Name of entity | - | - |
| 10.2 Place of incorporation or registration | - | - |
| 10.3 Consideration for acquisition or disposal | - | - |
| 10.4 Total net assets | - | - |
| 10.5 Nature of business | - | - |

Compliance statement

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

Sign here:



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Company Secretary

Date: 28 January 2020

Print name: Peter Webse

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.