

# Actinogen Medical

## XanaMIA passes interim analysis and marches on

Actinogen Medical's interim analysis of its XanaMIA Phase IIb/III study of lead candidate Xanamem (emestadastat) in patients with mild-to-moderate Alzheimer's disease (AD) was successful. The analysis surpassed interim futility thresholds and the independent data monitoring committee (DMC) recommended that the study proceed to completion without modification. The next major catalyst will be the top-line efficacy readout expected in November. The company also reported a A\$17m capital increase, consisting of a A\$12m now-completed offering to professional and sophisticated investors, and a A\$5m share purchase plan (SPP) to existing investors. We expect the capital increase to boost Actinogen's cash runway to mid-CY27, providing the company with ample flexibility to evaluate strategic or licensing options after the XanaMIA study readout. We now value Actinogen at A\$778.3m or A\$0.22 per share.

Year end	Revenue (AUDm)	PBT (AUDm)	EPS (AUC)	DPS (AUC)	P/E (x)	Yield (%)
6/24e	9.9	(11.4)	(0.53)	0.00	N/A	N/A
6/25e	5.5	(12.8)	(0.43)	0.00	N/A	N/A
6/26e	11.0	(15.8)	(0.47)	0.00	N/A	N/A
6/27e	10.4	(37.7)	(1.05)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS is fully diluted.

## Interim checkpoint passed, Q4 top-line readout next

The lack of study futility is a positive signal that, after having examined a meaningful proportion of efficacy data, the DMC has determined there is sufficient evidence of potential therapeutic activity to justify permitting the study to proceed to completion.

## Financing provides optionality and flexibility

The A\$17m capital increase and extension of Actinogen's cash runway (to mid-CY27) provides the company with greater flexibility to negotiate a potentially transformative licensing deal for Xanamem following the conclusion of XanaMIA should the top-line efficacy results be favourable. The company also retains the possibility to explore targeted regional licensing transactions over the next six to nine months ahead of the XanaMIA readout. Altogether, we believe the attainment of a global comprehensive deal after the study's conclusion remains the most likely outcome.

## Valuation: Higher rNPV, offset by share dilution

Given the positive interim XanaMIA results, we have raised our probability of success (PoS) estimate for the AD indication to 12.5% (from 10.0% previously) in our risk-adjusted net present value (rNPV) valuation approach. This was offset by fx changes and the pushing back of our potential launch estimate to CY30 (vs CY29 previously). Given these changes and a 12.7% increase in shares outstanding reflecting full completion of the A\$17m capital increase (share offering and SPP), we obtain a total equity valuation of A\$778.3m (versus A\$720.2m previously) or A\$0.22 per share (down from A\$0.23 previously, given the increased shares outstanding).

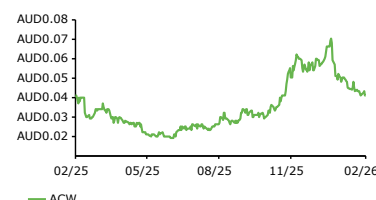
## Clinical and financial update

Healthcare

20 February 2026

<b>Price</b>	<b>AUD0.042</b>
<b>Market cap</b>	<b>AUD145m</b>
	A\$0.70/US\$
Pro forma net cash at 31 December 2025 (incl A\$12m February 2026 placement but excl A\$5m share purchase plan)	AUD20.4m
Shares in issue (incl February 2026 placement but excl share purchase plan)	3,461.9m
Free float	56.0%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

## Share price performance



%	1m	3m	12m
Abs	(15.0)	(22.7)	21.4
52-week high/low		AUD0.1	AUD0.0

## Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset, Xanamem, a specific and selective 11beta-HSD1 inhibitor designed to reduce excess cortisol in the brain. It is being advanced to treat Alzheimer's disease (its lead indication) and major depressive disorder.

## Next events

Xanamem AD pathway meetings with EMA and UK MHRA	CY26
XanaMIA Phase IIb/III study top-line results	Q4 CY26

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## Interim analysis passed, XanaMIA to proceed to completion

Actinogen reported on [30 January](#) that the independent DMC for its ongoing [XanaMIA Phase IIb/III pivotal study](#) in patients with mild-to-moderate AD has recommended that the study continue without modifications after completing its interim analysis of study data. The external DMC considered unblinded safety and efficacy data (reflecting Xanamem or placebo treatment) from c 37% of the expected final dataset, including data from 136 participants with one or more efficacy data points and 52 study participants who had completed the full 36 weeks of treatment.

The DMC concluded that the unblinded safety and efficacy data it reviewed support the continuation of the study towards its conclusion, expected in or around November 2026. The DMC analysis was based on a highly confidential process designed to preserve the statistical power of the trial and it included an interim futility analysis. This analysis was based on an assessment of whether the likelihood of the study meeting the primary efficacy endpoint was near nil (ie if 'futility' criteria are met). Fortunately, and as we had anticipated based on prior [XanADu](#) subset study data (discussed further below), the interim XanaMIA efficacy results surpassed the futility thresholds, meaning the DMC determined that the available data did not justify an early termination of the study for futility. As highlighted in [a prior note](#), while the DMC would not comment on any possible positive signals of efficacy, the lack of futility is a positive signal from the DMC that, after having examined a meaningful proportion of efficacy data, it determined there is sufficient evidence of potential therapeutic activity to justify permitting the study to proceed to completion. We also note that the DMC did not identify any major safety concerns, which again is reassuring but not surprising given that more than 400 patients have already been treated with the drug across multiple trials.

### Exhibit 1: Highlights of XanaMIA interim study analysis

#### Interim analysis positive trial recommendation

##### Assessments of safety and "efficacy futility"



##### Recommendation:

- Continue the XanaMIA trial without amendment to its final conclusion for the 247 participants

##### Methods:

- Independent Data Monitoring Committee (DMC) chaired by Alzheimer's disease trials expert Dr Hans Moebius
- Data confidentially reviewed included "unblinded" data on:
  - ✓ Safety (n=247, i.e. all enrolled participants)
  - ✓ Efficacy data from approximately 37% of total, expected trial dataset (code broken to see treatment group assignment) from Week 12 (n=136), Week 24 (n=87) and Week 36 data (n=52)

**Positive result confirms the trial cleared the pre-specified efficacy futility hurdle and unblinded safety review, materially de-risking the program as it advances toward final topline results in November**

Source: Actinogen presentation, February 2026

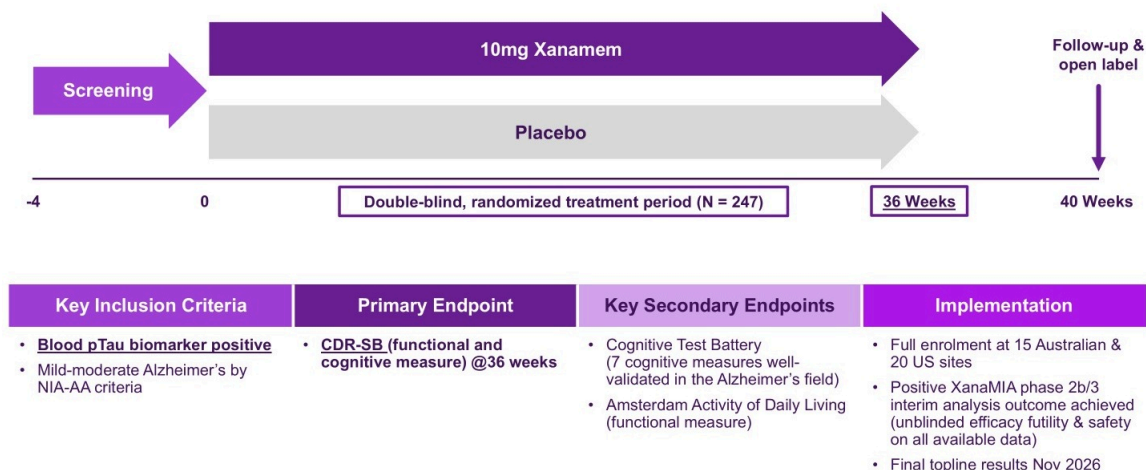
The XanaMIA Phase IIb/III study is designed to assess mild-to-moderate AD patients (with elevated blood levels of [phosphorylated Tau-181](#), or pTau-181, at baseline) across 35 sites in the US and Australia. Patients are randomised to take 10mg of Xanamem or a placebo once daily for 36 weeks and Actinogen recruited the final (247th) participant in the study in December 2025. The last participant's final evaluation visit is anticipated in September 2026.

## Exhibit 2: XanaMIA Phase IIb/III study overview

### 5. Evidence-based trial design & patient selection



Positive XanaMIA phase 2b/3 interim analysis outcome achieved, topline final results Nov 2026



Source: Actinogen presentation, February 2026. Note: NIA-AA, National Institute on Aging – Alzheimer's Association; CDR-SB, Clinical Dementia Rating Scale – Sum of Boxes.

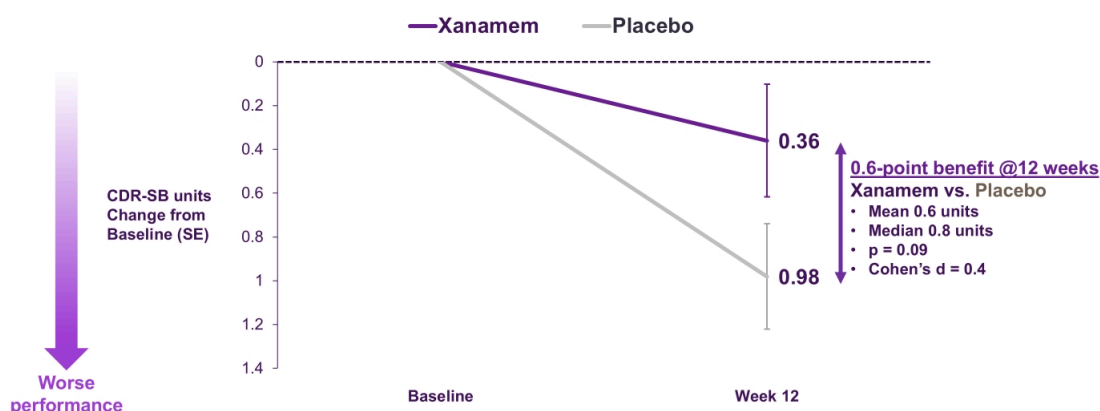
The primary endpoint is the drug's effect on AD progression using the FDA-recognised Clinical Dementia Rating – Sum of Boxes (CDR-SB), a comprehensive scale of functional capacities. The CDR-SB scale was used as the primary endpoint to support the FDA approval of Eisai and Biogen's Leqembi (lecanemab) in AD. XanaMIA's study design was supported by a subset analysis among patients with elevated pTau-181 at baseline from Actinogen's previous XanADu study (n=185) in patients with AD. This analysis showed statistically significant improvements versus the placebo on the CDR-SB scale in this group, suggesting that Xanamem's potential cognitive or disease-slowing effects may be sensitively detected by the CDR-SB endpoint.

## Exhibit 3: XanADu study results in patients with high pTau-181

### 3. Large Xanamem benefit in high pTau181 patients



Phase 2a biomarker study: major slowing of CDR-SB decline over 12 weeks (n=34)



Journal of Alzheimer's Disease 100 (2024) 139–150  
Plasma pTau181 Predicts Clinical Progression in a Phase 2 Randomized Controlled Trial of the 11-HSD1 Inhibitor Xanamem® for Mild Alzheimer's Disease  
Jack Taylor, Mark Jaros, Christopher Chen, John Harrison and Dana Hill

Investor Presentation 2 February 2026 13

Source: Actinogen presentation, February 2026

Given the positive DMC recommendation following the study's interim analysis, the XanaMIA trial will continue treating

ongoing participants with either 10mg of Xanamem or the placebo for a total of 36 weeks, as planned. Top-line final results are due in November 2026.

## Open-label XanaMIA extension study to start in Q1 CY26

All XanaMIA participants are potentially eligible to participate in the open-label extension phase of the trial (XanaMIA-OLE), due to open for enrolment in March. Subjects will receive 10mg of active Xanamem once daily and the study will be open to current and former participants in the XanaMIA study. The open-label extension will provide subjects with up to 25 months of treatment and will evaluate safety and a limited number of efficacy endpoints (such as CDR-SB).

### Exhibit 4: XanaMIA open-label extension study design

#### Open-label phase starting in Q1 2026

- Active Xanamem 10 mg offered to all current and prior XanaMIA phase 2b/3 trial participants irrespective of any gaps between completing the main trial and OLE availability
- No placebo control group
- Provides longer term safety data for at least 12 months and observational data on key efficacy endpoints such as the CDR-SB, cognition and activities of daily living
- Able to be reported at regular intervals e.g. every 6 months
- Will enable characterisation and comparison of efficacy endpoints trajectories between the group that got Xanamem in the main trial and then continue with Xanamem vs. placebo then Xanamem

Source: Actinogen presentation, February 2026

Altogether, we anticipate that regulators (eg the FDA) will review an eventual Xanamem marketing application more favourably, should supportive longer-term (beyond the 36-week period studied during the XanaMIA randomised trial) safety data be made available, even if the data arise from an open-label (non-blinded) extension phase.

## Additional clarity on second Phase III study

Following Actinogen's favourable [Type C meeting](#) with the Neurology-I division of the FDA last September, the company reported it had reached an agreement with the agency about the pathway towards potential future regulatory approval for Xanamem in AD. Specifically, the FDA agreed that, if XanaMIA results are positive, only one additional pivotal study and a limited number of ancillary clinical pharmacology studies and non-clinical trials will be required. Hence, the Type C meeting confirmed that the XanaMIA study would, therefore, qualify as one of the two pivotal trials required for marketing approval in AD.

Actinogen has specified that the additional pivotal trial will, like XanaMIA, be a well-controlled, two-arm study assessing 10mg of Xanamem versus a placebo, although it will be larger and will span multiple countries in addition to Australia and the US. We believe the study, which is scheduled to start in CY27 (thus after the completion of XanaMIA), will include sites in Europe and China, likely in order to satisfy future marketing approval applications in these jurisdictions (should the efficacy data be supportive). The company expects this study will enrol c 700 patients (vs c 247 for XanaMIA) and, while the full study design has not yet been made public, we believe the primary efficacy endpoint will measure treatment over a longer duration (such as 52 weeks after baseline), compared to the 36-week duration for XanaMIA. The registrational trials for Leqembi's and Kisunla's primary efficacy measures assessed their efficacy after approximately 78 weeks of treatment.

Given the more global nature of this Phase III study, we believe Actinogen will likely be more reliant on external contract research organisations for this study, which will likely increase the study cost per patient compared to XanaMIA (plus there may be additional data points or analytical measures compared to XanaMIA that were requested by the FDA during the Type C meeting in CY25 for this second study). Altogether, we estimate that the study will cost US\$100k per patient or up to US\$70m in total. Actinogen expects to engage in regulatory meetings with the European Medicines Agency and UK Medicines and Healthcare products Regulatory Agency in CY26 to confirm alignment with these authorities on the regulatory pathway towards approval.

## Funding extends runway past XanaMIA study completion

Actinogen announced a capital increase of up to A\$17.0m on [2 February](#), consisting of firm commitments from



professional and sophisticated investors for a A\$12.0m (gross) share placement, along with a A\$5.0m SPP offer to existing shareholders on the same financial terms as the placement. The share placement includes the subscription for A\$500,000 by Actinogen's CEO, Dr Steven Gourlay, as well as the subscription for A\$167,000 from other directors of the company. The participation by the company's CEO can be perceived as a vote of confidence in the prospects of the company and its lead pipeline molecule, Xanamem.

The placement calls for the issuance of c 285.7m new shares at A\$0.042 per share, reflecting a 6.7% discount to the last traded price of A\$0.045 per share on 28 January (prior to the reporting of the XanaMIA interim analysis). The placement settled on 6 February. Under the SPP, existing and eligible Actinogen shareholders (holders of record as of 30 January) will receive share purchase rights to purchase one new common share at a similar purchase price of A\$0.042 per share, resulting in the issuance of up to 119.05m new shares (A\$5.0m). In total, the combination of the placement and the SPP, if fully subscribed, would lead to the issuance of 404.8m new shares, or A\$17.0m (before issuance costs), resulting in a 12.7% increase in shares outstanding (to 3.597bn).

The closing date of the SPP offer is 24 February and the new SPP shares are expected to be issued in early March. We note that c 15.9m shares (c A\$667,000) from the share placement (c 5.6% of the placement) allotted to Actinogen's CEO and other directors will require shareholder approval at an upcoming extraordinary general meeting planned for 18 March 2026, prior to final issuance. Given that Actinogen shares are currently at the SPP issue price of A\$0.042 per share, our model assumes that the A\$5m SPP will be fully subscribed in H226 (H1 CY26), resulting in the full A\$17m in gross proceeds.

## Proceeds largely directed towards completion of the XanaMIA study

The proceeds are primarily being directed towards continuation and completion of the ongoing 36-week XanaMIA Phase IIb/III study assessing Xanamem in patients with biomarker-positive AD (as determined through elevated levels of pTau-181 biomarker at baseline). Actinogen estimates that c A\$9.6m from the fund-raise will be directed towards the trial, with c A\$3.4m directed towards the open-label extension and the remainder towards working capital, R&D and manufacturing activities, and costs of the offer.

### Exhibit 5: Planned use of funds from February 2026 financing

Sources & uses of funds <sup>1</sup>		
Sources of funds	\$m	
Placement & SPP	17.0	
<b>Total sources of funds</b>	<b>17.0</b>	
Uses of funds	\$m	
XanaMIA Phase 2b/3 Alzheimer's trial	9.6	
XanaMIA open label extension	3.4	
Other R&D and manufacturing	0.9	
Working capital and costs of the offer	3.1	
<b>Total uses of funds</b>	<b>17.0</b>	
Pro forma cash balance as at 31 December 2025		\$m
<b>Cash balance as at 31 December 2025</b>	<b>6.5</b>	
Placement & SPP <sup>1</sup>	17.0	
FY25 R&D tax incentive receivable	1.9	
R&D loan proceeds <sup>2</sup>	4.3	
<b>Pro forma cash balance as at 31 December 2025</b>	<b>29.7</b>	

- The majority of proceeds raised under the Placement will be used to fund the XanaMIA Phase 2b/3 Alzheimer's trial to completion, which is expected to occur in Q4 2026 with final topline results anticipated in November 2026
- Proceeds will also fund the XanaMIA open label extension, R&D and manufacturing and general working capital
- Combined with additional funding secured via R&D tax incentives and R&D loan proceeds as announced on 27 January 2026, the Placement provides the Company with a strong pro forma cash balance of \$29.7m as at 31 December 2025. This is expected to fund Actinogen beyond the XanaMIA Phase 2b/3 Alzheimer's trial topline results in November 2026

<sup>1</sup> Based on proceeds raised under the Placement and SPP, assuming the SPP is fully subscribed. Proceeds are prior to payment of offer costs.  
<sup>2</sup> Total R&D loan balance outstanding of \$4.3m.

Source: Actinogen presentation, February 2026

The company also provided an update on its pro forma cash position. It included an additional A\$1.9m in anticipated R&D tax incentives (RDTI) from the Australian government relating to its approved Advanced Overseas Finding application for FY25. This amount was in addition to the A\$5.5m it received from the Australian Tax Office (ATO) in October 2025. Actinogen also [announced in January 2026](#) that it had secured a A\$4.3m second tranche from its non-dilutive funding facility (of up to A\$13.8m) from Endpoints Capital (which was first announced [in June 2025](#)). This facility is secured by its upcoming anticipated RDTI payments from the ATO. While Actinogen received A\$3.0m as an initial tranche from the Endpoints Capital facility in June 2025, it repaid that initial loan when it received the A\$5.5m RDTI in October 2025.

The company estimates that, given its A\$6.5m December 2025 gross cash position, the A\$1.9m RDTI receivable (which was subsequently received by the company as a cash rebate [as announced on 11 February](#)), the A\$4.3m tranche from Endpoints Capital and assuming it receives the full A\$17m in proceeds from the placement and SPP, its pro forma cash position (as of end-December) would be A\$29.7m. Considering this cash position, Actinogen expects its funds on hand to last into mid-CY27, past the completion of the XanaMIA study.

## Financials

Actinogen recently reported its [Appendix 4C statement](#) reflecting operating results for the three and six months ending 31 December 2025. The company reported a six-month operating burn rate of A\$12.6m, excluding the A\$5.4m RDTI payment received in October 2025 (the net operating burn rate including this payment would have been A\$7.2m). The largest driver of the burn rate is the company's R&D expenditure, which is primarily driven towards ongoing progression of the XanaMIA study and came in at A\$9.4m. Annualised R&D spending run-rates were higher than the A\$12.3m level reported in FY25, which is understandable and expected given the increased total number of XanaMIA subjects being actively dosed and monitored during the period (as the study's enrolment continued to increase in the period, up until December).

As stated earlier, the company received a A\$5.5m RDTI payment from the ATO in October, and used A\$3.1m of the proceeds to pay down its debt to Endpoints Capital (and as stated above, in January 2026 it took a A\$4.3m loan from the Endpoints Capital facility). Given the pro forma (31 December) gross cash position of A\$29.7m described above, we estimate the company's pro forma net cash position at A\$25.4m. We estimate that this cash position will be sufficient to fund the company's operations into mid-CY27, which is past the conclusion of the XanaMIA study (expected in or around November 2026). This added cash cushion provides the company with optionality and operating flexibility to secure a global licensing deal for Xanamem should the results from the XanaMIA study be positive.

Given the 4C statement and the related details on expenditure rates over H126 (H2 of CY25), and the company's added clarity for its second Phase III program in AD (notably, a study size of c 700 patients and estimated cost of US\$100k per patient), we have adjusted our FY26 and FY27 estimates. We have adjusted the timing for the realisation of our full FY26 R&D tax credit revenue projection of A\$11.0m (unchanged vs prior forecast), to better reflect the A\$5.5m received in October 2025 and the additional A\$1.9m received in February 2026. We now expect that the remainder of the FY26-recognised tax credit revenue (c A\$3.6m) will be received in FY27. We expect an FY26 free cash outflow of A\$19.6m, versus A\$17.4m previously.

However, our adjustments are more pronounced for FY27. In particular, we have reduced our R&D total cost estimates for the second Phase III study, given that the study size of c 700 patients is lower than our prior estimate of c 1,000 patients. We now estimate that the second Phase III study will cost US\$75m (down from our prior estimate of US\$105m) and that it will be completed in CY29.

As this study is scheduled to start in early CY27 (assuming positive XanaMIA results), we have reduced our FY27 R&D expense estimate to A\$28.6m, from A\$60.6m previously, given that we believe it will take several months to ramp up enrolment. Hence, the costs towards the beginning of the study will be lower. As a result, we now estimate that the company's FY27 free cash outflow will be A\$37.6m, down from A\$64.5m previously. We expect FY28 R&D costs to be c US\$30m as the second Phase III study will be well underway by then (and as we anticipate top-line data in CY29).

### Exhibit 6: Changes to Actinogen forecasts

A\$m	FY26e (prior)	FY26e (new)	Difference (%)	FY27e (prior)	FY27e (new)	Difference (%)
R&D tax credits, grants and related revenue	11.0	11.0	(0.0)	22.0	10.4	(52.9)
Net R&D expenditures	21.2	20.0	(5.7)	60.6	28.6	(52.9)
EBITDA	(17.0)	(16.4)	(3.5)	(54.8)	(34.5)	(37.0)
Net cash flows from operations	(16.6)	(19.4)	16.5	(63.4)	(36.9)	(41.9)
Free cash flow	(17.4)	(19.6)	12.7	(64.5)	(37.6)	(41.6)

Source: Edison Investment Research

We expect the company's gross cash position (pro forma A\$29.7m) to be sufficient to fund the company's operations into mid-CY27 (end-FY27). With the XanaMIA top-line readout scheduled for November, this extended cash runway provides the company with greater flexibility to negotiate a potentially transformative licensing deal following the conclusion of XanaMIA should the top-line efficacy results be favourable. We also note that there remains the possibility for targeted regional licensing transactions over the next six to nine months ahead of the XanaMIA readout, which would depend on market conditions and strategic considerations for potential suitors or licensors. Altogether, the positive interim analysis provides the company with additional flexibility to assess potential deals both before and after the XanaMIA top-line

readout, although we believe the attainment of a global comprehensive deal after the study's conclusion remains the most likely outcome.

Our model continues to assume that Actinogen will also start a Phase IIb/III study for Xanamem in major depressive disorder (MDD) in CY27, although AD remains the company's priority and we do not expect material further clinical development in MDD until the XanaMIA study is completed (and the second Phase III AD study has commenced). Our cash utilisation estimates for FY27 and beyond would be reduced if the company postpones further clinical development in MDD. We also continue to project that Actinogen will receive R&D research tax credits (which correspond to up to 48.5% of R&D and related costs incurred in the prior fiscal year) from the Australian government.

Given that the second Phase III AD study is expected to start in H1 CY27 and that we expect the primary efficacy endpoint to be measured at least 52 weeks from baseline (vs 36 weeks for XanaMIA), we have pushed back our potential commercialisation timeline for Xanamem in AD to CY30 (from CY29 previously). We maintain our timing forecasts for a potential launch in CY29 for Xanamem in the MDD indication, but plan to revise our assumption as the company provides further guidance on development in this indication.

As our base-case scenario does not assume a commercial out-licensing partnership for Xanamem, our model continues to project that Actinogen will independently fund Xanamem towards approval and commercialisation. However, given that we model completion of the full A\$17m capital raise and, more importantly, that we have reduced our estimated total cost for the second Phase III AD study, we now estimate the total projected additional future funding needed to launch Xanamem in AD and MDD and obtain recurring operating profitability will be A\$225m (vs A\$285m previously).

## Valuation

Our valuation continues to be based on an rNPV analysis, which includes A\$25.4m in pro forma net cash at end-December 2025. We apply a discount rate of 12.5% and include Xanamem in the two lead indications. Given the positive interim XanaMIA results, which surpassed predefined futility thresholds and excluded any severe safety concerns, we believe it is appropriate to raise our PoS estimate for the AD indication to 12.5% (from 10.0% previously), which continues to reflect the very high hurdle rate for therapeutic drug candidates to generate clinical efficacy in this indication. We continue to use a PoS of 12.5% in the MDD indication. In addition to the new PoS factor in AD, we have rolled forward our estimates, mildly pushed back the AD launch timeline to CY30 (as stated above) and adjusted for forex (we now assume a rate of US\$0.70/A\$ vs US\$0.66/A\$ previously). Given these changes and a 12.7% increase in shares outstanding assuming full completion of the A\$17m offering and SPP, we obtain a total equity valuation of A\$778.3m (vs A\$720.2m previously) or A\$0.22 per share (down from A\$0.23 previously given the increased shares outstanding).

### Exhibit 7: Actinogen rNPV valuation

Product	Market	Launch	Sales (A\$m) in 2035	NPV (A\$m)	Probability of success	rNPV (\$Am)	rNPV/basic share (A\$)
Xanamem in cognitive impairment related to Alzheimer's disease	US	CY30	3,771	3,614.8	12.5%	419.6	0.12
Xanamem in cognitive impairment related to Alzheimer's disease	EU5 & Australia	CY30	1,785	1,723.0	12.5%	215.4	0.06
Xanamem in major depressive disorder	US	CY29	1,309	1,056.8	12.5%	116.4	0.03
Xanamem in major depressive disorder	EU5 & Australia	CY29	764	639.6	12.5%	80.0	0.02
Corporate costs				(78.5)	100.0%	(78.5)	(0.02)
Pro forma net cash at 31 Dec 2025				25.4		25.4	0.01
<b>Total equity value</b>				<b>6,981.3</b>		<b>778.3</b>	<b>0.22</b>

Source: Edison Investment Research

We highlight that the appreciation of the Australian dollar (against the US dollar) had a measurable effect on our valuation. Had the exchange rate remained at US\$0.66/A\$, our valuation would have been A\$828.7m or A\$0.23/share.

The top-line efficacy readout, slated for November 2026, will be the most defining catalyst for the company in at least the past seven years. The initial XanADu Phase II AD study readout in May 2019 is the closest comparable situation, although we would argue that the XanaMIA readout is more impactful given the pivotal nature of the study and the refinement of this study's entry criteria (by focusing on patients with biomarker-positive AD). A positive XanaMIA efficacy outcome could result in a sharp upward revision in our PoS estimate to over 40%. Below we provide a sensitivity analysis of how our valuation would be affected by different PoS estimates as well as different gross US annual treatment price projections (our US\$7,500 yearly price estimate may be conservative given the pricing for disease-

modifying anti-amyloid drugs like Leqembi and Kisunla). We highlight that an increase in PoS to 45% would raise the rNPV per share valuation to A\$0.68.

**Exhibit 8: rNPV per share (A\$) sensitivity to probability of success and gross US annual treatment price (US\$)**

	10.0%	12.5%	20.0%	32.5%	45.0%
4,500	0.09	0.11	0.17	0.27	0.37
6,000	0.14	0.17	0.25	0.39	0.52
7,500	0.18	<b>0.22</b>	0.32	0.50	0.68
9,000	0.22	0.27	0.40	0.61	0.83
10,500	0.27	0.32	0.47	0.72	0.98

Source: Edison Investment Research

We recognise, of course, that XanaMIA has the potential for broad adoption given its convenient once-daily dosage form, its excellent safety record to date (notably a lack of associated risk of amyloid-related imaging abnormalities with edema/effusion, as seen in anti-amyloid therapies) and the possibility for it to be used in combination with other AD drugs.

As stated above, we forecast A\$225m in additional financing will be required before FY29 to fund Actinogen's activities and the development of both the MDD and AD programmes, after which, provided it receives regulatory approval, Actinogen should be able to generate sufficient operating revenues to reach recurring profitability. Our model assumes all financing will be raised through illustrative debt, as per the usual Edison methodology. If our projected funding need of A\$225m is raised through equity issuances at the prevailing market price of c A\$0.042, our effective valuation would decrease to c A\$0.11 per share.

The amount of fund-raising estimated to be needed for Actinogen to independently bring Xanamem to commercialisation in these indications remains larger than the company's current market capitalisation. However, we note that the funding intervals may be staggered over several years, which may alleviate potential challenges associated with raising such funds. We believe Actinogen will seek non-dilutive funding arrangements and/or partnership arrangements, which may reduce the overall funding need, but such scenarios are not included in our forecasts. While our base-case scenario assumes internal Xanamem development for the AD and MDD programmes, if the company is successful in securing a licensing deal (or deals) for Xanamem with an established biopharma company (or companies), our R&D expenditure requirements for Actinogen and, consequently, our overall funding need projections would likely be substantially reduced. In addition, should the company exclusively prioritise the AD programme and avoid additional R&D spending on the MDD indication, our projected funding requirement would be reduced by over A\$65m.



**Exhibit 9: Financial summary**

	A\$(000)	2021	2022	2023	2024	2025	2026e	2027e
Year end 30 June		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>								
Revenue		1,984	3,640	4,888	9,932	5,490	11,008	10,393
Cost of Sales		0	0	0	0	0	0	0
Gross Profit		1,984	3,640	4,888	9,932	5,490	11,008	10,393
Sales, General & Administrative		(3,111)	(4,558)	(6,568)	(7,235)	(8,125)	(7,404)	(16,346)
Net Research & Development		(2,406)	(8,215)	(8,900)	(15,535)	(12,297)	(20,000)	(28,571)
EBITDA		(3,533)	(9,133)	(10,580)	(12,839)	(14,932)	(16,396)	(34,524)
Amortisation of intangible assets		(313)	(313)	(313)	(314)	(314)	(314)	(314)
Depreciation & other		(74)	(88)	(93)	(103)	(109)	(118)	(131)
Normalised Operating Profit (ex. amort, SBC, except.)		(3,318)	(7,933)	(9,156)	(11,635)	(13,377)	(16,514)	(34,656)
Operating profit before exceptionals		(3,631)	(8,245)	(9,469)	(11,948)	(13,691)	(16,828)	(34,969)
Exceptionals including asset impairment		0	0	0	0	0	0	0
Stock-based compensation & other		(289)	(1,288)	(1,517)	(1,307)	(1,664)	0	0
Reported Operating Profit		(3,920)	(9,533)	(10,985)	(13,256)	(15,354)	(16,828)	(34,969)
Net Finance income (costs)		5	36	233	212	622	666	(3,071)
Profit Before Tax (norm)		(3,313)	(7,897)	(8,923)	(11,423)	(12,755)	(15,848)	(37,727)
Profit Before Tax (FRS 3)		(3,915)	(9,497)	(10,752)	(13,044)	(14,732)	(16,162)	(38,040)
Tax		0	0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(3,313)	(7,897)	(8,923)	(11,423)	(12,755)	(15,848)	(37,727)
Profit After Tax and minority interests (FRS 3)		(3,915)	(9,497)	(10,752)	(13,044)	(14,732)	(16,162)	(38,040)
Average Basic Number of Shares Outstanding (m)		1,405.2	1,717.1	1,801.5	2,174.3	2,951.7	3,394.1	3,596.5
EPS - normalised (A\$)		(0.002)	(0.005)	(0.005)	(0.005)	(0.004)	(0.005)	(0.010)
EPS - normalised and fully diluted (A\$)		(0.002)	(0.005)	(0.005)	(0.005)	(0.004)	(0.005)	(0.010)
EPS - (IFRS) (A\$)		(0.003)	(0.006)	(0.006)	(0.006)	(0.005)	(0.005)	(0.011)
Dividend per share (A\$)		0	0	0	0	0	0	0
<b>BALANCE SHEET</b>								
Fixed Assets		3,287	2,889	2,520	2,436	2,051	1,879	2,194
Intangible Assets		3,033	2,720	2,408	2,094	1,781	1,668	1,854
Tangible Assets		17	13	113	341	270	211	340
Investments in long-term financial assets		237	156	0	0	0	0	0
Current Assets		15,091	20,417	12,688	18,876	22,430	24,412	16,057
Short-term investments		0	0	0	0	0	0	0
Cash		13,457	16,370	8,460	9,451	16,504	14,842	7,218
Other		1,634	4,047	4,228	9,426	5,926	9,570	8,839
Current Liabilities		(755)	(1,480)	(1,802)	(1,357)	(5,959)	(2,953)	(2,953)
Creditors		(755)	(1,480)	(1,802)	(1,357)	(2,953)	(2,953)	(2,953)
Short-term borrowings		0	0	0	0	(3,006)	0	0
Long-Term Liabilities		(165)	(87)	0	(258)	(187)	(4,344)	(34,344)
Long-term borrowings		0	0	0	0	0	(4,157)	(34,157)
Other long-term liabilities		(165)	(87)	0	(258)	(187)	(187)	(187)
Net Assets		17,458	21,740	13,407	19,696	18,336	18,994	(19,046)
<b>CASH FLOW STATEMENT</b>								
Operating Income		(3,920)	(9,533)	(10,985)	(13,256)	(15,354)	(16,828)	(34,969)
Movements in working capital		(1,513)	(3,143)	132	(5,577)	5,047	(3,644)	731
Net interest and financing income (expense)		5	36	233	212	622	666	(3,071)
Depreciation & other		74	88	93	103	109	118	131
Taxes and other adjustments		3,630	3,035	1,829	1,567	2,021	314	314
Net Cash Flows from Operations		(1,724)	(9,517)	(8,698)	(16,951)	(7,556)	(19,375)	(36,864)
Capex		(6)	(3)	(37)	(8)	(38)	(259)	(760)
Acquisitions/disposals		0	0	0	0	0	0	0
Interest received & other investing activities		0	0	(0)	0	0	0	0
Net Cash flows from Investing activities		(6)	(3)	(37)	(8)	(38)	(259)	(760)
Net proceeds from share issuances		10,195	12,491	903	18,041	11,708	16,820	0
Net movements in long-term debt		0	0	0	0	0	1,151	30,000
Dividends		0	0	0	0	0	0	0
Other financing activities		(84)	(71)	(78)	(92)	2,939	0	0
Net Cash flows from financing activities		10,111	12,420	825	17,950	14,647	17,971	30,000
Effects of FX on Cash & equivalents		0	49	0	0	0	0	0
Net Increase (Decrease) in Cash & equivalents		8,381	2,949	(7,910)	991	7,053	(1,663)	(7,624)
Cash & equivalents at beginning of period		5,040	13,422	16,370	8,460	9,451	16,504	14,842
Cash & equivalents at end of period		13,422	16,370	8,460	9,451	16,504	14,842	7,218
Closing net debt/(cash)		(13,694)	(16,527)	(8,460)	(9,451)	(13,498)	(10,685)	26,939
Lease debt		236	165	87	258	258	258	258
Closing net debt/(cash) inclusive of IFRS 16 lease debt		(13,458)	(16,361)	(8,373)	(9,192)	(13,240)	(10,426)	27,198
Free cash flow		(1,730)	(9,520)	(8,735)	(16,959)	(7,594)	(19,634)	(37,624)

Source: Actinogen accounts, Edison Investment Research

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