

Actinogen Medical

Quarterly update

Continued focus on Xanamem

Pharma and biotech

2 May 2023

Price **A\$0.07**

Market cap **A\$127m**

A\$0.66/US\$

Net cash (A\$m) at 31 March 2023 12.3

Shares in issue 1,816m

Free float 90%

Code ACW

Primary exchange ASX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 1.5 (28.3) (21.4)

Rel (local) 0.1 (26.5) (20.4)

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 β -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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Actinogen's Q323 update reiterated the company's focus on advancing its lead asset Xanamem. Patient recruitment in the Phase IIa XanaCIDD study in cognitive impairment (CI) associated with major depressive disorder (MDD) is ongoing, and the company plans to start the Phase IIb portion of the XanaMIA study in Q2 CY23 in the company's lead indication, Alzheimer's disease (AD). This study portion is designed to assess 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 AD. We continue to see the results from the XanaCIDD study (expected in late CY23 or early CY24) as the next major clinical data milestone and a potential share price catalyst. We expect the company's A\$12.3m cash balance at 31 March to fund operations into Q4 CY23.

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 Phase IIb expected to start imminently

We believe market participants will be keen to observe whether the Phase IIb portion of XanaMIA will confirm the positive AD efficacy findings shown by Xanamem in [a subset biomarker analysis](#) from the earlier [XanADu study](#). We expect top-line results in late CY24 or H1 CY25, which if positive 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. In the nearer term, data are expected in around six to 12 months from the six-week XanaCIDD proof-of-concept study in patients with persistent MDD and CI. As Xanamem targets excess brain cortisol, and given the benefits shown in healthy adults in earlier studies ([XanaHES](#) and the [Phase IIb portion of XanaMIA](#)), we believe it is plausible for cognitive benefits to also be shown in the MDD population.

Funding to be a key focus as trials progress

Actinogen reported an operating cash burn of A\$2.2m in Q323 (broadly in line when annualised with our unchanged FY23e A\$8.5m estimate) and had a cash balance of A\$12.3m at 31 March. We believe the company remains funded into Q4 CY23 (Q224) and continue to model it will raise A\$60m before end-FY24 given the expected rise in expenses once the AD study commences.

Valuation: Maintaining forecasts

Our forecasts are unchanged (please see [our prior note](#) for details) and our total equity valuation remains A\$702m, or A\$0.39 per share. While the total funding requirements to bring an AD drug to market are substantial, we believe Actinogen will seek non-dilutive funding and/or partnership arrangements, which may reduce the overall funding need, but such scenarios are not included in our base case forecasts.

Exhibit 1: 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	4,004	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
BALANCE SHEET						
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)
CASH FLOW STATEMENT						
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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