

Incannex Healthcare

Encouraging signals from PsiGAD interim review

Clinical development update

Pharma and biotech

15 March 2023

Price **US\$2.3**

Market cap **US\$146m**

ADR/Ord conversion ratio 1:25
US\$/A\$1.5

Net cash (A\$m) at 31 December 2022 41.4

ADRs in issue 63.5m

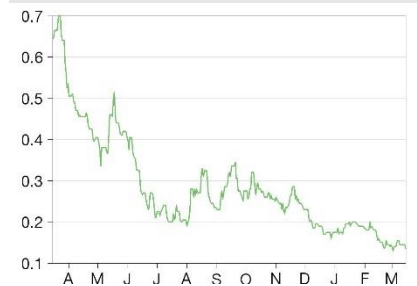
ADR code IXHL

ADR exchange NASDAQ-GM

Underlying exchange ASX

Depository DBK

Share price performance



Business description

Incannex Healthcare is an Australian dual-listed biotech company focused on developing medicinal cannabis pharmaceutical products and psychedelic medicine therapies. These therapies are being designed to target indications with unmet need, including obstructive sleep apnea, generalized anxiety disorder, trauma and inflammatory conditions.

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Incannex has [reported](#) positive interim safety data from its ongoing Phase II PsiGAD study. A review by an independent Data Safety Monitoring Board (DSMB) identified no safety concerns from the first 37 patients enrolled (expected to recruit 72 in total) in the trial and has recommended no changes to the study design. Additionally, based on the interim analysis of 29 patients who have completed the study protocol, the company projects a more than 85% probability that the psilocybin treatment arm will provide a statistically significant benefit over the placebo treatment arm of the study. While we advise caution in the interpretation of modelling projections to predict trial outcomes, these early observations of safety and potential efficacy, in our view, support the continuation of Incannex's psilocybin-assisted psychotherapy program for generalized anxiety disorder (GAD). We see trial completion (expected by Q423) as a key upcoming catalyst.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/21	2.0	(8.2)	(0.83)	0.0	N/A	N/A
06/22	0.8	(14.9)	(1.25)	0.0	N/A	N/A
06/23e	0.1	(20.7)	(1.43)	0.0	N/A	N/A
06/24e	0.1	(33.4)	(2.10)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

The ongoing Phase II PsiGAD study is assessing the effectiveness of the psychedelic, psilocybin, in conjunction with psychotherapy in patients suffering from GAD. The study is a triple-blind, active placebo-controlled trial aiming to recruit a total of 72 patients. The primary endpoint of the study is a reduction in the Hamilton Anxiety Rating Scale (HAM-A) score at 11 weeks relative to baseline. The HAM-A scale is a clinically recognized method of measuring anxiety symptoms, which has been used to [support FDA approval](#) of treatments for GAD. Patient recruitment commenced in Q1 CY22 and, to date, more than 45 participants have been enrolled, of whom 29 have completed the 10-week treatment protocol. Treatment for all 72 participants is expected to complete by Q423. We note that Incannex's [observations](#) on the potential statistically significant benefit of psilocybin are based on extrapolating the study results from the first 29 participants to the overall cohort of 72 patients and have not been independently verified by the DSMB.

As a reminder, in [February 2023](#), the Australian regulatory authority, the Therapeutic Goods Administration, permitted (effective 1 July) the off-label prescription of therapeutics containing psilocybin (for treatment-resistant depression) and MDMA (for post-traumatic stress disorder) by psychiatrists under controlled conditions, marking a key step towards acceptance of psychedelics as therapeutic options for mental disorders. GAD afflicts more than 3% of the US population ([c 6.8 million](#) US adults) with [c 50%](#) of treated cases not responding to first-line treatment, highlighting the significant unmet need in the space.

Final data from the PsiGAD Phase II study (expected in Q423) will be used to support an investigational new drug application with the FDA, which we see as a key inflection point for Incannex.

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