EDISON

Actinogen Medical

Capital increase

Funding the next stage of Xanamem development

Pharma and biotech

Actinogen recently provided a Q423 quarterly update summarising that its two development programmes for lead candidate Xanamem remain on track, with the Phase IIb XanaMIA study portion assessing the drug in lead indication Alzheimer's disease (AD) still scheduled to start in H2 CY23, with results still expected in H2 CY25. For the company's XanaCIDD study in patients with cognitive impairment (CI) associated with major depressive disorder (MDD), enrolment is approaching 25% and the company continues to expect results in H1 CY24 as it is opening new US-based study sites to compensate for regulatory delays in the UK. The company reported a 30 June cash position A$8.46m and has announced a A$10m rights offering allowing existing shareholders to purchase up to 400m shares at A$0.025 per share. After rolling forward our estimates, our pre-financing valuation adjusts slightly to A$645m, or A$0.36/share, versus A$640m (A$0.35/share) previously. Overall, we view the financing as a positive and necessary step to continue Xanamem development.

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	4.6	(8.9)	(0.005)	0.0	N/A	N/A
06/24e	4.0	(37.4)	(0.019)	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 Phase IIb clears regulatory hurdles

The Phase IIb portion of the XanaMIA study is designed to assess Xanamem versus placebo in 330 patients with biomarker-positive AD, as determined through an elevated level of phosphorylated Tau-181 (pTau-181) protein in the blood. Following the submission of updated documentation to the FDA on 5 June, relating to proposed modifications in the XanaMIA clinical study protocol and the use of the new tablet Xanamem formulation, the 30-day waiting period for FDA feedback has elapsed, permitting the company to proceed with study enrolment.

Financing to extend cash runway

We believe the A$10m rights offering will likely be largely (if not fully) subscribed, as the exercise price (A$0.025/share) remains below the current share price. We expect the associated funding to extend the company's cash runway into Q1 CY24 (Q3 FY24). We model Actinogen will raise an additional A$20m before end-FY24 given the expected rise in expenses once the AD study begins. We believe Actinogen will subsequently seek non-dilutive funding arrangements, which may reduce future funding needs.

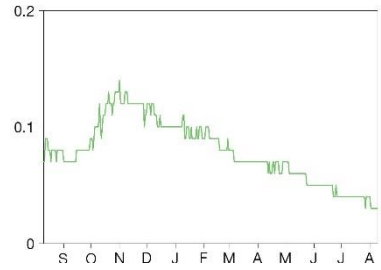
Valuation: Minor changes

After rolling forward our estimates, we now obtain a total pre-financing equity valuation of A$645m, or A$0.36 per share, versus A$640m (or A$0.35 per share), previously. If the rights offering is fully subscribed, as we anticipate is likely to occur, the per-share valuation would be revised to A$0.30 per share.

10 August 2023

Price	**A$0.03**
Market cap	**A$54m**
	A$0.66/US$
Net cash (A$m) at 30 June 2023	8.5
Shares in issue (excluding potential contribution from Q3 CY23 rights offering)	1,816m
Free float	90%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(13.2)	(45.9)	(56.6)
Rel (local)	(16.6)	(46.5)	(58.1)
52-week high/low	A$0.14	A$0.03	

Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11β-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	H2 CY23
Results for Phase II XanaCIDD study in cognitive impairment associated with major depressive disorder	H1 CY24

Analyst

Pooya Hemami OD MBA CFA +1 646 653 7026

healthcare@edisongroup.com

Edison profile page

Actinogen Medical is a research client of Edison Investment Research Limited

Xanamem progress remains on track

Actinogen recently presented its Q423 quarterly activity update providing context on the status of the company's development programmes involving lead candidate Xanamem, an inhibitor of enzyme 11β-Hydroxysteroid dehydrogenase type 1 (11β-HSD1) designed to penetrate the brain. As explained in our prior outlook note, much scientific literature suggests that excessive cortisol is associated with CI in patients with various chronic conditions, including age-related CI and AD. The naturally present enzyme 11β-HSD1 normally converts cortisone to cortisol inside cells and Xanamem is designed to reduce excessive cortisol production in the brain.

The company's lead programme for Xanamem in the treatment of CI associated with AD remains on schedule and it plans to start the upcoming Phase IIb portion of the XanaMIA trial in patients with AD in H2 CY23. After the submission of updated documentation to the FDA on 5 June relating to proposed modifications in the XanaMIA clinical study protocol and providing documentation supporting the use of the new tablet Xanamem formulation, as discussed in our prior note, the 30-day waiting period for FDA feedback has elapsed, permitting the company to proceed with study enrolment. Actinogen expects to report top-line data in H2 CY25 and interim data in late CY24 or early CY25.

The Phase IIb portion of XanaMIA is a placebo-controlled study that will assess Xanamem in patients with mild or moderate stages of biomarker-positive AD, as determined through an elevated level of pTau-181 protein in the blood. The study is designed to enrol 330 patients and patients will be randomised to treatment with 5mg, 10mg or placebo once a day for 36 weeks.

As a reminder, Actinogen reported biomarker data in Q4 CY22 using blood samples from a subset of patients in the prior 185-patient XanADu study in AD patients showing clinical activity and a relatively large effect size at 12 weeks using the FDA-recognised Clinical Dementia Rating Sum of Boxes (CDR-SB) in biomarker-positive AD patients (as determined through patients who had elevated pTau). The 34 patients (16 on Xanamem 10mg daily, 18 on placebo) with pTau levels at or above 6.74pg/ml showed a 0.6 mean difference (effect size) in CDR-SB (representing a 60% relative reduction in disease progression versus placebo) at 12 weeks between the placebo and treatment arms. The primary endpoint of the XanaMIA Phase IIb study will be the change in a cognitive composite of several tests and the CDR-SB functional score will be a secondary endpoint.

Given the limitations of currently approved AD treatments, including anti-amyloid antibodies such as Leqembi, if Xanamem demonstrates positive efficacy data in improving cognition and/or decelerating AD progression versus placebo in a prospectively defined population of AD patients with elevated pTau, we believe there could be material commercial, out-licensing and/or value realisation opportunities for the drug.

Adding US sites to keep XanaCIDD study on schedule

As it relates to its Xanamem programme in CI associated with MDD, in late 2022 the company started the 160-patient XanaCIDD Phase II study assessing the drug candidate in patients with persistent depressive symptoms and CI despite standard-of-care anti-depression therapy. Xanamem 10mg daily or placebo is being added to patients' existing anti-depression therapy and effects on cognition (using the Cogstate Cognitive Test Battery) and depression (using the Montgomery-Asberg Depression Rating Scale) will be evaluated.

The company indicates that enrolment is approaching 25% but it has noted that industry-wide delays by the UK Medicines and Healthcare products Regulatory Agency (MHRA) in approving study sites has impeded the study from activating sites in the UK thus far. The company had originally planned for the XanaCIDD study to recruit patients from the UK and Australia, but given

the MHRA-related delays, it is now opening sites in the US to compensate for such impediments, and it is maintaining its current guidance to report study results in H1 CY24.

Having demonstrated the ability to improve cognition in two earlier trials (XanaHES and the Phase Ib portion of XanaMIA) in healthy adults, Actinogen is confident that Xanamem can exert a similar cognitive improvement effects in MDD patients; this study will also explore whether the drug can have effects on depression as well. If the XanaCIDD study is successful in showing CI improvement, the company may advance it into pivotal studies.

Financials

Actinogen reported an operating cash burn of A$3.8m in Q423 and A$8.8m in FY23, with the latter coming in mildly above our prior A$8.5m estimate. The company reported a cash balance of A$8.46m at fiscal year-end of 30 June 2023. Subsequently Actinogen announced a A$10m shareholder rights issue programme, whereby existing shareholders (at the record date of 14 August) will have the right to, for every 4.54 shares held, purchase one new share at an exercise price of A$0.025 per share. If exercised, for every two new shares issued under the offer, subscribers will also receive a 36-month option to purchase an additional share at A$0.0375 per share. If the rights offer is fully subscribed, the company will receive A$10m in gross proceeds and issue 400m shares (excluding considerations for the attached 36-month options). The closing date of the rights offer is 4 September and the newly issued shares are expected to be tradeable as of 12 September. Given that Actinogen shares are currently trading at A$0.03 each, we believe it is likely the rights issue will be heavily subscribed and possibly fully subscribed. Hence, our financial model now includes an assumption for the full exercise of the A$10m rights offer in H124.

With the funding from the rights offering, we believe Actinogen is now funded into Q1 CY24 (Q324). We have not made any substantive adjustments to our future cost expectations but may revise our forecasts once formal FY23 results are released (anticipated before the end of August). We now model that Actinogen will raise an additional A$20m before end-FY24 given our expectations of increases in R&D expenses as the Phase IIb portion of the XanaMIA study ramps up and as the XanaCIDD study progresses. We assume an FY24 free cash outflow rate of A$38.3m, versus A$38.4m previously. Clinical trial and overall operating costs are expected to increase further in FY25 as the number of enrolled patients under ongoing assessment increases.

We maintain our expectations for potential launches of Xanamem in the AD and MDD indications in CY28 in both indications. Our base-case projection assumes that Actinogen will independently fund all studies needed for regulatory approval in these indications and, given our expectation of successful completion of the Q3 CY23 A$10m rights offering, we have reduced our total projected future funding need (excluding the A$10m rights offering) to A$445m (A$455m previously).

Valuation

Our valuation continues to be based on a risk-adjusted NPV (rNPV) analysis, which includes A$8.46m in net cash at the end of June 2023. 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 indication and 12.5% in the MDD indication. Given that the rights offering has not yet concluded (and no new shares have been issued), our valuation continues to be based on the existing number of shares outstanding and the end-FY23 net cash position. We have rolled forward our estimates and now obtain a total pre-financing equity valuation of A$645m (vs A$640m previously), or A$0.36 per share (vs A$0.35 previously). However, if we

assume the rights offer is subscribed in full (A$10m), the equity valuation per share would be reduced to A$0.30 given the additional 400m shares that would be issued.

Exhibit 1: 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 CI related to AD	US	CY28	3,828	3,735.4	10.0%	312.3	0.17
Xanamem in CI related to AD	EU5 and Australia	CY28	1,812	1,821.4	10.0%	182.1	0.10
Xanamem in CI related to MDD	US	CY28	1,247	1,085.9	12.5%	107.8	0.06
Xanamem in CI related to MDD	EU5 and Australia	CY28	728	666.8	12.5%	83.3	0.05
Corporate costs				(49.2)	100%	(49.2)	(0.03)
Net cash at 30 June 2023				8.5		8.5	0.00
Total equity value				7,268.6		644.8	0.36

Source: Edison Investment Research

As stated earlier, even assuming completion of the A$10m rights offering, we model the company will raise an additional A$20m before the end of FY24. In total, we forecast A$445m in additional financing 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 financing will be raised through illustrative debt, as per usual Edison methodology. If our projected funding need of A$445m is raised through equity issuances at the prevailing market price of c A$0.03, our effective value per share would decrease to A$0.065.

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 funds in excess of a company's market capitalisation. We also believe Actinogen will seek 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.

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 explore partnerships or non-dilutive funding strategies if the XanaMIA Phase IIb data are positive.

Exhibit 2: Financial summary

A$(000)	2020	2021	2022	2023e	2024e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,516	1,984	3,640	4,644	3,979
Cost of Sales	0	0	0	0	0
Gross Profit	3,516	1,984	3,640	4,644	3,979
Sales, General & Administrative	(2,962)	(3,111)	(4,558)	(5,552)	(4,917)
Net Research & Development	(5,537)	(2,406)	(8,215)	(9,148)	(36,364)
EBITDA	(4,983)	(3,533)	(9,133)	(10,056)	(37,301)
Amortisation of intangible assets	(314)	(313)	(313)	(313)	(313)
Depreciation & other	(99)	(74)	(88)	(85)	(201)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,888)	(3,318)	(7,933)	(9,272)	(37,502)
Operating profit before exceptionals	(5,396)	(3,920)	(9,533)	(10,454)	(37,815)
Exceptionals including asset impairment	0	0	0	0	0
Other	(194)	(289)	(1,288)	(869)	0
Reported Operating Profit	(5,590)	(4,209)	(10,821)	(11,323)	(37,815)
Net Finance income (costs)	65	5	36	348	78
Profit Before Tax (norm)	(4,822)	(3,313)	(7,897)	(8,924)	(37,424)
Profit Before Tax (FRS 3)	(5,331)	(3,915)	(9,497)	(10,106)	(37,737)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,822)	(3,313)	(7,897)	(8,924)	(37,424)
Profit After Tax and minority interests (FRS 3)	(5,331)	(3,915)	(9,497)	(10,106)	(37,737)
Average Basic Number of Shares Outstanding (m)	1,118.0	1,405.2	1,717.1	1,806.0	2,016.3
EPS - normalised (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.019)
EPS - normalised and fully diluted (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.019)
EPS - (IFRS) (A$)	(0.005)	(0.003)	(0.006)	(0.006)	(0.019)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	3,772	3,287	2,889	2,528	3,099
Intangible Assets	3,346	3,033	2,720	2,408	2,595
Tangible Assets	19	17	13	120	504
Investments in long-term financial assets	408	237	156	0	0
Current Assets	8,164	15,091	20,417	12,742	4,434
Short-term investments	0	0	0	0	0
Cash	5,040	13,457	16,370	8,460	152
Other	3,123	1,634	4,047	4,282	4,282
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)	(38)	(20,038)
Long term borrowings	0	0	0	0	(20,000)
Other long term liabilities	(304)	(165)	(87)	(38)	(38)
Net Assets	10,889	17,458	21,740	13,524	(14,213)
CASH FLOW STATEMENT					
Operating Income	(5,590)	(4,209)	(10,821)	(11,323)	(37,815)
Movements in working capital	(3,591)	(1,513)	(3,143)	(52)	0
Net interest and financing income (expense)	65	5	36	348	78
Depreciation & other	99	74	88	85	201
Taxes and other adjustments	6,161	3,920	4,323	2,165	313
Net Cash Flows from Operations	(2,856)	(1,724)	(9,517)	(8,777)	(37,223)
Capex	(23)	(6)	(3)	(37)	(1,085)
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)	(37)	(1,085)
Net proceeds from share issuances	0	10,195	12,491	903	10,000
Net movements in long-term debt	0	0	0	0	20,000
Dividends	0	0	0	0	0
Other financing activities	282	(84)	(71)	0	0
Net Cash flows from financing activities	282	10,111	12,420	903	30,000
Effects of FX on Cash & equivalents	0	0	49	(1)	0
Net Increase (Decrease) in Cash & equivalents	(2,596)	8,381	2,949	(7,910)	(8,308)
Cash & equivalents at beginning of period	7,637	5,040	13,422	16,370	8,460
Cash & equivalents at end of period	5,040	13,422	16,370	8,460	152
Closing net debt/(cash)	(5,448)	(13,694)	(16,527)	(8,460)	19,848
Lease debt	390	236	165	127	127
Closing net debt/(cash) inclusive of IFRS16 lease debt	(5,058)	(13,458)	(16,361)	(8,333)	19,974
Free cash flow	(2,878)	(1,730)	(9,520)	(8,813)	(38,308)

Source: Edison Investment Research, company reports

General disclaimer and copyright

This report has been commissioned by Actinogen Medical and prepared and issued by Edison, in consideration of a fee payable by Actinogen Medical. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom