

## June 2018 Quarterly Report

- Successful completion of XanADu Interim Analysis with recommendation from the independent DSMB to continue the study without modification
- \$15m Placement to fund further development of Xanamem with cornerstone investment from leading US biotech investor, Biotechnology Value Fund LP (BVF)
- Share Purchase Plan raises \$0.95m and a further investment from BVF and Australian Ethical, taking up some of the SPP shortfall, raises \$0.56m, bringing the total raised to \$16.5m
- Additional XanADu study sites now open in the US, bringing the total to 25, driving an expected acceleration in patient enrolment

**Sydney, 25 July 2018: Actinogen Medical ASX:ACW ('ACW' or 'the Company')** has today submitted its Appendix 4C for the three-month period ended 30 June 2018 and is pleased to release this Quarterly Activities Report.

### Operational Update

#### Successful Interim Analysis

Actinogen Medical achieved a key milestone during the quarter; the successful completion of an Interim Analysis of its Phase II XanADu clinical trial for the treatment of Alzheimer's disease. The Interim Analysis was undertaken by the independent *Data Safety and Monitoring Board (DSMB)* on data from the first fifty (50) evaluable patients to complete the trial. The Company received the recommendation from the DSMB to continue the trial without modification, affirming the positive benefit-risk safety profile of the 10mg daily Xanamem dose in Alzheimer's patients and acknowledging that importantly no treatment related serious events were reported.

The outcome of the Interim Analysis supports the further development of Xanamem in the treatment of Alzheimer's disease and in other potential indications. Following the recommendation to continue the trial without modification, Actinogen continues to enrol patients and as at 6<sup>th</sup> July had enrolled 117 of the planned 174 patients. The trial is on schedule, with all 174 patients expected to be enrolled by Q4 CY18, producing top-line results in Q2 CY19.

### Corporate Update

#### Capital Raise

In parallel with the Interim Analysis, Actinogen completed a \$15m capital raise via a Placement to institutional investors. The Placement was issued in two tranches, with shareholder approval for the second tranche received at an EGM on the 5<sup>th</sup> of July 2018.

The Placement was undertaken at \$0.05 per share, representing a 13.4% premium to the 5-day VWAP. Leading US specialist biotechnology investor, Biotechnology Value Fund LP (BVF), took a cornerstone position of \$10.5m alongside other leading Australian institutional investors Platinum Asset Management and Australian Ethical Investment.

The Company also launched and completed, post the quarter, a Share Purchase Plan (SPP) that raised an additional \$0.95m. Existing investors BVF and Australian Ethical opted to participate in a placement of some of the SPP shortfall, raising a further \$0.56m and bringing the total capital raised to \$16.5m. Following the placement and SPP, BVF became the largest shareholder of the Company with a 19.97% holding.

The funds raised will be used to advance the Xanamem development plans to enhance the data set and to value-add to ongoing discussions with potential future development partners.

### **Actinogen Medical on the world stage**

CEO, Dr Bill Ketelbey, attended and presented at the BIO International Convention, the world's largest and most prestigious biotech partnering convention, in Boston, US. The convention presented the opportunity for Actinogen to showcase the development progress of Xanamem following the successful Interim Analysis and to discuss potential development plans for Xanamem following the capital raise. The conference saw multiple global biotech industry leaders and businesses in attendance and provided Actinogen an opportunity to network with potential future development partners.

In late May the Company hosted a global investor conference call, which included the three members of the Xanamem Clinical Advisory Board. The call updated shareholders on the outcomes from the positive Interim Analysis and capital raise, and provided a forum for the shareholders and other participants to hear from the Advisory Board members and to have questions answered by these key Company advisors.

### **Outlook**

Following the successful completion of the XanADu Interim Analysis, Actinogen continues to progress enrolment into its Phase II clinical trial on schedule and in line with the Board's expectations. As reported, total of 117 patients had been recruited on July 6<sup>th</sup>, and the Board and Management look forward to completing the XanADu enrolment during Q4 CY18.

In July, the Company announced the opening of an additional five new XanADu study sites in the US. The US has proven to be the most productive region in terms of patient enrolment and the opening of the new sites is expected to accelerate patient recruitment. The new sites have already screened a significant number of potential new patients and successfully enrolled a number of these.

The additional \$16.5m from the Placement and SPP has positioned Actinogen well to further advance the development of Xanamem for the treatment of Alzheimer's disease and other indications.

**-ENDS-**

#### **Actinogen Medical**

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CEO & Managing Director

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## **About Actinogen Medical**

Actinogen Medical (ASX: ACW) is an ASX-listed biotech company focused on innovative approaches to treating cognitive decline that occurs in chronic neurodegenerative and metabolic diseases. Actinogen Medical is developing Xanamem a promising new therapy for Alzheimer's disease, a condition with a multibillion dollar market potential. In the US alone, the cost of managing Alzheimer's disease is estimated to be US\$250bn and is set to increase to US\$2tn by 2050, outstripping the treatment costs of all other diseases. Alzheimer's disease is now the leading cause of death in the UK and second only to ischaemic heart disease in Australia

## **About Xanamem™**

Xanamem's novel mechanism of action sets it apart from other Alzheimer's treatments. It works by blocking the excess production of cortisol - the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. This enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory, and to the development of amyloid plaques and neural death – all hallmarks of Alzheimer's disease.

## **About XanADu**

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem in subjects with mild dementia due to Alzheimer's disease. XanADu, will enrol 174 patients at 20 research sites across Australia, the UK and the USA. The trial is registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with the identifier: NCT02727699, where more details on the trial can be found, including the study design, patient eligibility criteria and the locations of the study sites

**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")**

30 June 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(12 months)</b>
		<b>\$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(4,223)	(8,014)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(256)	(487)
(d) leased assets	-	-
(e) staff costs	(29)	(111)
(f) administration and corporate costs	(220)	(611)
1.3 Dividends received	-	-
1.4 Interest received	17	37
1.5 Interest and other costs of finance paid	(4)	(11)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	11	1,267
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(4,704)</b>	<b>(7,930)</b>

Note: 1.2 (a) -The differential between research and development forecast and actual for the quarter reflects both an acceleration of the XanADu study enrolment and the initiation of additional Xanamem development work sooner than initially expected. Note 1.2(c) – reflects a one-off increase due to investor relations and business development programs and initiatives during the quarter. Note 1.2(f) – Increase for the quarter driven by recent capital raisings and office relocation.

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date (12 months)</b>
	<b>\$A'000</b>	<b>\$A'000</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	4	(33)
(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	12	53
2.5 Other (provide details if material)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>16</b>	<b>20</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	9,476	14,756
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	(515)	(831)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>8,961</b>	<b>13,925</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	5,731	3,989
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,704)	(7,930)

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (12 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	16	20
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,961	13,925
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>10,004</b>	<b>10,004</b>

<b>5. Reconciliation of cash and cash equivalents</b>	<b>Current quarter</b>	<b>Previous quarter</b>	
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>\$A'000</b>	<b>\$A'000</b>	
5.1	Bank balances	9,830	4,537
5.2	Call deposits	174	1,194
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>10,004</b>	<b>5,731</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 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

<b>Current quarter</b>
<b>\$A'000</b>
151
-

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**

- 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

<b>Current quarter</b>
<b>\$A'000</b>
-
-

-

**8. Financing facilities available**

*Add notes as necessary for an understanding of the position*

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	3,833
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	60
9.4	Leased assets	-
9.5	Staff costs	31
9.6	Administration and corporate costs	152
9.7	Other	-
<b>9.8</b>	<b>Total estimated cash outflows</b>	<b>4,076</b>

**10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**

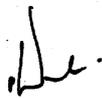
**Acquisitions**

**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: .....  
**Company Secretary**

Date: 25 July 2018

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.