

# Actinogen Medical

H123 update

## Getting ready for the next Alzheimer's study

Actinogen is on track to start US recruitment in Q2 CY23 for the six-month, placebo-controlled Phase IIb portion of the XanaMIA study. The study portion is designed to assess Xanamem in a population of patients with mild cognitive impairment (CI) and/or mild Alzheimer's disease (AD), who at baseline will have been confirmed as biomarker-positive for progressive AD. We believe market participants will be keen to observe whether this study portion will confirm [the positive efficacy findings](#) shown in a subset biomarker analysis from the earlier XanADu study. We expect the next material clinical data milestone for the company over the next 12 months will be the XanaCIDD study results, due in late CY23 or early CY24. This study aims to demonstrate whether Xanamem can show efficacy signals in patients with CI associated with major depressive disorder (MDD). After rolling our model forward and adjusting for forex, we now obtain an rNPV valuation of A\$702m (vs A\$651m previously).

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/21	2.0	(3.3)	(0.002)	0.0	N/A	N/A
06/22	3.6	(7.9)	(0.005)	0.0	N/A	N/A
06/23e	4.0	(9.4)	(0.005)	0.0	N/A	N/A
06/24e	4.1	(37.6)	(0.021)	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.

## XanaMIA Part IIb could lead to value uplift

We anticipate top-line results from the Phase IIb portion of XanaMIA in late CY24 or in H1 CY25. If positive, we believe the results may lead to material out-licensing or value realisation opportunities given the significant unmet need in AD, the drug's favourable safety profile demonstrated to date and its convenient oral dosing form. Considering that AD pivotal trials are [reported to cost more per patient than studies in nearly any other therapeutic area](#), we believe the company will likely explore partnerships or non-dilutive funding strategies if the data are positive.

## H123 financials broadly in line with expectations

Actinogen's H123 operating cash burn rate of A\$2.8m was dampened by the company's receipt in Q4 CY22 of an A\$4.2m R&D tax rebate, leading the company to finish CY22 with a [cash balance of A\\$14.5m](#). After adjusting for the R&D tax rebate, the company's H123 operating cash outflows trended mildly above our prior forecast of A\$8.4m in net FY23 operating cash outflow. Altogether, our forecasts for FY23 and FY24 are little changed, as we anticipate expenditures to increase in FY24 as the XanaMIA Phase IIb study portion ramps up.

## Valuation: Benefiting from a stronger US dollar

We have rolled forward our estimates and updated our forex assumptions to reflect a stronger US dollar versus the Australian dollar. The effect of these changes, notably the stronger US dollar, increases our total equity valuation to A\$702m (vs A\$651m previously), or A\$0.39 per share (vs A\$0.36 previously). We estimate Actinogen's funds on hand will last into Q4 CY23 and continue to model the company will raise A\$20m in FY23 (now H223) and A\$40m in FY24.

### Pharma and biotech

**15 March 2023**
**Price** **A\$0.07**
**Market cap** **A\$126m**

A\$0.66/US\$

Net cash (A\$m) at 31 December 2022 14.5

Shares in issue 1,806m

Free float 90%

Code ACW

Primary exchange ASX

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs (18.0) (26.3) (17.0)

Rel (local) (13.1) (23.8) (14.5)

52-week high/low A\$0.14 A\$0.04

### Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11 $\beta$ -HSD1 inhibitor designed to treat cognitive impairment (CI) that occurs in chronic neurodegenerative and neuropsychiatric diseases. Currently, Actinogen is targeting CI in two indications: the early stages of Alzheimer's disease and major depressive disorder.

### Next events

Start enrolment for XanaMIA Part IIb study in biomarker-confirmed early AD Q2 CY23

Results for Phase II XanaCIDD study in cognitive impairment associated with major depressive disorder Q4 CY23 or H1 CY24

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## H123 update shows continued progress for Xanamem

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Actinogen's H123 update confirmed that the company is on track to start US recruitment in Q2 CY23 for the six-month, placebo-controlled Phase IIb portion of the XanaMIA study. This study will assess the company's lead drug candidate Xanamem in patients with biomarker-positive AD, as determined through an elevated level of pTau-181 (phosphorylated Tau-181) protein in the blood. The company has completed initial development of a new tablet formulation that will be more convenient for patients to use, and Actinogen expects this formulation to be ready to be used in the Part IIb portion of XanaMIA and all subsequent Xanamem trials. Actinogen in [December 2022](#) announced that the first patient was randomised and treated in its XanaCIDD Phase II study in MDD, assessing the effects of Xanamem (using the original drug formulation) on cognitive performance and depression.

### XanaMIA Phase IIb aims to confirm therapeutic effect

The Phase IIb portion of XanaMIA is designed to assess the safety and efficacy of Xanamem in a population of patients with mild CI and/or mild AD, who at baseline will have been confirmed as biomarker-positive for progressive disease, as determined through the presence of an elevated level of [pTau-181 protein](#) in the blood. This study is designed to enrol 330 patients with mild AD and progressive disease. Patients will be randomised to treatment with 5mg, 10mg or placebo once a day, over a six-month period. The study's key efficacy endpoints will be the FDA-recognised Clinical Dementia Rating – Sum of Boxes (CDR-SB) scale and the Cogstate computerised test battery of attention and working memory. In Q422, the company received [the necessary approvals](#) from the FDA to proceed with US enrolment for the Phase IIb portion of XanaMIA.

The premise behind the planned Phase IIb portion of XanaMIA was discussed in [our initiation report](#). While [the initial results](#) reported in 2019 from the earlier 185-patient XanADu study in patients with suspected AD did not meet the primary endpoint (when all per-protocol patients were included), the company subsequently explored the effect and dynamics of blood biomarkers. Biomarker analysis was not included in the original trial design, but the company studied stored plasma samples from 72 of the 185 original patients in the study (reflecting data at both baseline and at week 12). At the time top-line XanADu results were reported in 2019, blood-based AD biomarker analysis was not available and AD clinical diagnosis was not confirmed by any biomarkers. In October 2022, the company reported [positive biomarker data](#) whereby a subset of patients from the [XanADu study](#) with elevated pTau (a recognised AD diagnostic biomarker) at baseline taking Xanamem demonstrated clinical activity and a relatively large effect size at 12 weeks using the CDR-SB scale.

Patients with pTau at or above 6.74pg/mL, representing 34 patients (16 on Xanamem 10mg daily, 18 on placebo), showed a 0.6 mean difference (effect size) on CDR-SB (representing a 60% relative reduction in disease progression versus placebo) at 12 weeks between the placebo and treatment arms.

This difference in CDR-SB versus placebo exceeded the level of CDR-SB improvements shown for [Aduhelm](#) in its [EMERGE study](#) and for [Legembi](#) as shown in the [Clarity AD](#) study (both at 78 weeks). We note that the XanADu biomarker analysis sample size is relatively small and recognise that there may be limitations in forecasting future trial outcomes based on study analyses determined using retrospective clinical data. Nonetheless, we view these biomarker results as highly encouraging in that they demonstrate the potential for meaningful Xanamem clinical activity in biomarker-confirmed AD patients, if replicated in a prospective trial. The objective of the Phase IIb portion of XanaMIA is to confirm whether Xanamem can reproduce a similar treatment effect in a

prospectively designed study that enrolls patients with elevated pTau (such as the Phase IIb portion of XanaMIA).

## Phase IIb results could lead to value realisation opportunities

Top-line results from the Phase IIb portion of XanaMIA, which we anticipate in late CY24 or in H1 CY25, could, if positive, introduce the possibility of material out-licensing or value realisation opportunities, in our view. Given that AD pivotal trials are [reported to cost more per patient than studies in nearly any other therapeutic area](#), we believe the company will likely explore partnerships or non-dilutive funding strategies if the data are positive, given the high amount of funding likely to be needed to fund AD registration studies through to completion. We expect the AD programme would require two separate Phase III studies prior to a possible FDA regulatory approval filing. While the Phase IIb portion of XanaMIA may potentially qualify as one of the pivotal studies required for approval in early AD, our base case forecasts assume that two additional AD studies will be required for approval (although we may revisit our assumptions once the Phase IIb study is completed and/or further information on the AD development plan becomes available).

The AD market remains substantial, in our view, and the recent FDA [accelerated approval of Biogen/Eisai's Leqembi](#) may raise investor awareness of the sector. We note that the Centers for Medicare & Medicaid Services (CMS) [has decided against](#) expanding reimbursement coverage for the drug until it can obtain an approval through the traditional FDA pathway, which [could occur in July 2023](#) given the PDUFA date for Eisai's supplemental Biologics License Application (sBLA) seeking traditional approval for the drug. The US Veterans Health Administration [recently announced](#) it will provide coverage for Leqembi. Nonetheless, potential advantages of Xanamem are its oral mode of administration and its favourable safety record thus far, as shown in [multiple Phase I and II studies to date](#).

## XanaCIDD to investigate Xanamem effects in patients with MDD

The XanaCIDD study started in late 2022 and aims to enrol about 160 patients across Australia and the UK who have persistent depressive symptoms and CI despite taking standard-of-care anti-depression therapy. Having demonstrated the ability to improve cognition in two trials (XanaHES and the Phase Ib portion of XanaMIA) in healthy adults, Actinogen is confident that Xanamem can exert similar cognitive improvement effects in MDD patients; this study will also explore whether the drug can have effects on depression as well.

Xanamem 10mg daily or placebo will be added to patients' existing anti-depressant therapy and effects on cognition (using the Cogstate Cognitive Test Battery) and depression (using the Montgomery Asberg Depression Rating Scale) will be evaluated.

MDD is a common disorder, with a [c 5% prevalence](#) globally. CI is a feature in most MDD patients and commonly persists even when depression symptoms subside. Elevated cortisol [levels have been associated with depression](#) and modification of brain cell cortisol levels has been proposed as a strategy to treat [both depression and its associated CI](#). As Xanamem targets excess brain cortisol, and given the benefits shown in healthy adults in XanaHES and the Phase Ib portion of XanaMIA, we believe it is plausible for cognitive benefits to be shown in patients with persistent MDD. If the XanaCIDD study is successful in showing CI improvement, the company may then move to advance it into pivotal studies. Given that no US-approved antidepressant has a CI label, we believe there is a significant opportunity for Xanamem in this market if it can demonstrate an improvement in CI in this population. Study results are expected in late CY23 or early CY24.

## Increasing US representation on corporate team

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The company recently appointed Dr Dana Hilt as its chief medical officer (CMO). Dr Hilt is based in the United States and has over 25 years of drug development experience, largely focused on treatments targeting central nervous system diseases, notably including AD. Actinogen also recently appointed US-based Dr Nicki Vasquez as an independent non-executive director. Dr Vasquez, currently chief portfolio strategy & alliance officer at Sutro Biopharma, is an immunologist and biopharmaceutical executive with over 25 years of drug discovery research and development experience. Previously, Dr Vasquez was vice president of program & portfolio management at StemCells, where she established project management functions for research and clinical stage programs in indications including AD. We view the appointment of US-based executives as supportive of the company's planned entrance in H1 CY23 into US clinical AD drug development and US study sites through the XanaMIA Phase IIb study.

## Financials and valuation

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Actinogen reported an H123 operating cash burn rate of A\$2.8m, which was dampened by the company's receipt in October 2022 of an A\$4.2m R&D tax rebate, leading the company to finish CY22 with a cash balance of A\$14.5m. After adjusting for the R&D tax rebate, the company's H123 operating cash outflows trended mildly above our prior forecast for A\$8.4m in net FY23 operating cash outflow. Following the H123 results, we have adjusted our forex assumptions (to A\$0.66/US\$ vs A\$0.69/US\$ previously) and also mildly increased our FY23 R&D and G&A cost assumptions, while modestly reducing FY24e R&D expenses to reflect the pushing back of a portion of future AD study costs into FY25. Altogether, we now model FY23e and FY24e free cash outflow rates of A\$9.6m and A\$38.4m, versus our prior assumptions of A\$9.5m and A\$39.4m, respectively. We expect the burn rate to ramp up significantly in FY24 to fund the bulk of the XanaMIA Phase IIb portion and XanaCIDD study costs.

Our valuation continues to be based on a risk adjusted NPV analysis, which includes A\$14.5m in net cash at the end of December 2022. We apply a discount rate of 12.5% and include Xanamem in the two lead indications. We continue to use a probability of success of 10.0% for Xanamem to reach the market in the AD project and 12.5% in the MDD project. We note the company has expressed potential interest in expanding Xanamem development to CI related to schizophrenia and/or bipolar disorders, which may offer upside potential, but we will await the commencement of clinical studies in such programmes prior to including such initiatives in our valuation.

Our local-currency sales forecasts and timing estimates are unchanged from [our initiation report](#), but we have rolled forward our estimates and updated our forex assumptions to reflect a stronger US dollar versus the Australian dollar. The effect of these changes, notably the increased strength of the US dollar, increases our total equity valuation to A\$702m (vs A\$651m previously), or A\$0.39 per share (vs A\$0.36 previously). Our valuation is sensitive to the A\$/US\$ exchange rates, given that the majority of our expected future potential revenue for Xanamem will come from the US market. Had the forex rate been unchanged (compared to our initiation note) at A\$0.69/US\$, our valuation would now be A\$670m, or A\$0.37 per share. Hence, every 1 cent change in the A\$/US\$ exchange rate would result in a c A\$10.5m change in our equity valuation, or about c A\$0.0058 per share, with a strengthening US dollar causing appreciation in our Actinogen valuation, and a weakening US dollar doing the reverse.

While the company's share price has decreased c 40% since our initiation report on [18 October 2022](#), there have been no fundamental adverse developments affecting Xanamem's commercial prospects or potential market launch timing, in our view. In fact, we view the FDA acceptance in December 2022 of the company's request to enrol US patients the Phase IIb portion of XanaMIA as

a positive event. Altogether, we believe recent market performance is primarily due to macroeconomic factors and increased investor caution in an environment of rising interest rates amid general concerns of an economic recession. We estimate this level of risk-aversion is affecting development-stage biopharmaceutical companies, and particularly those expected to require additional capital within approximately 12–18 months given market expectations of challenges associated with raising funds in the current environment.

**Exhibit 1: 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	H2 CY27	3,994	3,827.7	10.0%	340.5	0.19
Xanamem in cognitive impairment related to Alzheimer's disease	EU5 & Australia	H2 CY27	1,890	1,853.0	10.0%	185.3	0.10
Xanamem in cognitive impairment related to major depressive disorder	US	H2 CY27	1,301	1,116.8	12.5%	117.8	0.07
Xanamem in cognitive impairment related to major depressive disorder	EU5 & Australia	H2 CY27	759	677.2	12.5%	84.6	0.05
Corporate costs				(41.0)	100%	(41.0)	(0.02)
Net cash at 31 December 2022				14.5		14.5	0.01
Total equity value				7,448.1		701.8	0.39

Source: Edison Investment Research

We estimate the company's funds on hand will last into Q4 CY23 (Q224). We continue to model the company will raise A\$20m in FY23 (now H223) and A\$40m in FY24. In total, we forecast A\$410m in additional financings (up from A\$390m previously) will be required before FY29 to fund the development of both the CI-MDD and AD programmes, after which, provided it receives regulatory approval, the company should be able to generate sufficient operating revenues to reach recurring profitability. Our model assumes all financings will be raised through illustrative debt, as per usual Edison methodology. If our projected funding need of A\$410m is raised through equity issuances at the prevailing market price of c A\$0.07, our effective value per share would decrease to A\$0.14 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, although we note that the funding intervals may be staggered over the next several years, which may alleviate potential challenges associated with raising amounts of funds in excess of a company's market capitalisation. We also believe the company will be seeking non-dilutive funding arrangements and/or partnership arrangements (actions towards the latter would likely particularly increase after the XanaMIA Phase IIb portion is completed), which may reduce the overall funding need, but such scenarios are not included in our forecasts.

**Exhibit 2: Financial summary**

	A\$(000)	2020	2021	2022	2023e	2024e
Year end 30 June		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Revenue		3,516	1,984	3,640	4,004	4,086
Cost of Sales		0	0	0	0	0
Gross Profit		3,516	1,984	3,640	4,004	4,086
Sales, General & Administrative		(2,962)	(3,111)	(4,558)	(4,999)	(4,337)
Net Research & Development		(5,537)	(2,406)	(8,215)	(9,394)	(36,364)
EBITDA		(4,983)	(3,533)	(9,133)	(10,389)	(36,614)
Amortisation of intangible assets		(314)	(313)	(313)	(313)	(313)
Depreciation & other		(99)	(74)	(88)	(93)	(279)
Normalised Operating Profit (ex. amort, SBC, except.)		(4,888)	(3,318)	(7,933)	(9,614)	(36,894)
Operating profit before exceptionals		(5,396)	(3,920)	(9,533)	(10,795)	(37,206)
Exceptionals including asset impairment		0	0	0	0	0
Other		(194)	(289)	(1,288)	(869)	0
Reported Operating Profit		(5,590)	(4,209)	(10,821)	(11,664)	(37,206)
Net Finance income (costs)		65	5	36	261	(736)
Profit Before Tax (norm)		(4,822)	(3,313)	(7,897)	(9,353)	(37,629)
Profit Before Tax (FRS 3)		(5,331)	(3,915)	(9,497)	(10,534)	(37,942)
Tax		0	0	0	0	0
Profit After Tax and minority interests (norm)		(4,822)	(3,313)	(7,897)	(9,353)	(37,629)
Profit After Tax and minority interests (FRS 3)		(5,331)	(3,915)	(9,497)	(10,534)	(37,942)
Average Basic Number of Shares Outstanding (m)		1,118.0	1,405.2	1,717.1	1,802.3	1,831.6
EPS - normalised (A\$)		(0.004)	(0.002)	(0.005)	(0.005)	(0.021)
EPS - normalised and fully diluted (A\$)		(0.004)	(0.002)	(0.005)	(0.005)	(0.021)
EPS - (IFRS) (A\$)		(0.005)	(0.003)	(0.006)	(0.006)	(0.021)
Dividend per share (A\$)		0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>						
Fixed Assets		3,772	3,287	2,889	3,534	4,029
Intangible Assets		3,346	3,033	2,720	2,908	3,095
Tangible Assets		19	17	13	627	934
Investments in long-term financial assets		408	237	156	0	0
Current Assets		8,164	15,091	20,417	31,189	32,752
Short-term investments		0	0	0	0	0
Cash		5,040	13,457	16,370	27,556	29,119
Other		3,123	1,634	4,047	3,633	3,633
Current Liabilities		(744)	(755)	(1,480)	(1,708)	(1,708)
Creditors		(744)	(755)	(1,480)	(1,708)	(1,708)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(304)	(165)	(87)	(20,038)	(60,038)
Long term borrowings		0	0	0	(20,000)	(60,000)
Other long term liabilities		(304)	(165)	(87)	(38)	(38)
Net Assets		10,889	17,458	21,740	12,978	(24,964)
<b>CASH FLOW STATEMENT</b>						
Operating Income		(5,590)	(4,209)	(10,821)	(11,664)	(37,206)
Movements in working capital		(3,591)	(1,513)	(3,143)	597	0
Net interest and financing income (expense)		65	5	36	261	(736)
Depreciation & other		99	74	88	93	279
Taxes and other adjustments		6,161	3,920	4,323	2,165	313
Net Cash Flows from Operations		(2,856)	(1,724)	(9,517)	(8,548)	(37,350)
Capex		(23)	(6)	(3)	(1,051)	(1,087)
Acquisitions/disposals		0	0	0	0	0
Interest received & other investing activities		0	0	0	0	0
Net Cash flows from Investing activities		(23)	(6)	(3)	(1,051)	(1,087)
Net proceeds from share issuances		0	10,195	12,491	903	0
Net movements in long-term debt		0	0	0	20,000	40,000
Dividends		0	0	0	0	0
Other financing activities		282	(84)	(71)	(39)	0
Net Cash flows from financing activities		282	10,111	12,420	20,864	40,000
Effects of FX on Cash & equivalents		0	0	49	(80)	0
Net Increase (Decrease) in Cash & equivalents		(2,596)	8,381	2,949	11,186	1,563
Cash & equivalents at beginning of period		7,637	5,040	13,422	16,370	27,556
Cash & equivalents at end of period		5,040	13,422	16,370	27,556	29,119
Closing net debt/(cash)		(5,448)	(13,694)	(16,527)	(7,556)	30,881
Lease debt		390	236	165	127	127
Closing net debt/(cash) inclusive of IFRS 16 lease debt		(5,058)	(13,458)	(16,361)	(7,429)	31,008
Free cash flow		(2,878)	(1,730)	(9,520)	(9,599)	(38,437)

Source: Actinogen Medical accounts, Edison Investment Research

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