

Actinogen Medical

FY25 update

An eventful period ahead for Xanamem

Healthcare

Actinogen's FY25 results highlighted the company's progress in advancing its lead candidate, Xanamem, through its pivotal XanaMIA Phase IIb/III study in patients with biomarker-positive Alzheimer's disease (AD). With the recruitment of the 100th patient in the study on 30 June, Actinogen remains on track to report a pre-planned interim efficacy (futility) analysis in early Q126. We expect a successful outcome would strengthen confidence in the AD programme. Financial results were in line with expectations and Actinogen reiterated that it remains funded into mid-late CY26. Our valuation is largely unchanged, at A\$720.2m, or A\$0.23/share.

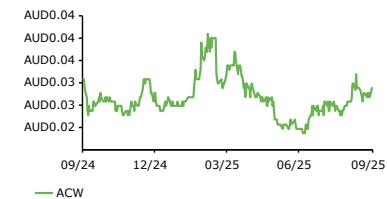
| Year end | Revenue (AUDm) | PBT (AUDm) | EPS (AUc) | DPS (AUc) | P/E (x) | Yield (%) |
|----------|----------------|------------|-----------|-----------|---------|-----------|
| 6/24 | 9.9 | (11.4) | (0.53) | 0.00 | N/A | N/A |
| 6/25 | 5.5 | (12.8) | (0.43) | 0.00 | N/A | N/A |
| 6/26e | 11.0 | (17.2) | (0.53) | 0.00 | N/A | N/A |
| 6/27e | 22.0 | (62.5) | (1.94) | 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.

16 September 2025

| | |
|--------------------------|-----------------|
| Price | AUD0.027 |
| Market cap | AUD86m |
| Net cash at 30 June 2025 | AUD13.5m |
| Shares in issue | 3,175.5m |
| Free float | 56.0% |
| Code | ACW |
| Primary exchange | ASX |
| Secondary exchange | N/A |

Share price performance



Top-line XanaMIA data anticipated in Q4 CY26

The XanaMIA interim analysis is a key catalyst as it will be the first major clinical readout for Xanamem in AD since the subset analysis from the XanADu study first reported in Q422. If this interim analysis supports the continuation of the trial, which we believe is likely given the XanADu subset data, investor and industry confidence in the programme may get a boost. The next critical milestone would then be the study's primary efficacy readout, expected in Q4 CY26.

Positive FDA meeting clarifies AD pathway

Following a successful Type C Meeting with the FDA, Actinogen reached a common understanding with the agency on the development pathway towards a potential future regulatory approval for Xanamem in AD. Importantly, the FDA agreed that if XanaMIA results are positive, only one additional pivotal clinical study will be required for commercialisation. The agreements reached with the FDA help solidify the company's position as it seeks to engage with potential partners.

Valuation: Essentially unchanged at A\$0.23/share

Actinogen's FY25 free cash outflow came in at A\$7.6m, slightly better than our A\$7.7m outflow estimate. We expect the company's FY26 cash burn rate to remain mostly consistent, and that its end-June cash on hand (A\$16.5m) should be sufficient for it to maintain operations to mid- to late CY26. Our risk-adjusted net present value (rNPV) valuation continues to use a probability of success (PoS) of 10% for Xanamem to reach the market in the AD indication and a PoS of 12.5% in the major depressive disorder (MDD) indication. Following minor model revisions, our total equity valuation adjusts very slightly to A\$720.2m (versus A\$724.6m previously), or A\$0.23 per share (unchanged).

| | 1m | 3m | 12m |
|------------------|--------|--------|--------|
| Abs | 17.4 | 22.7 | (30.8) |
| 52-week high/low | AUc4.2 | AUc1.9 | |

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

| | |
|---|---------|
| Completion of enrolment for Phase IIb/III XanaMIA study in AD | Q1 CY26 |
| Interim results for XanaMIA study | Q1 CY26 |

Analysts

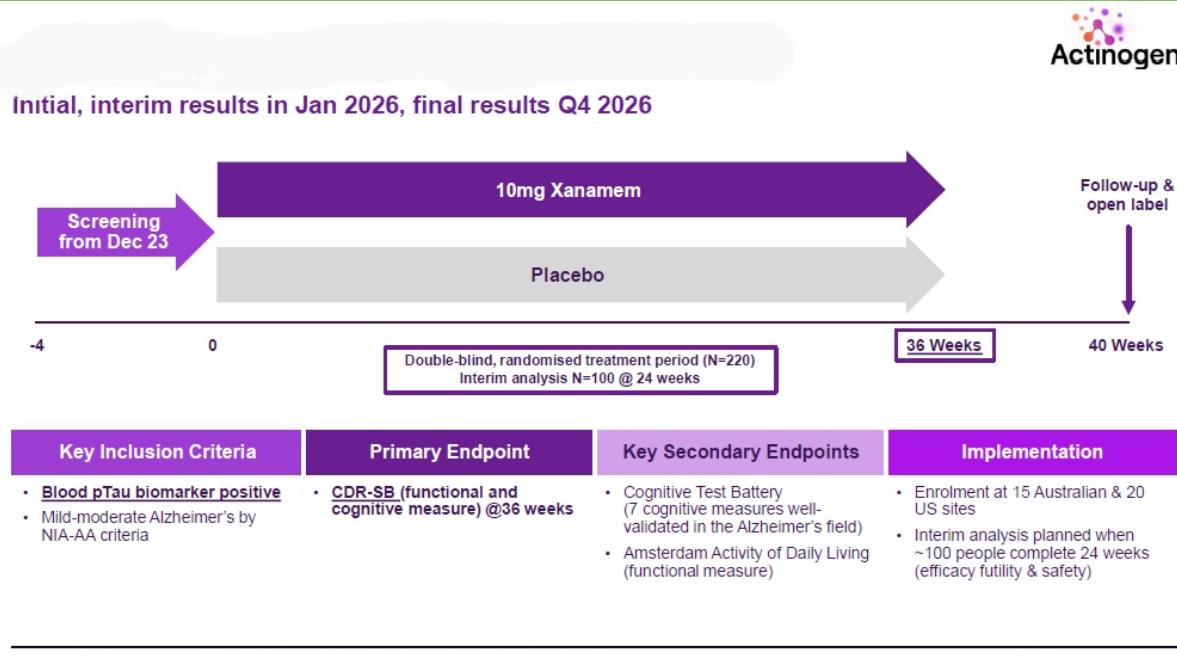
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Wrapping up a year of Xanamem progress

Actinogen's [FY25 results announcement](#) highlighted a period of progress for the company and its lead product candidate, Xanamem (emestedastat), with the company [recently](#) surpassing the milestone of recruiting its 100th patient for its [36-week XanaMIA Phase IIb/III study](#) of Xanamem in patients with biomarker-positive AD (as determined through elevated levels of [phosphorylated Tau-181](#), or pTau-181, at baseline). The XanaMIA study in AD is the company's lead development programme, and it is designed to enrol c 220 mild-to-moderate AD patients (with elevated blood levels of pTau-181 at baseline), predominantly across sites in the US and Australia. Study patients are randomised to take Xanamem 10mg or placebo once daily for 36 weeks.

Exhibit 1: XanaMIA Phase IIb/III study overview



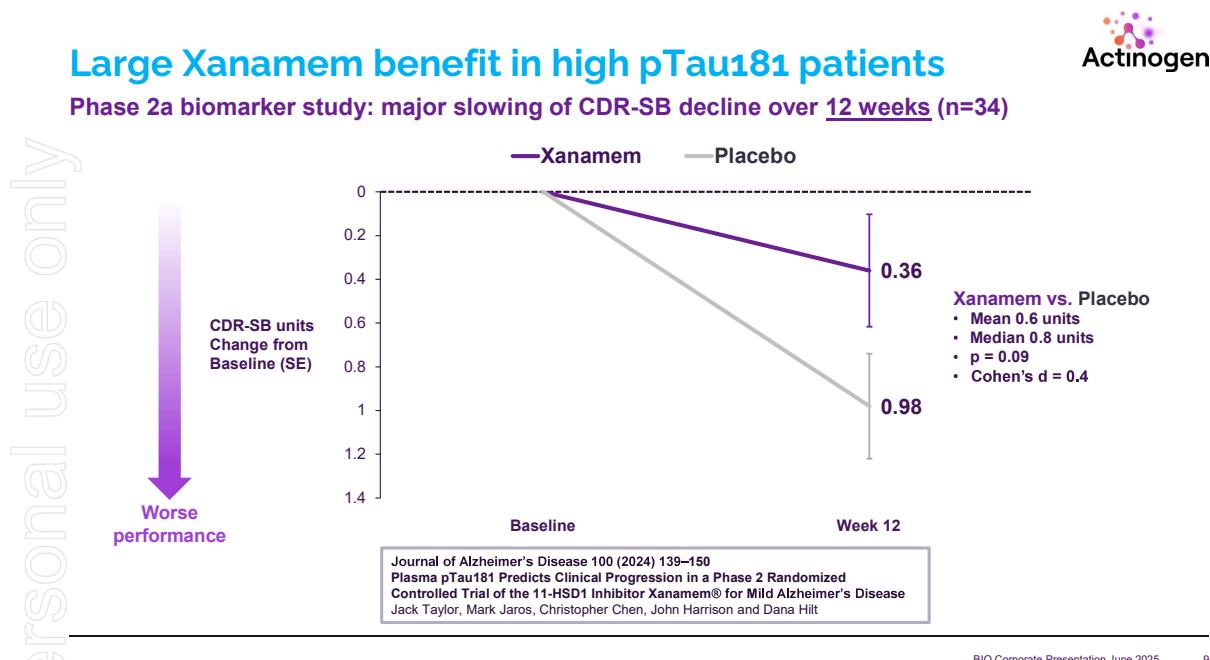
NIA-AA=National Institute of Aging - Alzheimer's Association; CDR-SB Clinical Dementia Rating Scale – Sum of Boxes

Bioshares Q&A August 7, 2025

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Source: Actinogen presentation, August 2025. Note: NIA-AA, National Institute of Aging; 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. As discussed in [our prior note](#), 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 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 2: XanADu study results in high pTau-181 patients


Source: Actinogen presentation, June 2025

Other notable FY25 highlights include the [completion](#) of the [XanaCIDD Phase IIa study](#) in MDD and the company holding a [Type C meeting](#) with the US FDA to clarify the steps needed and study endpoints required for future MDD studies in order to seek marketing approval in depression.

The company reported that it had reached a common understanding with the FDA in terms of what additional clinical trials, clinical pharmacology and non-clinical study data are required to potentially file for marketing approval for Xanamem in MDD. The company plans to use the agreements reached with the FDA in discussions with potential partners and granting agencies.

We expect the company to focus its R&D efforts on the development of Xanamem for AD, as it does not intend to independently fund or start future Xanamem studies in depression (prior to the conclusion of the XanaMIA study), although it continues to explore grants or other non-dilutive forms of capital to help fund the next depression study.

FDA Type C meeting on AD programme confirms the way forward

Actinogen [in September reported](#) that, following a successful Type C meeting with the Neurology-I division of the FDA, it reached agreement from the agency on the pathway towards a 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. Importantly, 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. The additional pivotal trial will, like XanaMIA, be a well-controlled two-arm study assessing 10mg Xanamem versus placebo. The non-clinical studies requested by the FDA are intended to further assess the metabolism and excretion pathways of the drug. Actinogen also received clarification and a common understanding on manufacturing considerations (such as the regulatory starting materials in drug substance synthesis).

Altogether, the information and agreements received from the FDA provide clarity on the regulatory steps needed for approval, which could solidify and support the company's position as it engages with potential development and marketing partners. Further, Actinogen expects to engage in a similar regulatory meeting with the European Medicines Agency (EMA) in CY26, and subsequently with other regulators including the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

Next key clinical milestone: Interim (futility) analysis in Q1 CY26

The company is on track to report a pre-planned interim efficacy (futility) analysis in early Q126, as this assessment

will begin once the 100th study participant reaches 24 weeks of treatment. With the enrolment of the 100th patient now complete, the 24-week visit 'trigger' to commence the interim data analysis will occur in late December 2025, with the resulting review from the trial's independent data monitoring committee (DMC) expected to occur in January 2026. The XanaMIA interim analysis is a key catalyst for Actinogen as it will be the first major clinical readout for Xanamem in AD since the subset analysis from the XanADu study first reported in Q422.

The DMC is expected to review all unblinded interim safety and efficacy data from all available participant visits (in both the treatment and placebo arms) up until that point (including many subjects who would have completed the full 36-week treatment period) and perform the required statistical and data analyses. The DMC will make a recommendation on whether the study should be permitted to continue as planned, and without disclosing details of its data review. The DMC will not comment on any possible positive signals of efficacy, as its pre-specified futility analysis is limited to determining whether the study should be terminated early in the event either:

- of the identification of major safety concerns (which we believe is highly unlikely given that more than 400 patients have already treated with the drug across multiple trials), or
- it is determined that the likelihood of the study meeting the primary efficacy endpoint is near nil (ie if 'futility' criteria are met).

Subsequently, the results of the interim (futility) analysis will be reported by the company. If, as we anticipate is highly probable (given the positive signals from the XanADU subset analysis), the interim results surpass the futility thresholds, investors and market participants may react favourably to this critical test milestone.

Pharmacokinetics data supportive of new tablet formulation

Actinogen [recently completed](#) a pharmacokinetics (PK) study that confirmed that the new tablet formulation (also currently employed in the XanaMIA study) of Xanamem, when taken both with and without food, demonstrates the expected blood plasma levels of drug exposure or PK, and is comparable with the PK data from prior human studies of the drug (including the XanADU study, XanaCIDD, [XanaHES](#) and [XanaMIA-DR](#) study in healthy subjects). This supports the company's current plan to use the 10mg once-daily dose as the targeted therapeutic dose in the AD and MDD indications.

The PK study involving 16 healthy individuals was conducted at the CMAX Clinical Research centre in Adelaide. The subjects were assessed on two occasions, one week apart. Each subject received a 10mg tablet of Xanamem, once while fasting and once after a high fat meal. Blood levels of Xanamem were then measured repeatedly over the subsequent 48 hours.

Key PK results include the median time to maximum blood concentration of four to six hours (four hours fasted, six hours after a high fat meal), and very similar Xanamem drug exposures (area under the concentration-time curves) and elimination half-lives of 15 hours in both the fasted and fed scenarios. The comparability of the drug exposures for both the fasting and fed arms suggest that in a commercial setting, Xanamem should provide full flexibility for patient dosing (meaning that the patient would likely have the option to choose to take the drug either with or without food).

This new tablet formulation is expected to be the dosage form that the company commercialises and brings to market. Actinogen reported that in FY25 its contract manufacturer, Asymchem, completed production of a 15kg scale-up batch of drug substance, which will be manufactured in the US into Xanamem tablets for use in current and future trials. Completion of the manufacturing batch also indicates that the company is ready or future commercial-scale production, should Xanamem obtain regulatory approval.

Recap of recent developments in the AD treatment space

One of Xanamem's commercial advantages, given its convenient once-daily oral-dosing form and its attractive safety profile to date, is that if approved it can potentially be used in combination with other AD treatments. That said, its overall commercial competitiveness will still depend on how its efficacy compares with other AD treatments that may be on the market. To that end, below we highlight some recent events in the AD drug treatment space.

The most recent FDA drug approvals in AD have been Biogen/Eisai's Leqembi (lecanemab) (in January 2023) and Eli Lilly's Kisunla (donanemab) (in July 2024); both are anti-amyloid drugs requiring systemic administration. While [initial expectations](#) for such anti-amyloid drugs were in the multibillion dollar range, sales trends since launch have been more modest but are now growing at a strong clip, with Leqembi reporting sales of JPY23.1bn (c US\$157m) in [Q2 CY25](#), up 369% y-o-y, including JPY7.7bn in China (much of this was due to a one-time stockpiling effect due to tariff risks)

and JPY9.1bn in the Americas (up 98% y-o-y). Kisunla's [Q225 sales](#) reached \$49m (vs \$21m in Q125). Leqembi sales may receive a longer-term boost with the FDA [approving in August 2025](#) a sub-cutaneous autoinjector form of the drug for maintenance dosing. Currently, both Leqembi and Kisunla must be administered via repeated intravenous infusion (typically once every four weeks) at a healthcare facility. This new approval will allow a once-weekly at-home injection option to patients who have taken Leqembi for 18 months and thereby potentially eliminates the need for such patients to continue to regularly visit an infusion centre for treatment.

Roche in July announced [an update](#) on its development plans for its proprietary anti-amyloid development bispecific antibody candidate, trontinemab. Trontinemab is differentiated from existing approved anti-amyloid drugs in that it is based on Roche's proprietary Brainshuttle technology, which combines an amyloid beta-binding antibody with a transferring receptor (TfR1) shuttle module. The TfR1 shuttle molecule is designed to facilitate enhanced access of the drug past the blood-brain barrier (BBB) to enable high central nervous system (CNS) drug exposure at relatively low doses, with the aim of delivering effective and rapid amyloid clearance with potentially a lower risk of Amyloid-related imaging abnormalities-edema/effusion (ARIA-E). Results from the ongoing [Phase Ib/IIa Brainshuttle AD study](#) showed that in the 3.6mg/kg cohort, trontinemab reduced amyloid levels below the 24 centiloid positivity threshold in 91% of participants (n=49/54) after 28 weeks of treatment, and the company also reported early and significant reductions in fluid AD biomarkers including total tau and pTau-181. ARIA-E was only observed in <5% of participants (n=149 across both dose cohorts). Roche plans to start two Phase III studies (TRONTIER 1 and TRONTIER 2) in H225, which will use Roche's Elecsys pTau217 companion blood-based biomarker diagnostic test.

One key data point expected in H2 CY25 will be the top-line 104-week data from both of Novo Nordisk's ongoing Phase III studies ([EVOKE](#) and [EVOKE PLUS](#)) assessing oral semaglutide versus placebo in patients with early AD. Each of the two placebo-controlled studies have [enrolled c 1,840 patients](#) (total n=3,680) and will assess the CDR-SB score from baseline to 104 weeks as the primary endpoint. Novo Nordisk reports that its Phase III programme for semaglutide was supported by four [real-world evidence trials](#) that have suggested materially lower risks or odds of dementia in patients with GLP-1 drug exposure. One of the suggested mechanisms why GLP-1 drugs such as semaglutide may be protective in AD is that they [may improve glucose metabolism](#) in brain cells as well as reduce oxidative stress and inflammation. GLP-1 drugs have an established record of safety and their oral dosage form, like Xanamem, provides key differentiation versus the anti-amyloid drugs on the market that require more invasive intravenous administration (or injection after 18 months in the case of Leqembi).

We also note that Johnson & Johnson (JNJ) continues to advance two Phase II AD programmes, both with [FDA Fast Track Designations](#), and both targeting the formation of disease-associated [tau proteins](#). JNJ has completed enrolment (n=523) of its [Phase IIb Autonomy study](#) assessing posdinemab, its monoclonal antibody candidate directed against tau protein, in patients with AD, and it expects to report top line primary efficacy data (the change from baseline in Integrated Alzheimer's Disease Rating Scale (iADRS) Total Score at Week 104) in H1 CY26. The [Phase IIb Retain study](#) is ongoing and assessing JNJ's anti-Tau active immunotherapy candidate, JNJ-2056 (in-licensed from AC Immune), in up to 500 patients with preclinical (pre-symptomatic) AD. This immunotherapy candidate is designed to prime the immune system to target tau protein and patients will receive up to nine injections for the first three years of the study. A readout for this trial may not occur until after 2030.

A relatively less encouraging development in the AD space is that Alzheon's Phase III APOLLOE4 study for oral valitramiprosate/ALZ-801 in patients with early AD [did not meet the primary endpoint](#).

Financials

Actinogen's FY25 results were largely in line with [our prior estimates](#), with free cash outflow of A\$7.6m, slightly better than our A\$7.7m estimate. Revenue of A\$5.5m consists essentially of R&D tax incentives (RDTI) expected to be provided by the Australian government as a reimbursement for the company's R&D activities and spending. Under the Australian government's RDTI programme, Actinogen is eligible to receive cash rebates corresponding to up to 48.5% of its R&D and related costs.

The reported revenue of A\$5.5m was below our A\$7.1m estimate, but most of this difference is explained by the company not having recorded an additional A\$1.88m of additional potential RDTI in FY25, as this amount remains subject to an [Advance Overseas Finding \(AOF\)](#) approval by the Australian Tax Office. The company expects to receive an AOF decision in H126 (H2 CY25). Actinogen expects to receive a cash rebate from the Australian government for its FY25 RDTI, which could be up to A\$7.4m if the AOF application is approved, in Q4 CY25 (Q226). We note in Q225 (Q4 CY24), Actinogen received a A\$9.0m RDTI payment from the Australian government (for R&D activities conducted in FY24); this payment is higher than what is expected in Q4 CY25 because the company had higher R&D spending (A

\$15.5m) in FY24 than in FY25, largely due to the XanaCIDD study in MDD (which was completed in mid-CY24).

Reported R&D spending of A\$12.3m came in mildly below our A\$12.9m estimate, but this effect was offset by SG&A expenses of A\$8.1m exceeding our A\$6.8m estimate. Given these effects and the lower than anticipated reported revenue, the normalised operating loss came in at A\$13.4m, higher than our A\$12.0m estimate.

R&D advance supports operating runway

Actinogen [entered into a debt facility](#) with Endpoints Capital in June that is secured by its upcoming anticipated RDTI payments from the Australian government. Actinogen received A\$3.0m as an initial tranche from the Endpoints funding facility, and inclusive of these funds, it reported a gross cash position of A\$16.5m at 30 June 2025 (net cash position of A\$13.5m). Actinogen could be entitled to an additional A\$2.9m in funding from Endpoints in Q3 CY25 (Q126), and an additional A\$7.9m in relation to the company's FY26 RDTI. The company expects to repay these loans as the RDTI cash rebates are received from the Australian government (as stated above, we expect the next payment to occur in Q4 CY25). Overall, we expect the advance R&D facility with Endpoints should strengthen the company's liquidity and access to capital into H2 CY26 (FY27).

Minor revisions to FY26 forecasts, spending rate to increase in FY27

As the XanaMIA study has ramped up and enrolment has surpassed the midpoint target, we expect Actinogen's quarterly cash burn rate to stabilise and remain mostly consistent throughout FY26, prior to the study's expected conclusion (in Q4 CY26 or Q227). Actinogen expects its end-June cash on hand (A\$16.5m) to be sufficient to maintain operations to mid-late CY26 (or into FY27), in line with our projections.

Exhibit 3: Changes to Actinogen forecasts

| All amounts in A\$m | FY25e (prior) | FY25 (actual) | Difference (%) | FY26e (prior) | FY26e (new) | Difference (%) | FY27e (new) |
|---|---------------|---------------|----------------|---------------|-------------|----------------|-------------|
| R&D tax credits, grants and related revenue | 7.1 | 5.5 | (22.9) | 11.0 | 11.0 | 0.0 | 22.0 |
| Net R&D expenditures | 12.9 | 12.3 | (4.5) | 21.2 | 21.2 | 0.0 | 60.6 |
| EBITDA | (12.5) | (14.9) | 19.1 | (16.6) | (17.0) | 2.6 | (54.8) |
| Net cash flows from operations | (7.1) | (7.6) | 7.0 | (16.1) | (16.6) | 3.5 | (63.4) |
| Free cash flow | (7.7) | (7.6) | (1.4) | (16.8) | (17.4) | 3.4 | (64.5) |

Source: Edison Investment Research

We continue to estimate net FY26 R&D expenses of A\$21.2m, but we have raised our FY26 SG&A estimate to A\$6.8m (vs A\$6.3m previously), resulting in an FY26 operating cash burn rate estimate of A\$16.6m (vs A\$16.1m previously). As stated above, we estimate that Actinogen has sufficient funds on hand to maintain operations into H127 (H2 CY26), consistent with management's guidance.

We introduce FY27 forecasts, which project a substantial increase in R&D expenditure. As confirmed by the company's recent Type C meeting on the AD programme, Actinogen will need to pursue a single additional Phase III study in AD (after XanaMIA) prior to filing for regulatory approval. Given the size and scope of the typical 'big pharma' Phase III AD studies, which typically enrol well over 1,000 patients, we expect this second Xanamem Phase III AD trial will be significantly larger (in terms of the number of patients recruited) than XanaMIA. We assume that it will start in H1 CY27, and we also expect the company will start a Phase IIb/III study in MDD in H1 CY27.

Our base assumption is for A\$60.6m in FY27 R&D spending, to be spent across the second and much larger Phase III study for Xanamem in AD, as well as a Phase IIb/III study in MDD. In addition, we have increased SG&A forecast to A\$16.2m, given that we expect the company to increase its spending on promotional activities for Xanamem to raise awareness of the product and also as the company ramps up potential out-licensing/partnership discussions following the conclusion of the XanaMIA study.

We 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. We maintain our timing forecasts for a potential launch in CY29 for Xanamem in both the AD and MDD indications.

As our base-case scenario does not assume a commercial out-licensing partnership for Xanamem, our model continues to project the total projected future funding needed to launch Xanamem in AD and MDD and obtain recurring operating profitability will be A\$285m, which includes an anticipated A\$7.8m in FY26 from the Endpoints Capital facility.

Valuation

Our valuation is based on an rNPV analysis, which includes A\$13.5m in net cash at end-June 2025. We apply a discount rate of 12.5% and include Xanamem in the two lead indications. We continue to use a PoS of 10% for Xanamem to reach the market in the AD indication and a PoS of 12.5% in the MDD indication. Following very minor model revisions, we obtain a total equity valuation of A\$720.2m (versus A\$724.6m previously), or A\$0.23 per share (unchanged).

Exhibit 4: Actinogen rNPV valuation

| Product | Market | Launch | Sales (A\$m) in 2034 | NPV (A\$m) | Probability of success | rNPV (\$Am) | rNPV/basic share (A\$) |
|--|-----------------|--------|----------------------|----------------|------------------------|--------------|------------------------|
| Xanamem in cognitive impairment related to Alzheimer's disease | US | CY29 | 3,493 | 3,878.1 | 10.0% | 363.5 | 0.11 |
| Xanamem in cognitive impairment related to Alzheimer's disease | EU5 & Australia | CY29 | 1,653 | 1,860.1 | 10.0% | 186.0 | 0.06 |
| Xanamem in major depressive disorder | US | CY29 | 1,242 | 1,170.7 | 12.5% | 135.1 | 0.04 |
| Xanamem in major depressive disorder | EU5 & Australia | CY29 | 724 | 703.5 | 12.5% | 87.9 | 0.03 |
| Corporate costs | | | | (65.8) | 100.0% | (65.8) | (0.02) |
| Net cash at 30 June 2025 | | | | | 13.5 | 13.5 | 0.00 |
| Total equity value | | | | 7,560.0 | | 720.2 | 0.23 |

Source: Edison Investment Research

As stated above, the most material medium-term catalyst for Actinogen is the interim analysis (in early CY26) of the Phase IIb/III XanaMIA study, which prospectively enrolls patients with elevated pTau-181. Investors will be looking to see whether these data confirm the longer-term safety of Xanamem and whether the interim efficacy data are sufficient to support continuation of the trial to its conclusion. Given the widespread economic and social costs of AD and the limitations of current approved treatments, we anticipate positive interim data could hasten material out-licensing or value-realisation opportunities.

We continue to forecast A\$285m 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\$285m is raised through equity issuances at the prevailing market price of c A\$0.028, our effective valuation would decrease to c A\$0.075 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.

Given that AD registration-enabling trials are reported to [cost more per patient](#) than studies in nearly any other therapeutic area, we expect Actinogen will likely accelerate efforts to attain partnerships or non-dilutive funding strategies for the next pivotal AD study (to start in H127) if the interim XanaMIA Phase IIb data are supportive.

Exhibit 5: Financial summary

| A\$(000) | 2021 | 2022 | 2023 | 2024 | 2025 | 2026e | 2027e |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | IFRS |
| Year end 30 June | | | | | | | |
| PROFIT & LOSS | | | | | | | |
| Revenue | 1,984 | 3,640 | 4,888 | 9,932 | 5,490 | 11,008 | 22,045 |
| Cost of Sales | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gross Profit | 1,984 | 3,640 | 4,888 | 9,932 | 5,490 | 11,008 | 22,045 |
| Sales, General & Administrative | (3,111) | (4,558) | (6,568) | (7,235) | (8,125) | (6,784) | (16,215) |
| Net Research & Development | (2,406) | (8,215) | (8,900) | (15,535) | (12,297) | (21,212) | (60,606) |
| EBITDA | (3,533) | (9,133) | (10,580) | (12,839) | (14,932) | (16,989) | (54,775) |
| Amortisation of intangible assets | (313) | (313) | (313) | (314) | (314) | (314) | (314) |
| Depreciation & other | (74) | (88) | (93) | (103) | (109) | (118) | (173) |
| Normalised Operating Profit (ex. amort, SBC, except.) | (3,318) | (7,933) | (9,156) | (11,635) | (13,377) | (17,107) | (54,949) |
| Operating profit before exceptional | (3,631) | (8,245) | (9,469) | (11,948) | (13,691) | (17,420) | (55,262) |
| 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) | (17,420) | (55,262) |
| Net Finance income (costs) | 5 | 36 | 233 | 212 | 622 | (60) | (7,539) |
| Profit Before Tax (norm) | (3,313) | (7,897) | (8,923) | (11,423) | (12,755) | (17,167) | (62,487) |
| Profit Before Tax (FRS 3) | (3,915) | (9,497) | (10,752) | (13,044) | (14,732) | (17,480) | (62,801) |
| 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) | (17,167) | (62,487) |
| Profit After Tax and minority interests (FRS 3) | (3,915) | (9,497) | (10,752) | (13,044) | (14,732) | (17,480) | (62,801) |
| Average Basic Number of Shares Outstanding (m) | 1,405.2 | 1,717.1 | 1,801.5 | 2,174.3 | 2,967.7 | 3,223.7 | 3,223.7 |
| EPS - normalised (A\$) | (0.002) | (0.005) | (0.005) | (0.005) | (0.004) | (0.005) | (0.019) |
| EPS - normalised and fully diluted (A\$) | (0.002) | (0.005) | (0.005) | (0.005) | (0.004) | (0.005) | (0.019) |
| EPS - (IFRS) (A\$) | (0.003) | (0.006) | (0.006) | (0.006) | (0.005) | (0.005) | (0.019) |
| Dividend per share (A\$) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| BALANCE SHEET | | | | | | | |
| Fixed Assets | 3,287 | 2,889 | 2,520 | 2,436 | 2,051 | 2,404 | 2,968 |
| Intangible Assets | 3,033 | 2,720 | 2,408 | 2,094 | 1,781 | 1,968 | 2,154 |
| Tangible Assets | 17 | 13 | 113 | 341 | 270 | 437 | 814 |
| 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 | 12,390 | 9,025 |
| Short-term investments | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cash | 13,457 | 16,370 | 8,460 | 9,451 | 16,504 | 6,883 | 2,407 |
| Other | 1,634 | 4,047 | 4,228 | 9,426 | 5,926 | 5,507 | 6,618 |
| Current Liabilities | (755) | (1,480) | (1,802) | (1,357) | (5,959) | (5,959) | (5,959) |
| Creditors | (755) | (1,480) | (1,802) | (1,357) | (2,953) | (2,953) | (2,953) |
| Short-term borrowings | 0 | 0 | 0 | 0 | (3,006) | (3,006) | (3,006) |
| Long-Term Liabilities | (165) | (87) | 0 | (258) | (187) | (7,981) | (67,981) |
| Long-term borrowings | 0 | 0 | 0 | 0 | 0 | (7,794) | (67,794) |
| Other long-term liabilities | (165) | (87) | 0 | (258) | (187) | (187) | (187) |
| Net Assets | 17,458 | 21,740 | 13,407 | 19,696 | 18,336 | 856 | (61,945) |
| CASH FLOW STATEMENT | | | | | | | |
| Operating Income | (3,920) | (9,533) | (10,985) | (13,256) | (15,354) | (17,420) | (55,262) |
| Movements in working capital | (1,513) | (3,143) | 132 | (5,577) | 5,047 | 419 | (1,111) |
| Net interest and financing income (expense) | 5 | 36 | 233 | 212 | 622 | (60) | (7,539) |
| Depreciation & other | 74 | 88 | 93 | 103 | 109 | 118 | 173 |
| 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) | (16,630) | (63,425) |
| Capex | (6) | (3) | (37) | (8) | (38) | (785) | (1,051) |
| 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) | (785) | (1,051) |
| Net proceeds from share issuances | 10,195 | 12,491 | 903 | 18,041 | 11,708 | 0 | 0 |
| Net movements in long-term debt | 0 | 0 | 0 | 0 | 0 | 7,794 | 60,000 |
| 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 | 7,794 | 60,000 |
| 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 | (9,621) | (4,476) |
| Cash & equivalents at beginning of period | 5,040 | 13,422 | 16,370 | 8,460 | 9,451 | 16,504 | 6,883 |
| Cash & equivalents at end of period | 13,422 | 16,370 | 8,460 | 9,451 | 16,504 | 6,883 | 2,407 |
| Closing net debt/(cash) | (13,694) | (16,527) | (8,460) | (9,451) | (13,498) | 3,917 | 68,393 |
| 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) | 4,175 | 68,651 |
| Free cash flow | (1,730) | (9,520) | (8,735) | (16,959) | (7,594) | (17,415) | (64,476) |

Source: Edison Investment Research, company accounts

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