EDISON

Actinogen Medical

Clinical trial results

XanaCIDD data narrow the focus in depression

Pharma and biotech

While the results from Actinogen's XanaCIDD exploratory Phase IIa study in patients with major depressive disorder (MDD) did not meet the primary endpoint in terms of improving cognitive impairment (CI) symptoms, they did show signs of efficacy in terms of treating depression symptoms. Notably, a statistically significant improvement was reported at four weeks after the six-week treatment period. The company's strategy in MDD will now focus on treating depression symptoms and Actinogen will investigate the path forward for a Phase IIb trial that could start as early as H2 CY25. As our model now reflects the larger target market of treating symptoms of depression (versus CI) in MDD, our risk-adjusted net present value rises to A$603m (vs A$544m previously).

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/22	3.6	(7.9)	(0.005)	0.0	N/A	N/A
06/23	4.9	(8.9)	(0.005)	0.0	N/A	N/A
06/24e	7.9	(14.2)	(0.006)	0.0	N/A	N/A
06/25e	7.6	(14.0)	(0.005)	0.0	N/A	N/A

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

XanaCIDD shows promise in depression symptoms

While the top-line results from Actinogen's exploratory, randomised Phase IIa XanaCIDD study assessing Xanamem in patients with CI and MDD did not meet the primary CI endpoint, they showed notable improvements in treating depression symptoms. Management will review the data with regulators and experts over the coming months ahead of potentially starting a larger Phase IIb study focused on treating depression symptoms in H2 CY25.

Minimal CI read-through to XanaMIA Phase IIb study

We do not believe the XanaCIDD CI results have a material negative bearing on Xanamem's ability to mediate an effect in AD patients, given that the underlying pathology of AD and potential implication of cortisol differs substantially from MDD. Treating short-term CI associated with MDD is very different from measuring the ability to slow long-term functional and cognitive decline in AD patients. The XanaMIA Phase IIb AD study (currently underway) will measure cognitive effects after 36 weeks of treatment, much longer than the period studied in XanaCIDD.

Valuation: Revision upwards to A$603m

After rolling forward our estimates and reflecting our new assumptions for the MDD indication, we determine a valuation of A$602.9m (vs A$543.9m previously), or A$0.22 per share (vs A$0.23 per share previously), with the per-share valuation lower given the increase in shares outstanding. While Actinogen's share price has declined c 65% since the release of the XanaCIDD results, it remains at comparable levels to when we published our last update report in May. We continue to believe that the larger opportunity for Xanamem lies in CI related to AD and we view the recent decision by the company to start including US study sites for the XanaMIA Phase IIb trial as highly favourable, as it increases the potential significance of the interim data readout expected in mid-CY25, and also the value realisation potential.

22 August 2024

Price	**A$0.026**
Market cap	**A$71m**
	A$0.67/US$
Net cash at 30 June 2024	A$9.5m
Shares in issue	2,712m
Free float	90%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(69.1)	(7.4)	(6.1)
Rel (local)	(69.2)	(8.7)	(16.4)
52-week high/low	A$0.09		A$0.02

Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11β-HSD1 inhibitor designed to reduce cortisol secretion in the brain. Xanamem is being advanced to treat cognitive impairment (CI) in patients with Alzheimer's disease, and also as a therapy to treat depression symptoms in patients with major depressive disorder.

Next events

Interim results for Phase IIb XanaMIA study in CI associated with AD	Mid-CY25
Potential start of Phase IIb study in major depressive disorder	H2-CY25

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Edison profile page

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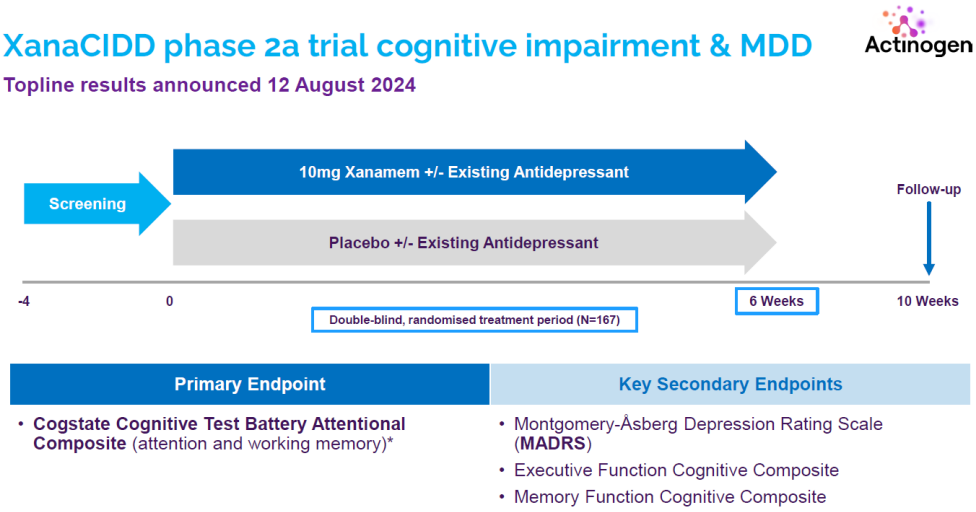
XanaCIDD results to orient MDD program to depression

Actinogen reported mixed top-line results from its exploratory, randomised Phase IIa XanaCIDD study assessing lead candidate Xanamem (at a 10mg once-daily dosage) in 167 patients with CI and persistent MDD. While the study did not meet its primary efficacy endpoint of demonstrating a cognitive improvement over placebo, it did show separation in terms of treatment effect in resolving depression symptoms, including a statistically significant improvement at 10 weeks (four weeks following the end of the six-week treatment period). Given that the results from the company's first trial in patients with MDD point to an emerging signal for Xanamem's ability to treat depression symptoms, the company now plans to orient future Xanamem MDD studies towards the treatment of depression symptoms (rather than CI), which could still be a material opportunity given that over 21 million individuals in the US suffer from MDD.

Summary of study design and results

Patients in the XanaCIDD study were randomised to six weeks of Xanamem (10mg) treatment or placebo, and 165 had completed at least one efficacy assessment. 134 of the subjects continued their concurrent stable anti-depressant therapy during the trial, and Xanamem (or placebo) was applied as a monotherapy in the remaining patients (n=31), who had a prior history of antidepressant treatment.

Exhibit 1: XanaCIDD study design



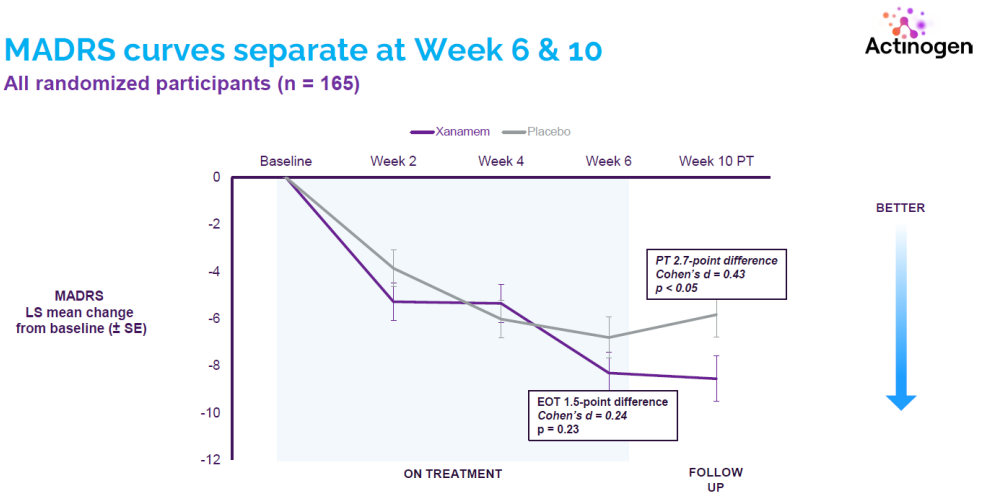
Source: Actinogen corporate presentation August 2024

The double-blinded six-week trial did not meet its primary efficacy endpoint, which was the change from baseline to end-of-treatment (EOT) using the computerised 'Attention composite' in the Cogstate Cognitive Test Battery (CTB). Management noted that the placebo arm demonstrated an unexpectedly large improvement in the CTB Attention composite, which likely impeded the ability of the trial to demonstrate a differentiated result in the Xanamem arm.

As XanaCIDD was an exploratory study and the first to examine Xanamem primarily in younger adults (the median age was 49) as opposed to older individuals (the focus of the prior XanaHES, XanADu and XanaMIA Part A studies), there was a degree of uncertainty as to whether cognitive effects would be seen in this study population. The company noted that the CTB was previously shown to be a sensitive measure of short-term Xanamem-mediated cognition benefit in the prior XanaHES and XanaMIA Part A trials in cognitively normal, older volunteers.

The second efficacy objective of the trial was to assess whether Xanamem would improve depression symptoms using the recognised Montgomery-Asberg Depression Rating Scale (MADRS). In all patients (n=165), a trend towards benefit was seen at the six-week EOT visit (two-sided p=0.23, not reaching statistical significance) versus placebo, and a meaningful and statistically significant 2.7 point difference in the MADRS score (two-sided p<0.05) was shown at four weeks after the EOT visit (week 10 of the study).

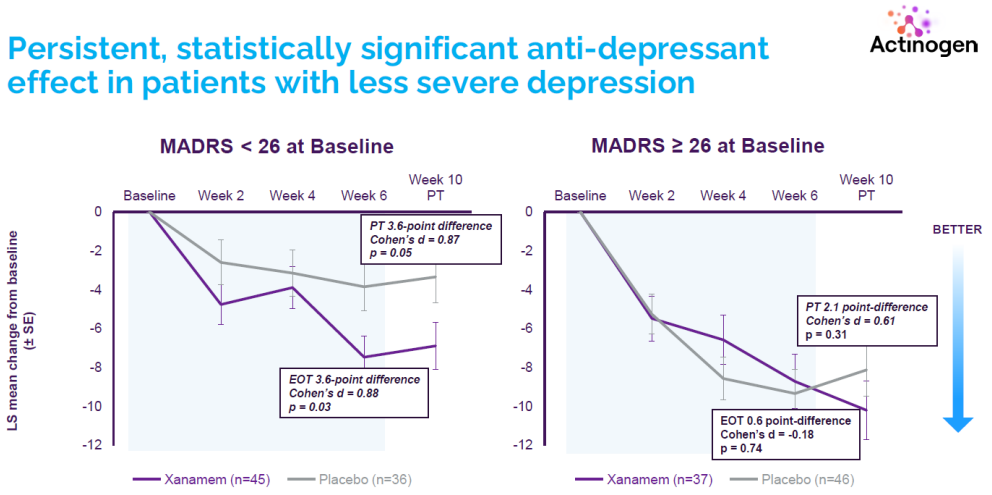
Exhibit 2: Xanamem effects on MADRS at weeks 6 (EOT) and 10 (four weeks after EOT)



Source: Actinogen corporate presentation August 2024. Note: EOT, end of treatment. MADRS, Montgomery-Asberg Depression Rating Scale.

In addition, the company reported in two pre-specified sub analysis groups that there were stronger improvements in MADRS depression scores versus placebo. Actinogen reported a clinically and statistically significant improvement in the 81 patients with less severe depression (baseline MADRS under 26) at baseline, compared to those with more severe disease (MADRS at or above 26).

Exhibit 3: Stronger XanaCIDD effects on MADRS in patients with less severe depression

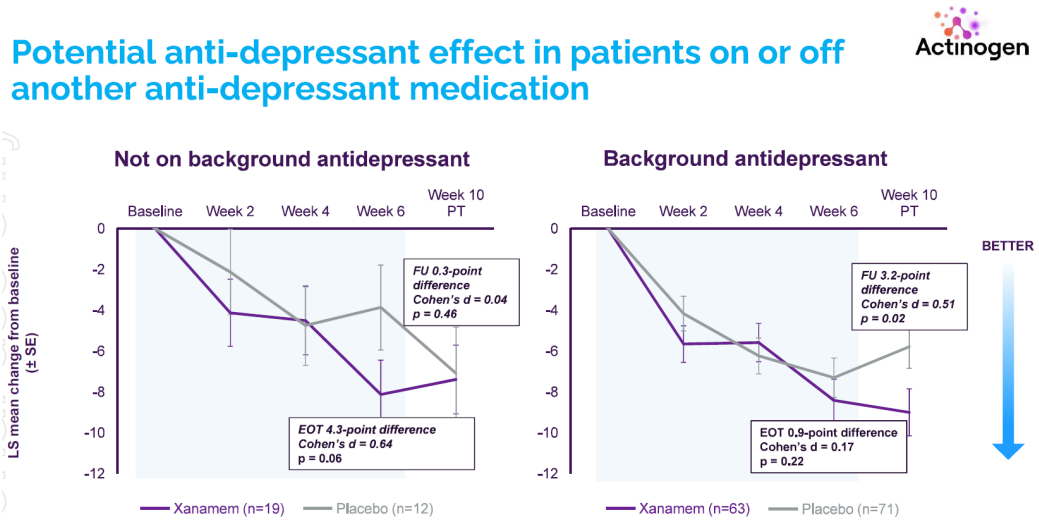


Source: Actinogen corporate presentation August 2024. Note: EOT, end of treatment. MADRS, Montgomery-Asberg Depression Rating Scale.

The company also reported a differentiated MADRS efficacy result at the EOT among the 31 patients who were not taking antidepressants (ie using Xanamem as monotherapy), although we note that this effect had reversed at four weeks after EOT. Hence, we estimate further analysis will

be needed in the monotherapy sub-population in order to better assess the potential for heightened efficacy in this sub-group.

Exhibit 4: Xanamem data based on whether other anti-depressant medications were taken



Source: Actinogen XanCIDD results news release and presentation

Actinogen also reported that Xanamem was well tolerated and safe with a favourable safety profile, consistent with prior studies. There was no pattern of treatment-related adverse events related to the drug, which is favourable and consistent with our expectations.

MADRS trends show promise in depression

In terms of magnitude of effect, we note that the 10-week (four-week post EOT) result in terms of MADRS reduction versus placebo is 2.7 points, which compares favourably to the effectiveness of existing approved drugs for MDD.

For instance, Trintellix (vortioxetine, Takeda/Lundbeck), with c US$0.64bn in FY23 sales and approved in MDD, was analysed in a meta-analysis of placebo-controlled trials, which found that over a six to eight week treatment duration, MADRS total scores reduced on average by 2.27, 3.57 and 4.57 versus placebo for daily doses of 5mg, 10mg and 20mg, respectively. Rexulti (brexpiprazole, Otsuka/Lundbeck), approved as an adjunctive therapy in MDD and with c US$0.67m in FY23 sales, was shown in its second MDD pivotal trial to cause an additional 2.0 reduction in the MADRS score from baseline to six weeks, compared to the addition of placebo.

In terms of existing marketed drugs seeking label expansion to MDD, we note that Caplyta (lumateperone, sold by Intra-Cellular Therapies), with US$462m in FY23 global sales (up 85% y-o-y), and currently approved for the treatment of schizophrenia and bipolar depression, is also being explored in this area. In June 2024, Intra-Cellular Therapies reported positive top-line results from its second Phase III study assessing the drug as an adjunctive therapy in MDD, reporting a 4.5-point reduction in MADRS at six weeks. While this is a robust finding, we note that the drug has shown a more substantial frequency of adverse events compared to Xanamem thus far, including dizziness, somnolence, nausea and fatigue.

Altogether we view the improvement in MADRS vs placebo at 10 weeks (four weeks after EOT) as competitive and potentially promising, especially in light of a favourable safety profile. This result is potentially indicative of a persistence of treatment effect on depression, which may imply that a biological modification may have occurred. However, our enthusiasm over this result is somewhat tempered by the fact that the six-week (EOT) measure of MADRS did not show statistical significance versus placebo. Altogether, we believe the effectiveness in reducing depression

symptoms would need to be more consistently shown in a larger study, and preferably covering a longer treatment duration and specifically designed to assess the drug's effectiveness on depression symptoms as a primary endpoint.

Next MDD steps are a larger Phase IIb study

As a whole, given trends towards efficacy in depression, Actinogen expects to continue advancing Xanamem in MDD and will focus the next study on this patient group to target the product's effectiveness in reducing depression symptoms, rather than CI. We note that treating depression symptoms in MDD is a much more straightforward and established pathway with regulators (such as the FDA and EMA) compared to treating CI in these patients. Actinogen also indicates that trial data will be further explored in the coming months and reviewed with depression opinion leaders and regulators to further evaluate the path forward for Xanamem in depression. The analysis may determine that Xanamem's effectiveness may be more potent in certain subgroups (such as a monotherapy or patients in less severe disease stages, as discussed above) and may direct future studies (in terms of endpoints or study populations) accordingly.

Following the completion of data analysis (which may take approximately two to three months) and feedback from regulators (including the FDA), Actinogen plans to investigate the path towards potentially starting a Phase IIb study (which it expects to serve as one of the two pivotal studies required for registration) in H2 of CY25. We expect this Phase IIb study to also include US study sites. Given the 10-week endpoint data shown in XanaCIDD, we believe the forthcoming study will assess Xanamem for a longer period than six weeks.

We believe the company will be seeking partnerships or other forms of non-dilutive funding for this next MDD study, although it is also possible the company could seek to fund this program internally with internal funds. We currently model that the company's Phase IIb study in MDD will start in H2 CY25 and a larger Phase III in MDD will start in CY26 (consistent with our prior estimates). We continue to assume that the company obtains market approval in MDD in CY28.

XanaCIDD shows limited read-through in Alzheimer's indication

In terms of readthrough to the company's primary indication, CI related to Alzheimer's disease (AD), while Xanamem's cortisol-inhibition mechanism of action was not shown to provide cognitive benefit in MDD in XanaCIDD, we do not view these results as necessarily having any material cross-over or negative bearing on the drug candidate's ability to mediate an effect in AD patients.

As a reminder, Xanamem's intended mechanism of action is to penetrate the brain and then inhibit the enzyme 11β-Hydroxysteroid dehydrogenase type 1 (11β-HSD1). As discussed in further detail in our initiation report, much scientific literature suggests that excessive cortisol is associated with CI in patients with various chronic conditions, including age-related CI and AD. As the naturally present enzyme 11β-HSD1 normally converts cortisone to cortisol inside cells, Xanamem is designed to reduce excessive cortisol production in the brain. The underlying pathology and targeted treatment objective for AD and MDD vary significantly, and multiple studies have implicated excessive cortisol in AD pathophysiology. We also note that treating short-term CI associated with MDD (the primary endpoint for XanaCIDD) is a very different process from measuring Xanamem's potential ability to decelerate the long-term functional and cognitive decline in AD patients.

Further, there is a significant difference between the ages of the underlying population treated in XanaCIDD (average age 49 at recruitment) compared to the three previously completed studies in older adults where Xanamem has already shown a positive effect on cognition:

- XanADu, a double-blinded Phase II trial assessing the drug versus placebo in 185 mild AD patients between 2017 and 2019; a subset analysis in patients with elevated p-Tau 181

biomarker at baseline showed statistically significant improvements versus placebo in terms of the FDA-recognised Clinical Dementia Rating – Sum of Boxes (CDR-SB) measure of efficacy in AD.

- XanaHES, a single-blinded placebo-controlled Phase I study in healthy elderly volunteers (n=42) that started in early 2019 and was completed in Q419; and
- the Phase Ib portion of XanaMIA, which started in July 2021, assessing 5mg and 10mg doses of Xanamem, with positive Phase Ib data in healthy older volunteers reported in April 2022.

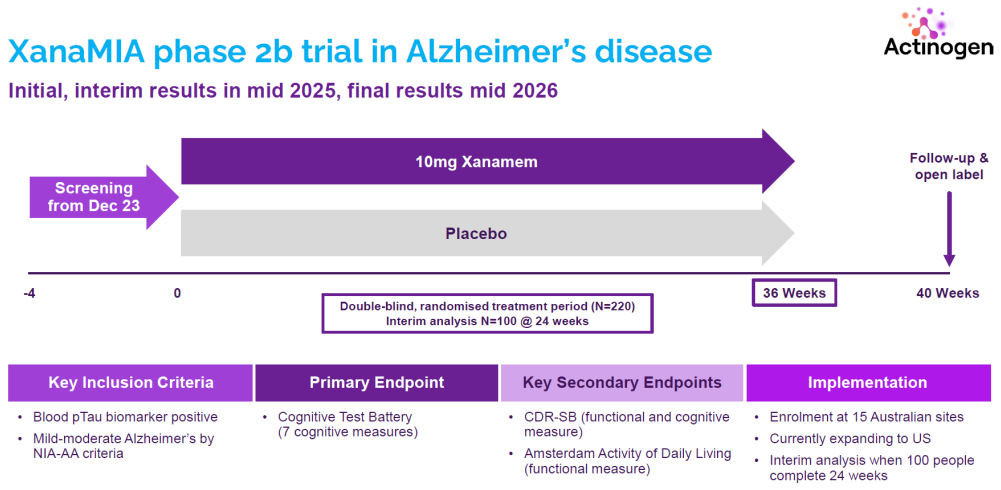
In addition to the above, we note that the XanaMIA Phase IIb study currently underway in patients with biomarker-positive AD (through elevated levels of p-Tau 181 biomarker at baseline) is designed to measure cognitive effects after 36 weeks of treatment, a much longer treatment duration than the six-week period whereby participants took drug (or placebo) in XanaCIDD. Hence, the XanaMIA Phase IIb study is better designed to assess the more sustained effects on cognition in this considerably different patient population (older adults with early AD, compared to the MDD population in XanaMIA).

We also note that the primary endpoint of XanaMIA Phase IIb uses a different primary endpoint than the CTB Attention score used in XanaCIDD. As a reminder, the primary endpoint for the XanaMIA Phase IIb AD trial is a cognitive test battery comprising seven different digital assessments, and a key secondary endpoint is the CDR-SB scale. Altogether, this confirmatory study will include assessments of both functional and cognitive measures to adequately measure the potential slowing of disease progression.

XanaMIA Phase IIb to recruit US patients earlier than expected

The first randomised patient in Actinogen's Phase IIb XanaMIA trial of Xanamem in lead indication AD received their first treatment on 12 April. This study is designed to enrol c 220 patients with biomarker-positive mild-to-moderate AD, as confirmed through an elevated level of phosphorylated Tau-181 (pTau-181) protein in their blood at baseline. Study patients are being randomised to take Xanamem 10mg or placebo once daily for 36 weeks.

Exhibit 5: XanaMIA Phase IIb study design



Source: Actinogen corporate presentation August 2024. Note: NIA-AA, National Institute of Aging – Alzheimer's Association. CDR-SB, Clinical Dementia Rating – Sum of Boxes.

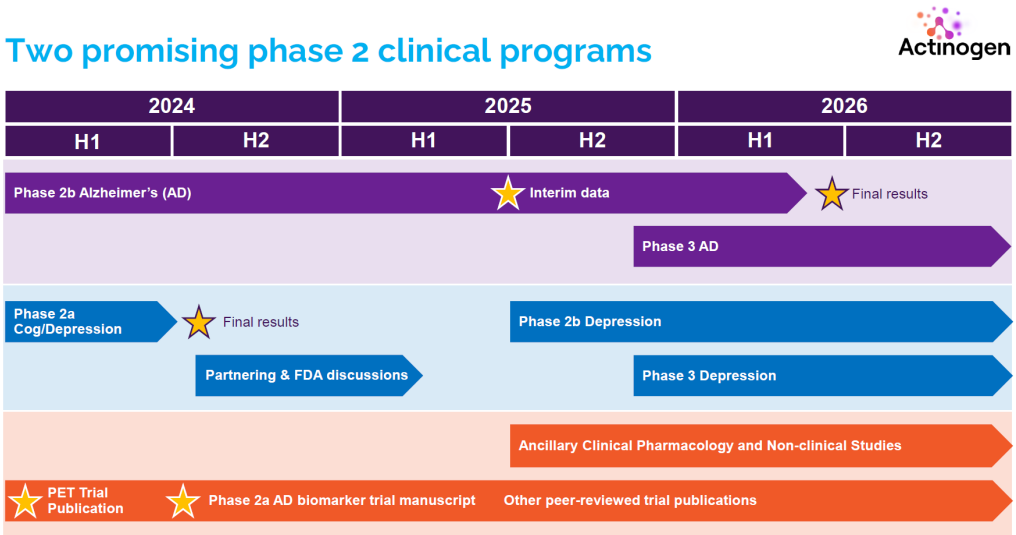
While Actinogen in Q4 CY23 had determined, in order to conserve capital, that the study would concentrate on Australian study sites for the first c 100 patients, the company more recently indicated that through cost efficiencies it will now be able recruit AD subjects from US study sites earlier than planned, including many of these first c 100 patients. Actinogen expects to start recruiting US subjects in the coming weeks, and it still plans to perform an interim study analysis on the first c 100 subjects (of which up to a third may now be from US study sites). Initial efficacy and safety results will be analysed when these patients reach 24 weeks of treatment, and the company expects to report these results in mid-CY25.

We believe the inclusion of US participants in the interim analysis will strengthen the overall viability and robustness of the data, and thus increase the likelihood of positive partnership or licensing discussions and outcomes if these data are positive. Actinogen expects to report final results in mid-CY26 (our model continues to assume these results in CY26).

The design of the XanaMIA Phase IIb study is informed by a subset analysis reported in Q4 CY22 in 34 patients with elevated pTau-181 blood levels from the previous 185-patient XanADu trial in mild AD. This subset of patients (16 on Xanamem 10mg daily, 18 on placebo) with biomarker-positive AD (pTau of at least 6.74pg/mL) showed clinical activity and a relatively large effect size at 12 weeks using the CDR-SB scale.

If XanaMIA Phase IIb results are positive, the next step would be a Phase III study (which we assume would serve as one of the two registrational trials required for US approval). The company is projecting that it could start a Phase III study in AD in H1 CY26 and we anticipate it would require an additional confirmatory Phase III study prior to receiving marketing approval in AD.

Exhibit 6: Management expectations of Actinogen's upcoming study timelines



Source: Actinogen corporate presentation August 2024

Financials

In Actinogen's 4C Statement for the three months ending 30 June, the company reported a net operating cash outflow of A$5.1m, driven by A$3.8m in R&D related payments. The company expects its rate of R&D expenditure to start to decline in Q2 FY25 (Q4 CY24) given the conclusion of the XanaCIDD study. Altogether the company reported a cash burn rate for the 12 months ending 30 June of A$17.1m, and finished the period with A$9.45m in net cash and equivalents, lower than our prior estimate (A$13.6m). The Q2 CY24 cash outflow was higher than we expected due to higher than projected R&D cash outflows and transaction costs related to the A$8.9m capital

increase. We believe that working capital utilisation may have also contributed to the lower-than-expected cash position, and we now assume a greater release of working capital in FY25.

Actinogen maintains its guidance for its funds on hand to maintain operations into late CY25 (H2 CY25). Subsequent to 30 June, the company received A$0.6m in proceeds from the exercise and conversion of options, which further supports the company's runway guidance.

Below is a summary of our minor adjustments to our FY24 and FY25 forecasts.

Exhibit 7: Changes to Actinogen forecasts

A$m	FY24e (prior)	FY24e (new)	Difference (%)	FY25e (prior)	FY25e (new)	Difference (%)
R&D tax credits, grants and related revenue	7.86	7.91	0.57	7.72	7.60	-1.49
Net R&D expenditures	16.21	16.30	0.57	15.91	15.67	-1.49
EBITDA	(14.71)	(14.98)	1.89	(13.97)	(14.08)	0.77
Net cash flows from operations	(13.32)	(17.06)	28.08	(12.40)	(8.51)	-31.34
Free cash flow	(13.49)	(17.07)	26.47	(13.12)	(9.23)	-29.64

Source: Edison Investment Research

We expect the company's cash on hand to fund operations into FY26 (H2 CY25), in line with company guidance. We continue to project that the company will receive R&D research tax credits (which correspond to up to 48.5% of R&D costs incurred in the prior fiscal year) from the Australian government.

We continue to forecast a potential launch timeline for Xanamem in patients with AD in CY29 and assume commercialisation of the drug for patients with MDD in CY28, although as stated above, we now expect the main indication in MDD patients will be treating depression symptoms rather than CI. Our base-case projection assumes that Actinogen will independently fund all studies needed for regulatory approval in these indications.

We maintain our expectation that R&D costs ramp up significantly (more than double) in FY26 as more US patients are recruited into the XanaMIA Phase IIb study, and as the company plans to begin its Phase IIb study in MDD and may begin Phase III pivotal studies in AD. We continue to assume the total projected future funding need to launch Xanamem in these indications and obtain recurring operating profitability will be A$360m.

Valuation

Our valuation is based on a risk-adjusted net present value (rNPV) analysis, which includes A$9.45m in net cash at end-June 2024. We have also adjusted our model to reflect the A$0.67/US$ exchange rate (versus A$0.66/US$ previously). We apply a discount rate of 12.5% and include Xanamem in the two lead indications: AD and now depression in MDD (versus CI in MDD previously). As stated above, we expect Actinogen to now primarily pursue the treatment of depression symptoms, rather than CI improvement, in the MDD population. As a result, we have made some adjustments to our market assessment of the addressable MDD population, although we may make further revisions once the company completes its review of the XanaCIDD data and of future clinical study plans (for instance, if it determines that it will orient future trials more towards a subset of the MDD population, such as those with less severe disease or those not on current antidepressant drug therapy).

The prevalence of MDD in the United States is c 21 million and when assessing Xanamem's prospects for CI related to MDD, we had estimated that only 80% of MDD patients had cognitive effects, and that only 30% of these would consider seeking treatment. When now assessing the addressable market for depression symptoms in MDD, while starting with a considerably larger total addressable market, we also consider that compliance and adherence to depression drug therapy is generally low (Keyloun et al reported adherence to initial treatment drops from 41% to 21% between months three and 12) and that many diagnosed patients are not even provided

pharmacological therapy (Soria-Saucedo et al determined than less than 20% of individuals with a diagnosis of depression received pharmacotherapy or psychotherapy). Further the MDD market is more competitive (than CI related to MDD), given the availability of competitors such as Trintellix, Rexulti, Eli Lilly's Cymbalta (and generic duloxetine), Lundbeck's Lexapro (and generic escitalopram), Viatris's Effexor XR (and generic venlafaxine). Hence, we estimate a lower peak market share of 5% for treating depression symptoms in MDD (vs 7.5% for treating CI in MDD patients, previously). Given the above effects, we now estimate 2034 (peak) US sales in MDD for Xanamem of US$876m (vs US$751m previously).

Given the mixed results from XanaCIDD (MADRS change did not reach statistical significance at EOT, but it did at four weeks post EOT), we are maintaining our 12.5% probability of success estimate for Xanamem in the MDD indication, as well as our unchanged 10% estimate for Xanamem to reach the market in the AD indication.

Exhibit 8: Actinogen rNPV valuation

Product	Market	Launch	Sales (A$m) in 2034	NPV (A$m)	Probability of success	rNPV (A$m)	rNPV/basic share (A$)
Xanamem in cognitive impairment related to Alzheimer's disease	US	CY29	3,441	3,337.6	10.0%	286.8	0.11
Xanamem in cognitive impairment related to Alzheimer's disease	EU5 & Australia	CY29	1,629	1,630.0	10.0%	163.0	0.06
Xanamem in major depressive disorder	US	CY28	1,308	1,148.5	12.5%	116.5	0.04
Xanamem in major depressive disorder	EU5 & Australia	CY28	763	695.8	12.5%	87.0	0.03
Corporate costs				(59.7)	100%	(59.7)	(0.02)
Net cash at 30 June 2024				9.5		9.5	0.00
Total equity value				**6,761.5**		**602.9**	**0.22**

Source: Edison Investment Research

After rolling forward our estimates and reflecting our new assumptions for the MDD indication, we determine a valuation of A$602.9m (vs A$543.9m previously), or A$0.22 per share (vs A$0.23 per share previously), with the per share valuation lower given the increase in shares outstanding (reflecting the A$8.9m Q2 CY24 capital increase and post-period option conversions).

While Actinogen's share price has declined c 65% since the release of the XanaCIDD results, it remains at comparable levels to when we published our last update report in May. Hence while some investors may have been disappointed that XanaCIDD did not meet efficacy endpoints in CI, we believe that that this share price reaction does not reflect the emerging opportunity for Xanamem to treat depression symptoms in the MDD population, as supported by the MADRS result readouts described above. Further, we continue to believe that the larger opportunity for Xanamem lies in CI related to AD and we view the recent news of inclusion of US study sites for the XanaMIA Phase IIb study as highly favourable, as it increases the potential significance of the interim data readout expected in mid-CY25.

In terms of upcoming catalysts and milestones for Actinogen, we believe that the further analysis of the XanaCIDD study data and developments for the next Phase IIb study in MDD (including regulatory feedback and/or developments on funding for this study) could provoke investor interest over the next six to 12 months.

The largest potential catalyst, which we expect market participants will be keen to observe, will be the interim analysis (mid-CY25) of the Phase IIb XanaMIA study, which prospectively enrols patients with elevated pTau-181. Investors will be looking to see whether these data will confirm the positive efficacy findings shown in the XanADu subset biomarker analysis. Given the widespread economic and social costs of AD and the limitations of current approved treatments, we anticipate positive Phase IIb data, even at the interim readout (in mid-CY25), could introduce the possibility of material out-licensing or value realisation opportunities. We reiterate that as these interim data are now expected to include results from US study sites, there may be a greater possibility for value realisation if these results are positive.

As stated earlier, we forecast A$360m in additional financing will be required before FY29 to fund the development of both the MDD and AD programs, 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 usual Edison methodology. If our projected funding need of A$360m is raised through equity issuances at the prevailing market price of c A$0.026, our effective valuation would decrease to A$0.06 per share.

The amount of fund-raising estimated to be necessary for Actinogen to independently bring Xanamem to commercialisation in these indications is larger than the company's current market capitalisation. However, we note that the funding intervals may be staggered over the next several years, which may alleviate potential challenges associated with raising funds in excess of a company's market capitalisation. We also 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. Hence, while our base case modelling 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), then our R&D expenditure requirements for Actinogen, and, consequently, our overall funding need projections, would likely be significantly reduced.

Considering that AD pivotal trials are reported to cost more per patient than studies in nearly any other therapeutic area, we believe Actinogen will likely accelerate efforts to attain partnerships or non-dilutive funding strategies if interim XanaMIA Phase IIb data (expected in mid-CY25) are supportive.

Exhibit 9: Financial summary

A$'000s	2020	2021	2022	2023	2024e	2025e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	3,516	1,984	3,640	4,888	7,907	7,601
Cost of Sales	0	0	0	0	0	0
Gross Profit	3,516	1,984	3,640	4,888	7,907	7,601
Sales, General & Administrative	(2,962)	(3,111)	(4,558)	(6,568)	(6,587)	(6,007)
Net Research & Development	(5,537)	(2,406)	(8,215)	(8,900)	(16,304)	(15,672)
EBITDA	(4,983)	(3,533)	(9,133)	(10,580)	(14,984)	(14,078)
Amortisation of intangible assets	(314)	(313)	(313)	(313)	(236)	(236)
Depreciation & other	(99)	(74)	(88)	(93)	(100)	(173)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,888)	(3,318)	(7,933)	(9,156)	(14,504)	(14,251)
Operating profit before exceptionals	(5,396)	(3,920)	(9,533)	(10,985)	(15,320)	(14,486)
Exceptionals including asset impairment	0	0	0	0	0	0
Other	(194)	(289)	(1,288)	(1,517)	(580)	0
Reported Operating Profit	(5,590)	(4,209)	(10,821)	(12,502)	(15,900)	(14,486)
Net Finance income (costs)	65	5	36	233	272	260
Profit Before Tax (norm)	(4,822)	(3,313)	(7,897)	(8,923)	(14,232)	(13,991)
Profit Before Tax (FRS 3)	(5,331)	(3,915)	(9,497)	(10,752)	(15,048)	(14,226)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,822)	(3,313)	(7,897)	(8,923)	(14,232)	(13,991)
Profit After Tax and minority interests (FRS 3)	(5,331)	(3,915)	(9,497)	(10,752)	(15,048)	(14,226)
Average Basic Number of Shares Outstanding (m)	1,118.0	1,405.2	1,717.1	1,806.0	2,263.9	2,711.6
EPS - normalised (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.006)	(0.005)
EPS - normalised and fully diluted (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.006)	(0.005)
EPS - (IFRS) (A$)	(0.005)	(0.003)	(0.006)	(0.006)	(0.007)	(0.005)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	3,772	3,287	2,889	2,520	2,193	2,503
Intangible Assets	3,346	3,033	2,720	2,408	2,172	2,436
Tangible Assets	19	17	13	113	21	67
Investments in long-term financial assets	408	237	156	0	0	0
Current Assets	8,164	15,091	20,417	12,688	17,162	3,237
Short-term investments	0	0	0	0	0	0
Cash	5,040	13,457	16,370	8,460	9,451	833
Other	3,123	1,634	4,047	4,228	7,711	2,404
Current Liabilities	(744)	(755)	(1,480)	(1,802)	(2,186)	(2,186)
Creditors	(744)	(755)	(1,480)	(1,802)	(2,186)	(2,186)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(304)	(165)	(87)	0	0	0
Long term borrowings	0	0	0	0	0	0
Other long term liabilities	(304)	(165)	(87)	0	0	0
Net Assets	10,889	17,458	21,740	13,407	17,168	3,554
CASH FLOW STATEMENT						
Operating Income	(5,590)	(4,209)	(10,821)	(12,502)	(15,900)	(14,486)
Movements in working capital	(3,591)	(1,513)	(3,143)	132	(2,925)	5,307
Net interest and financing income (expense)	65	5	36	233	272	260
Depreciation & other	99	74	88	93	100	173
Taxes and other adjustments	6,161	3,920	4,323	3,346	1,396	236
Net Cash Flows from Operations	(2,856)	(1,724)	(9,517)	(8,698)	(17,057)	(8,511)
Capex	(23)	(6)	(3)	(37)	(8)	(719)
Acquisitions/disposals	0	0	0	0	0	0
Interest received & other investing activities	0	0	0	(0)	0	0
Net Cash flows from Investing activities	(23)	(6)	(3)	(37)	(8)	(719)
Net proceeds from share issuances	0	10,195	12,491	903	18,041	612
Net movements in long-term debt	0	0	0	0	0	0
Dividends	0	0	0	0	0	0
Other financing activities	282	(84)	(71)	(78)	15	0
Net Cash flows from financing activities	282	10,111	12,420	825	18,056	612
Effects of FX on Cash & equivalents	0	0	49	0	0	0
Net Increase (Decrease) in Cash & equivalents	(2,596)	8,381	2,949	(7,910)	991	(8,618)
Cash & equivalents at beginning of period	7,637	5,040	13,422	16,370	8,460	9,451
Cash & equivalents at end of period	5,040	13,422	16,370	8,460	9,451	833
Closing net debt/(cash)	(5,448)	(13,694)	(16,527)	(8,460)	(9,451)	(833)
Lease debt	390	236	165	87	45	45
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(5,058)	(13,458)	(16,361)	(8,373)	(9,406)	(789)
Free cash flow	(2,878)	(1,730)	(9,520)	(8,735)	(17,065)	(9,230)

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