EDISON

Incannex Healthcare

Q123 trading update

IHL-42X gearing up for FDA studies

Pharma and biotech

Incannex Healthcare announced the initiation of a bioavailability/bioequivalence (BA/BE) study assessing the company's lead clinical asset IHL-42X. Results from the BA/BE study are a prerequisite to pursue the FDA's 505(b)(2) new drug application regulatory pathway, which forms a critical part of management's expedited clinical development strategy for its assets, so we see the commencement as positive preparatory activity. Additionally, management intends to open an investigational new drug (IND) application with the FDA in Q1 CY23 to initiate Phase II/III studies of IHL-42X. Incannex's clinical strategy is to progress development through later-stage FDA studies, so we view this confirmation from management as encouraging for IHL-42X's overall development. We continue to value Incannex at US$714.7m or US$11.74 per ADR.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (A$)	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	0.0	(20.6)	(1.38)	0.0	N/A	N/A
06/24e	0.0	(33.4)	(2.24)	0.0	N/A	N/A

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

As a reminder, IHL-42X is Incannex's most advanced clinical asset, a synergistic combination of dronabinol (synthetic THC) and acetazolamide, being investigated for the treatment of obstructive sleep apnoea (OSA), a respiratory disorder in which individuals experience irregular and disruptive breathing during sleep. The BA/BE study will be conducted in Australia by CMAX Clinical Research and Novotech CRO and will recruit 116 participants to assess the pharmacokinetic and tolerability profile of the combination of dronabinol and acetazolamide.

IHL-42X has previously demonstrated an encouraging safety and efficacy profile from its key proof-of-concept Australian Phase II study, which we believe will significantly support its planned IND application in Q1 CY23. Incannex had previously communicated that it would look to file an IND in Q4 CY22; however, we do not see this slight delay as having significant implications on IHL-42X's developmental timeline.

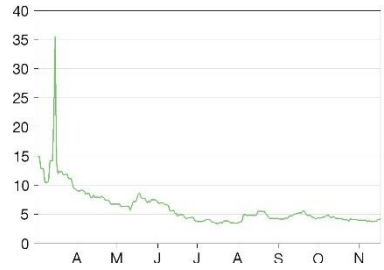
Should the IND for IHL-42X be approved, Incannex intends to initiate an international, multi-site Phase II/III study in H1 CY23 that would include trial sites in the United States. The study would assess the efficacy of IHL-42X in patients with OSA across a 12-month treatment period at the doses established from its Australian Phase II study.

Additionally, we believe the latest news provides a positive outlook in the broader context of Incannex's development pipeline as the company aims to pursue and leverage Australian trial data to guide future trial design and expedite FDA regulated studies.

18 November 2022

Price	**US$4.2**
Market cap	**US$211m**
	ADR/Ord conversion ratio 1:25
Net cash (US$m) at end Q123	21.4
ADRs in issue	60.9m
ADR code	IXHL
ADR exchange	NASDAQ-GM
Underlying exchange	ASX
Depositary	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 designed to target indications with unmet need, including obstructive sleep apnea, generalized anxiety disorder, trauma and inflammatory conditions.

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