EDISON

Incannex Healthcare

H1 results update

Strong cash position supports clinical progression

Pharma and biotech

Following its Q223 cash flow report in February, Incannex has reported detailed interim H123 results. The period was mainly focused on enhanced clinical efforts across its drug development portfolio, including initiation of a bioavailability and bioequivalence study for its lead clinical asset IHL-42X, a positive pre-IND meeting with the FDA on IHL216A (for concussion and traumatic brain injury) and the completion of patient dosing in the Phase I trial of IHL-675A. IHL-675A is being considered for rheumatoid arthritis (RA), inflammatory bowel disease and lung inflammation, and the company started a Phase II study in late February 2023 in RA. We expect continued clinical progress over CY23, including anticipated IND applications and additional clinical study starts. With the recent private placement of A$13m (US$8.7m), the company's net cash position stood at A$41.4m (US$27.8m), which, based on our estimates, provides a cash runway to the second half of FY24. We value Incannex at US$745.8m or US$11.75/ADR (US$736.6m or US$11.7/ADR previously).

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.

Clinical development across the portfolio

During H123, Incannex recorded developments across its clinical pipeline. For its proprietary inhaled drug product, IHL-216A, the company received detailed feedback for the future clinical development plan from the FDA, followed by a positive pre-IND meeting and pre-IND package submission in August 2022. Additionally, Incannex plans to submit an IND application in the first quarter of CY23 for IHL-42X in obstructive sleep apnea and, if approved, may initiate an international, multi-site Phase II/III study in the first half of CY23. Furthermore, Incannex has now started a Phase II study assessing the efficacy and safety of IHL-675A in RA patients.

A$13m private placement to extend the cash runway

In December 2022, Incannex raised a total of A$13m (gross proceeds) through a private placement, issuing 63.4m new common shares at A$0.0205/share. In addition to this, the subscribers were offered an equal number (63.4m) of new options, exercisable at A$0.285 per option. The options, if exercised in full, might raise a further A$18.1m in proceeds. Post the private placement, we now expect Incannex to need A$55m in additional funding before reaching profitability in FY26.

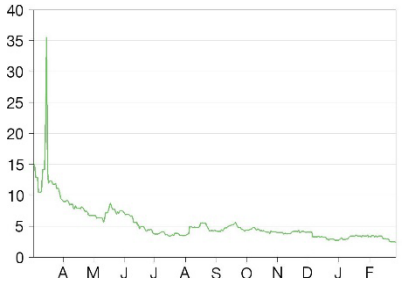
Valuation: US$745.8m or US$11.75 per ADR

Our valuation for Incannex increases slightly to US$745.8m or US$11.75 per ADR (US$736.6m or US$11.7 per ADR previously), mainly due to rolling our model forward and foreign exchange movements. With a net cash position of A$41.4m, based upon our projections, we estimate an operational cash runway into H224.

1 March 2023

Price	**US$2.6**
Market cap	**US$150m**
ADR/Ord conversion ratio 1:25	US$/A$ 0.67
Net cash (A$m) at 31 December 2022	41.4
ADRs in issue	63.5m
ADR code	IHXL
ADR exchange	NASDAQ-GM
Underlying exchange	ASX
Depository	DBK

Share price performance



%	1m	3m	12m
Abs	(29.3)	(41.8)	N/A
Rel (local)	(27.8)	(41.10	N/A
52-week high/low	US$35.5	US$2.5	

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.

Next events

Open FDA IND for IHL-42X	Q1 CY23

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Edison profile page

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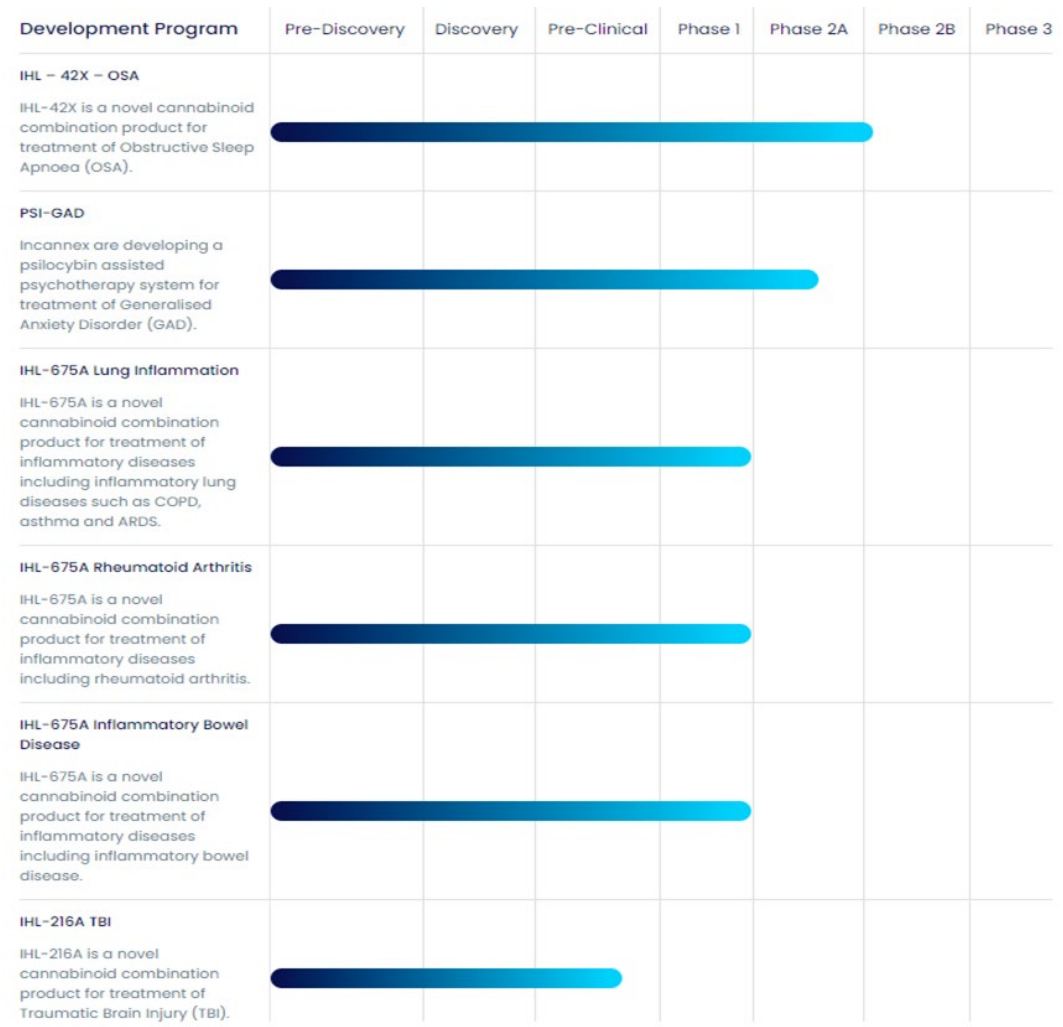
Aiming for FDA studies in 2023

Incannex continues to make headway in advancing its busy clinical pipeline and 2023 is shaping up to be a critical year for the company's lead assets. Management intends to submit an investigational new drug (IND) application with the FDA in the first quarter of CY23 for IHL-42X (dronabinol and acetazolamide) in the treatment of obstructive sleep apnea (OSA), which, if approved, would set Incannex up to initiate an international Phase II/III clinical study in the first half of CY23. Interim data from the Australian Phase II trial (Psi-GAD1) of psilocybin-assisted psychotherapy in the treatment of generalized anxiety disorder (GAD) is currently being reviewed by an independent data safety monitoring board. We expect to see these interim trial results in the first quarter of CY23, representing a near-term potential clinical catalyst for Incannex. Finally, the results of an Australian Phase I study of IHL-675A (cannabidiol (CBD) and hydroxychloroquine (HCQ)) found the anti-inflammatory cannabinoid combination treatment to be safe and well tolerated in healthy volunteers. While IHL-675A potentially has a broad scope across anti-inflammatory indications, Incannex is initially focusing on RA and has now initiated an Australian Phase II trial in this setting. Global sales of RA drugs reached c US$29bn in 2021 (source: Evaluate Pharma), highlighting the potential scope in this target market.

Exhibit 1: Incannex clinical pipeline



Source: Incannex company website

IHL-42X leading the way in the clinic

IHL-42X continues to be Incannex's flagship asset, and is now closest to progressing into what would be the company's first FDA-regulated clinical studies. Incannex has already begun preparatory activities to support such trials through the initiation of a bioavailability/bioequivalence (BA/BE) study for IHL-42X in November 2022. 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. As a reminder, the FDA's 505(b)(2) approval pathway allows companies to leverage pre-existing safety data for marketed therapies, potentially negating the requirement for certain safety studies, which, ultimately, may help conserve cash resources and accelerate commercialization. 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 the first quarter of CY23. 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.

Positive developments towards greater psychedelic acceptance

Incannex's ongoing Australian Phase II Psi-GAD1 study is a triple-blind, active placebo-controlled trial to assess the safety, efficacy and tolerability of psilocybin-assisted psychotherapy in patients with GAD. A team of experienced clinicians is conducting the Psi-GAD1 trial at Monash University's BrainPark. The study aims to recruit a total of 72 patients and, when interim analysis commenced in January 2023, it had enrolled 45 participants, with 29 having completed the 10-week treatment protocol. The interim analysis will be conducted by an independent data safety monitoring board formed of subject experts. Incannex's management intends to use the interim analysis to make key decisions on regulatory strategy and potential pivotal studies.

Additionally, a significant regulatory development that, in our view, could potentially have a positive impact on the clinical utility, uptake and overall sentiment surrounding psychedelics, as well as support Incannex's psychedelic program's future development, was the Therapeutic Goods Administration's (TGA's) decision to grant patients access to psychedelic medicines under certain treatment settings. The TGA, which is the Australian regulatory authority, announced it will permit psychiatrists to prescribe (off-label) therapeutics containing psilocybin (for treatment-resistant depression, TRD) and MDMA (for post-traumatic stress disorder, PTSD). Following the TGA's decision, Australia has become the first country to officially recognize MDMA and psilocybin as potentially clinically efficacious medicines. Under the ruling, psilocybin and MDMA will now transition from being Schedule 9 drugs (prohibited for patient use) to Schedule 8 or controlled drugs (for PTSD and TRD, respectively), allowing them to be prescribed under certain strict pre-conditions by qualified psychiatrists, effective 1 July. Given there are currently no 'approved' products containing these psychedelics, usage is likely to be off label for now and limited to the most extreme cases. Lack of reimbursement at present is also likely to restrict usage, although we believe data from these first users would be crucial to inform broader clinical development and regulatory decision-making.

An initial focus on rheumatoid arthritis for IHL-675A

Incannex's latest asset, IHL-675A, has already generated initial clinical results in the form of safety data from an Australian Phase I study. The Phase I trial recruited three patient cohorts (n=12 per cohort), with each group being treated with either IHL-675A, CBD or HCQ. The results of the study

recorded no serious adverse events among patients in each of the study arms. Following these positive results, Incannex has continued to progress the development of IHL-675A and, more recently, initiated a blinded, placebo-controlled Phase II study, focusing on the treatment of RA patients. The trial intends to recruit up to 120 patients across trial sites in Australia and New Zealand, investigating the safety and effect on pain and function of IHL-675A, with trial participants being assessed over a 24-week period. The results of the study, if positive, will form a key component of the data package Incannex intends to use when approaching the FDA in the support of future clinical trial design and pursuit of the 505(b)(2) new drug application regulatory pathway.

If approved in RA, we expect IHL-675A would be competing with several multi-billion-dollar drugs for market share such as AbbVie's Rinvoq (2021 global sales US$1.6bn) and Eli Lilly's Olumiant (2021 global sales US$1.0bn) as well as competition from biosimilars of AbbVie's longstanding multi-billion-dollar Humira (2021 global sales US$6.8bn). Owing to this, we believe it will be exceptionally important for Incannex to differentiate IHL-675A in the RA market possibly through long-term safety and/or use in highly specific subsets of patients as well as through pricing.

Valuation

We value Incannex at US$745.8m or US$11.75 per ADR (versus US$736.6m or US$11.7 per ADR previously), based on a risk-adjusted NPV for IHL-42X in OSA and psilocybin in GAD and a net cash position of US$27.8m (A$41.4m) at 31 December 2022. Our model applies a discount rate of 12.5%. We have currently excluded IHL-675A from our valuation until we obtain further context on the drug candidate's development and commercialization strategy; however, this has potential to offer further upside. Our latest valuation is little changed overall and reflects the effects of rolling forward our model, foreign exchange movements and updating the net cash amount. However, our underlying assumptions and long-term outlook remain unchanged. A breakdown of our rNPV valuation is shown in Exhibit 2.

Exhibit 2: Incannex Healthcare rNPV valuation

Product	Launch	Peak	Peak sales (US$m)	Value (US$m)	Probability	rNPV (US$m)	rNPV/ADR (US$)
Obstructive sleep apnea – IHL-42X	2026	2032	3,065.8	3,568.5	20%	710.1	11.19
Psilocybin (Psi-GAD) in generalized anxiety disorder	2027	2032	186.6	129.7	10%	8.0	0.13
Net cash at 31 December 2022				27.8	100%	27.8	0.44
Valuation				**3,725.9**		**745.8**	**11.75**

Source: Edison Investment Research

Financials

As expected, Incannex reported no revenue in H123. However, it recorded other operating income of A$1.0m pertaining to an R&D tax refund. Total operating expenses for H123 were A$9.7m, a 65.1% y-o-y increase and largely in line on an annualized basis with our estimate for FY23 operating expenses (A$20.7m). The higher operating expenses year-on-year were mainly driven by increased R&D expenses, which rose 83.8% y-o-y to A$4.4m in H123, indicating expanded clinical activity across its development pipeline (IHL-216A, IHL-42X, IHL-675A and Psi-GAD1 study). We estimate R&D costs to come in at A$9.8m in FY23 and A$21.6m in FY24, with the anticipated initiation of the Phase II/III IHL-42X study as well as additional trials for Psi-GAD and IHL-675A. Other factors contributing to an increase in operating expenses were share-based payments and payroll expenses. Operating cash outflows were A$8.1m in H123, higher than A$5.4m in H122.

In December 2022, Incannex announced a fund-raise of A$13m in gross proceeds through a private placement to a healthcare-focused group of institutional investors. The company issued 63.4m new

shares of common stock at A$0.205/share, as per the placement terms. Also, the subscribers were offered an equivalent number (63.4m) of new options, exercisable at A$0.285 per option. If fully exercised, these options may raise a further A$18.1m in proceeds. The company intends to utilize the proceeds of the raise to develop its clinical pipeline (including 22 cannabinoid developmental assets acquired as part of the APIRx acquisition). After the private placement, Incannex had a net cash position of A$41.4m at 31 December 2022, which management has communicated should be adequate to fund its clinical programs and working capital requirements into the first quarter of CY25. However, we anticipate higher operating expenses in FY24 due to likely clinical advancements across Incannex's drug development pipeline and estimate a cash runway into the second half of FY24 as per our projected burn rates. We note that our expenditure forecasts differ from the company's current guidance, which guidescalls for a funding runway into CY25. Furthermore, we expect Incannex will require A$55m in additional funding (excluding the effect of the attached options in the December fund raise) before reaching profitability in FY26 with the launch of IHL-42X. We account for this raise as illustrative debt in our model. Alternatively, if the funding is realized through an equity issue instead (assuming at the current trading price of US$2.6/ADR), Incannex would have to issue 14.2m ADRs or 355m shares, resulting in our per ADR valuation coming down to US$9.7/ADR from US$11.89 currently (ADRs outstanding would increase from 63.4m to 77.7m).

Exhibit 2: Financial summary

Accounts: IFRS; year end 30 June; A$000s	2020	2021	2022	2023e	2024e
PROFIT & LOSS					
Total revenues	822	1,973	789	77	79
Cost of sales	(450)	(912)	(6)	0	0
Gross profit	372	1,061	782	77	79
Total operating expenses	(4,301)	(9,225)	(15,686)	(20,729)	(33,482)
Research and development expenses	(2,111)	(4,750)	(5,372)	(9,848)	(21,600)
SG&A	(864)	(1,236)	(3,027)	(3,399)	(4,157)
Operating income (reported)	(3,929)	(8,164)	(14,904)	(20,652)	(33,403)
Finance income/(expense)	0	0	0	0	0
Exceptionals and adjustments	0	0	0	0	0
Net loss from discontinued operations	(768)	0	0	0	0
Profit before tax (reported)	(4,698)	(8,164)	(14,904)	(20,652)	(33,403)
Profit before tax (normalized)	(4,698)	(8,164)	(14,904)	(20,652)	(33,403)
Income tax expense (includes exceptionals)	0	0	0	0	0
Net income (reported)	(4,698)	(8,164)	(14,904)	(20,652)	(33,403)
Net income (normalized)	(4,698)	(8,164)	(14,904)	(20,652)	(33,403)
Basic average number of shares, m	684.0	978.0	1,191.2	1,439.7	1,587.0
Basic EPS (cents per share)	(0.69)	(0.83)	(1.25)	(1.43)	(2.10)
Adjusted EPS (cents per share)	(0.69)	(0.83)	(1.25)	(1.43)	(2.10)
Dividend per share (cents per share)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Tangible assets	0	0	0	147	96
Intangible assets	0	0	0	52,717	52,717
Right-of-use assets	0	0	0	224	224
Other non-current assets	0	0	0	0	0
Total non-current assets	0	0	0	53,088	53,037
Cash and equivalents	3,603	9,124	37,501	29,635	21,330
Current tax receivables	0	0	0	0	0
Trade and other receivables	413	169	295	292	307
Inventory	183	0	0	0	0
Other current assets	36	36	84	259	259
Total current assets	4,236	9,329	37,880	30,186	21,896
Non-current loans and borrowings	0	0	0	0	25,000
Non-current lease liabilities	0	0	0	182	182
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	0	0	0	182	25,182
Accounts payable	955	755	2,011	1,240	1,302
Illustrative debt	0	0	0	0	0
Current lease obligations	0	0	0	50	50
Other current liabilities	117	0	0	0	0
Total current liabilities	1,072	755	2,011	1,291	1,353
Equity attributable to company	3,164	8,574	35,869	81,802	48,399
	0	0	0	0	0
CASH FLOW STATEMENT					
Operating income	(4,698)	(8,164)	(14,904)	(20,652)	(33,403)
Depreciation and amortization	37	0	0	51	51
Share based payments	565	1,172	1,465	1,640	0
Other adjustments	97	91	(594)	0	0
Movements in working capital	91	(10)	1,226	(943)	47
Cash from operations (CFO)	(3,907)	(6,910)	(12,807)	(19,904)	(33,305)
Capex	13	0	0	(166)	0
Acquisitions & disposals net	0	29	0	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	13	29	0	(166)	0
Capital changes	7,469	12,401	41,185	12,222	0
Debt Changes	(65)	0	0	0	25,000
Other financing activities	0	0	0	(23)	0
Cash from financing activities (CFF)	7,404	12,401	41,185	12,199	25,000
Cash and equivalents at beginning of period	93	3,603	9,124	37,501	29,635
Increase/(decrease) in cash and equivalents	3,510	5,520	28,377	(7,871)	(8,305)
Effect of FX on cash and equivalents	0	0	0	5	0
Cash and equivalents at end of period	3,603	9,124	37,501	29,635	21,330
Net (debt)/cash	3,603	9,124	37,501	29,635	21,330

Source: Incannex Healthcare company accounts, Edison Investment Research. Note: Intangible assets of A$52.7m in FY23 (and also reflected in subsequent years) are related to the acquisition of APIRx Pharmaceuticals in August 2022.

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