EDISON

Actinogen Medical

Further positive XanaCIDD results on depression

Additional XanaCIDD data

Pharma and biotech

New data were revealed from Actinogen Medical's ongoing analysis of the now-completed XanaCIDD study that support the view that the company's lead drug candidate, Xanamem, may provide consistent and durable benefits in treating depression symptoms compared to placebo. The XanaCIDD study was designed to assess a 10mg daily dose of Xanamem versus placebo in patients with major depressive disorder (MDD) over a six-week treatment period. In line with the top-line results reported on 12 August, the new data confirm that maximal treatment effects on depression on all endpoints occurred at week 10, or four weeks after the end of the six-week treatment period. The results appear to be consistent with the molecule having a durable clinical effect in terms of controlling brain cortisol and potentially exerting anti-depressant activity.

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.

Actinogen has reported new data from its Phase IIa XanaCIDD study that build on the earlier reported top-line results that showed a statistically significant ($p<0.05$) improvement at week 10 on the MADRS scale assessing depression symptoms. The newly reported results continue to demonstrate the strongest effects occurred at week 10, indicative of a durable treatment effect. Positive effects on the MADRS scale were also shown in five of six pre-specified subgroups. Effects on depression symptoms were also confirmed with findings from a second, well-validated endpoint, the Patient Global Impression of Severity score in depression. The company plans to host a webinar to discuss the updated trial results on 29 August at 11am, AEST.

If improvements in addressing depression symptoms are consistently shown in future trials, Xanamem has the potential to be differentiated from existing approved drug treatments for depression due to its unique mechanism of action involving the suppression of cortisol formation in the brain. So far, the drug has shown a favourable safety profile across multiple studies involving over 380 patients in total. Actinogen will assess the path forward with regulators and key opinion leaders for a Phase IIb study in MDD that could start as early as H2 CY25.

While the potential in depression is promising, we believe that the larger opportunity for Xanamem lies in its potential as a treatment to slow progression of cognitive impairment in patients with Alzheimer's disease (AD). The largest potential clinical catalyst in this area will be the interim analysis (expected in mid-CY25) of the first c 100 patients from the ongoing Phase IIb XanaMIA study, which prospectively enrols AD patients with elevated pTau-181. Investors will look R=at whether these data will confirm the positive efficacy findings shown in the XanADu subset biomarker analysis.

27 August 2024

Price	**A$0.045**
Market cap	**A$122m**
Net cash (A$m) at 30 June 2024	9.5
Shares in issue	2,712m
Free float	90%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

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 in patients with Alzheimer's disease and as a therapy to treat depression symptoms in patients with major depressive disorder.

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