EDISON

Incannex Healthcare

Initiation of coverage

Addressing unmet needs via unique approach

Pharma and biotech

Incannex Healthcare is an Australian biotech specializing in the development of treatments for chronic conditions through a unique approach. Specifically, the company is investigating the use of cannabinoids and psychedelics, leveraging its synergistic combination intellectual property (IP). Most recently, it has achieved proof-of-concept in Australia for IHL-42X, its lead asset for the treatment of obstructive sleep apnea (OSA). The company intends to file an investigational new drug application (IND) with the FDA (in CY Q422) following positive Phase II results from its Australian clinical trial data. Incannex is also progressing development of its (Australian) Phase II clinical asset, psilocybin in combination with psychotherapy in generalized anxiety disorder (GAD). We value Incannex at US$695.7m or US$11.42 per ADR.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/20	0.8	(4.7)	(0.69)	0.0	N/A	N/A
06/21	2.0	(8.2)	(0.83)	0.0	N/A	N/A
06/22e	0.9	(9.7)	(0.82)	0.0	N/A	N/A
06/23e	0.1	(14.9)	(1.01)	0.0	N/A	N/A

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

Differentiated development platform

Incannex is focused on the development of a global and diverse footprint over large indications (employing cannabinoids and psychedelics) to address chronic illness with limited treatment options. The company's platform leverages its IP and pre-existing public data for compounds (through the pursuit of 505(b)(2) NDA regulatory pathways) during clinical development to accelerate commercialization and improve the probability of clinical success. Incannex has received FDA agreement for IHL-42X to forgo preclinical animal studies prior to opening an IND.

APIRx acquisition expands addressable footprint

Incannex announced the acquisition of APIRx Pharmaceuticals, which management anticipates will increase the throughput of investigated cannabinoid treatments. APIRx has established foundational capabilities and is progressing with 22 cannabinoid developmental programs. Established manufacturing/supply relationships for the core IHL programs at both a drug substance and drug product level should create new opportunities.

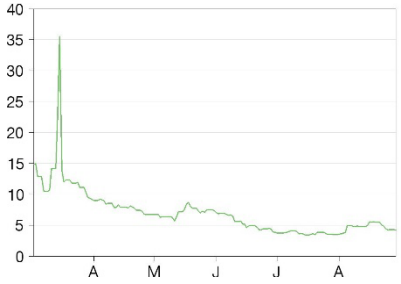
Valuation: US$695.7m or US$11.42 per ADR

We value Incannex at US$695.7m or US$11.42 per ADR, based on a risk-adjusted NPV for IHL-42X in OSA and psilocybin in GAD. As of the end of June, the company had a net cash position of A$37.5m (US$26.1m). Based on the CY Q222 burn rate of A$3.9m (US$2.7m) and adjusted for the anticipated increased in R&D spending, we estimate that the company has a cash runway into CY H223 (ie H124).

30 August 2022

Price	**US$4.24**
Market cap	**US$258m**
	ADR/Ord conversion ratio 1:25
Net cash (US$m, unaudited) at end Q422	26.1
ADRs in issue	60.9m
ADR Code	IXHL
ADR exchange	NASDAQ-GM
Underlying exchange	ASX
Depository	DBK

Share price performance



%	1m	3m	12m
Abs	21.5	(43.4)	N/A
Rel (local)	24.5	(41.6)	N/A
52-week high/low	US$35.5	US$3.44	

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

Phase IIa Psi-GAD interim data readouts	Q422
Open FDA IND for IHL-42X	Q422
Full year results	Q322

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Edison profile page

Investment summary

Company description: Gearing up for the US market

Incannex is a Melbourne-based biotechnology company focused on the development of new therapeutic cannabinoid combinations to address chronic areas with limited competing treatment options. These combinations primarily employ a cannabinoid plus a generic medicine, or psychedelic plus psychotherapy. The company (excluding its recent acquisition) is actively managing three clinical programs. The company's most advanced program is IHL-42X for the treatment of OSA. Incannex has completed a Phase II study with IHL-42X and is planning to file an IND to initiate FDA regulated trials, which management expects in CY23. All clinical programs have, so far, been conducted in Australia.

The second Phase II program (Psi-GAD) is investigating the use of psilocybin combined with psychotherapy for the treatment of patients with GAD. The study is underway, and we expect final patient enrolment to be completed in Q322. The company also recently initiated a Phase I trial to investigate its multi-use inflammatory drug, IHL-675A (a combination of cannabidiol (CBD) and hydroxychloroquine sulfate (HCQ). Incannex is pursuing three indications with IHL-675A: rheumatoid arthritis, inflammatory bowel disease and lung inflammation.

We believe that the company's clinical strategy of conducting smaller proof-of-concept studies in Australia to support US IND applications and management's regular discussions with the FDA to guide trial design provides encouraging signs for future trial approvals by the FDA. Of further note, Incannex's lead clinical candidates (IHL-42X, IHL-675A and IHL-216A) are manufactured under good manufacturing practice (GMP) conditions with no raw materials being naturally derived. Incannex has also now halted supply of cannabinoid products through the Australian Special Access Scheme to focus on the development of drugs targeting regulatory approval.

It is worth noting that management's strategy to pursue synergistic combination patent filings of its assets has the potential to create extensive protection within the cannabinoid treatment market. The IP position for the combinations will be further supported by method of use and formulation patents. Combination patents could therefore be a significant source of value for the company should approval be granted.

Valuation: US$695.7m or US$11.42 per ADR

Based on a risk-adjusted NPV for IHL-42X in OSA (peak sales US$3,065m, rNPV of US$665.5m) and psilocybin in GAD (peak sales US$187m, rNPV of US$4.0m), we value Incannex at US$695.7m or US$11.42 per ADR. Our estimates include the company's net cash position of A$37.5m (US$26.1m), as full financials for FY22 have yet to be published except for the unaudited cash number, as at 30 June 2022, and employ a 12.5% discount rate. We expect Incannex to develop and manage its clinical trials and leverage third-party contract manufacturing partnerships to commercialize its products.

Financials: Funding into FY24

The company is yet to publish its full financial results for FY22; however, from its Q422 Appendix 4C statement (unaudited) Incannex had a cash position of A$37.5m (US$26.1m) at the end of June 2022. Based on the company's current burn rate (CY Q222) of A$3.9m (US$2.7m) and projected R&D spend (increase in FY23), we estimate a cash runway into CY H223 (FY H124). During FY22 the company completed two short-dated option programs to raise a total of A$41.2m in financing. The Q122 raise resulted in the issuance of 159m new shares, representing gross proceeds of A$17.66m. The Q422 raise resulted in 67.3m new shares and gross proceeds of A$23.6m. The

over A$40m in gross proceeds we anticipate should capitalize the company through trial readouts from the Phase II Psi-GAD program and the initiation of FDA trials of IHL-42X, which is anticipated in FY23. Incannex continues to make headway on its own and has not entered into any licensing agreements with external partners. Management's current intentions are to develop and commercialize its own assets; however, the company is open to partnering if the deal economics are beneficial.

Sensitivities: Variables for the underdeveloped market

Although Incannex is subject to risks associated with drug research and development, the shorter targeted time horizon for development of different formulations of generic therapies leveraging IP and incorporating cannabinoids with a broader number of targeted therapies likely provides some reprieve.

The most prominent near-term risks could be failure to gain IND approval by the FDA. Additionally, the cannabinoid therapeutic market is significantly underdeveloped, making future drug pricing and market dynamics challenging to predict. As the US is a key target market for the company, there may be challenges associated with gaining coverage within US healthcare reimbursement systems. Epidiolex (a cannabis-derived drug) is eligible for reimbursement as it is used to treat life-debilitating seizures in patients with Lennox-Gastaut syndrome or Dravet syndrome. However, in the eyes of insurers, OSA may not be classified as a critical condition and may not apply for such reimbursement schemes. As such, socioeconomic factors may play a significant role in overall clinical uptake.

Additionally, in the United States, while sentiment around the therapeutic benefits of cannabinoids is evolving, there remain certain commercial challenges, requiring a cultural shift requiring buy in from payers, providers and consumers. While our model accounts for financing(s) as long-term debt, the company may need to issue equity instead, the pricing of which may not be favorable for current shareholders and could lead to significant dilution.

Incannex: A broad developmental pipeline

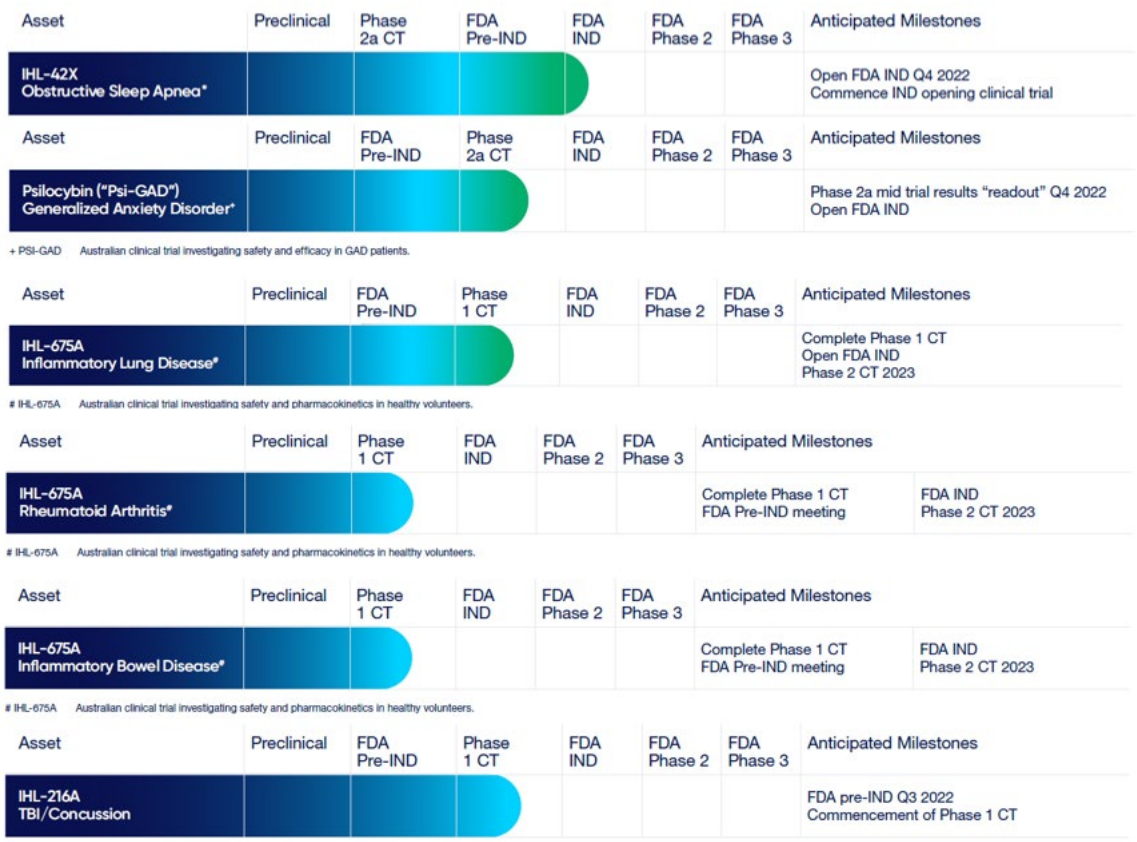
Incannex's lead asset, IHL-42X, is a formulation of dronabinol and acetazolamide, which the company is investigating for the treatment of OSA. Dronabinol, or synthetic tetrahydrocannabinol (THC), is currently approved for the treatment of nausea and vomiting in chemotherapy patients. Acetazolamide is approved in the United States for the treatment of indications including glaucoma, hypertension and heart failure. Both dronabinol and acetazolamide have demonstrated efficacy as monotherapies for the treatment of OSA, however neither are currently approved in this indication. Incannex has shown a positive synergistic effect in patients treated with a dronabinol/acetazolamide combination (IHL-42X).

The ongoing Psi-GAD Australian Phase II trial (ACTRN12621001358831) is investigating the use of psilocybin, a natural psychoactive compound isolated from certain species of mushrooms, in patients with GAD. Psilocybin is being investigated for the treatment of various neurological disorders, however it is not approved by the FDA in any indication. Incannex intends to use the initial data readouts from Psi-GAD to inform the design of a follow-up Phase IIb study.

Additionally, the company has two early-stage assets in development, IHL-675A and IHL-216A. IHL-675A began recruiting patients in a Phase I Australian clinical study in Q322 to treat rheumatoid arthritis, inflammatory bowel disease and lung inflammation. Phase II studies in each of these indications are expected to follow in CY23 and CY24. IHL-216A, a combination of CBD and the anesthetic agent isoflurane, is currently in preclinical development for the treatment of traumatic

brain injury (TBI). Preclinical animal models have shown encouraging data and management is aiming to begin clinical studies in CY23.

Exhibit 1: Incannex's development pipeline



Source: Incannex Corporate Presentation, August 2022

Unique patent opportunity

Incannex's development platform leverages the potential to expedite the route to market (by utilizing Australian clinical trials to guide FDA IND approval) and the unique IP position of the company's candidates. Assuming clinical benefit is demonstrated, Incannex can secure exclusivity over the use of the combination therapies. For example, a patent application is pending for IHL-42X and preliminary feedback from the patent examiner has considered the key claims of the application to be novel and inventive. An exception to this patent strategy is psilocybin, where we expect it is unlikely the company will secure a patent to cover the drug as a clinical monotherapy. However, we anticipate the company may be able to patent the Psi-GAD treatment protocol, including formulations and patient dosing regimens. The filing of synergistic combination patents for Incannex's lead products would, if approved, further enhance the company's exclusivity and competitive advantage in the market.

IHL-42X: Lead asset progressing

Obstructive sleep apnea an unmet need

OSA is a respiratory disorder in which individuals experience irregular and disruptive breathing patterns during sleep, most commonly caused by excess weight and obesity in adults. If left untreated, OSA can increase the risk of developing serious long-term health conditions such as

hypertension, heart attack and stroke. The continuous positive airway pressure (CPAP) machine, a device that uses a mask or nosepiece to deliver constant and steady air pressure to patients while they sleep, represents the current standard of care in OSA. However, the device suffers from poor patient compliance, primarily due to patient discomfort. The machines often have a life span of around five years, but require significant maintenance as they can provide a breeding ground for bacteria, potentially leading to respiratory infections. CPAP machines can range in price from US$250–1,000, with insurance providers covering either a fraction or the majority of the cost, depending on the policy. It is estimated that c 15% of the US population suffers from moderate to severe OSA and we assume those patients with more severe OSA will be prescribed a CPAP device. While there are currently no approved therapies for the treatment of OSA, Sunosi, a medication that reduces daytime sleepiness, has been approved to treat the symptoms (estimated sales in 2028 US$165m, EvaluatePharma). Due to the limited treatment options available for patients with OSA, we believe this represents an area of unmet therapeutic need.

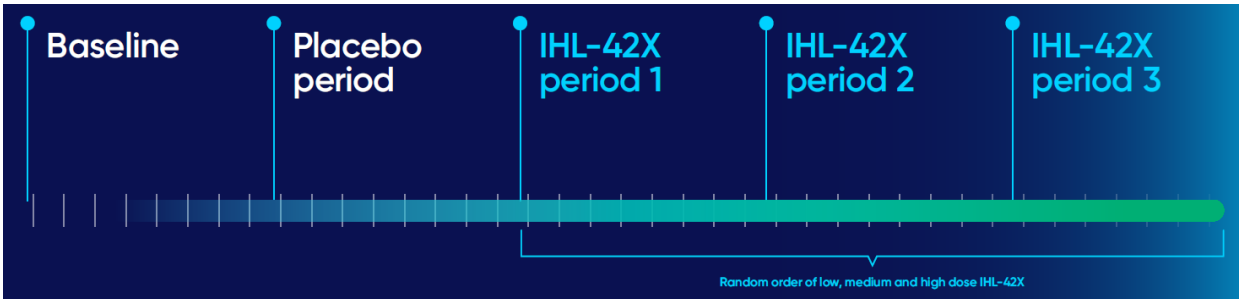
Dual mechanisms of action

While the exact roles of dronabinol and acetazolamide in the treatment of OSA have not been fully elucidated, they are hypothesized to have an impact on respiratory regulation through two different mechanisms. Dronabinol acts as a partial agonist of the cannabinoid receptor type 1 and type 2 (CB1 and CB2) in the brain, activation of which has been shown in both preclinical and clinical models to stabilize respiration during sleep. Acetazolamide is known to induce metabolic acidosis (increased acid production in the body) which, in turn, reduces loop gain (breathing instability) that may lead to apnea. IHL-42X aims to leverage the beneficial effects of both drugs in combination.

IHL-42X Phase II completion

In Q222, Incannex reported the completion of and results from its proof-of-concept, Phase II Australian clinical trial (ACTRN12620000916943). This randomized study assessed the therapeutic benefit of IHL-42X in patients with suspected or diagnosed OSA, Exhibit 2.

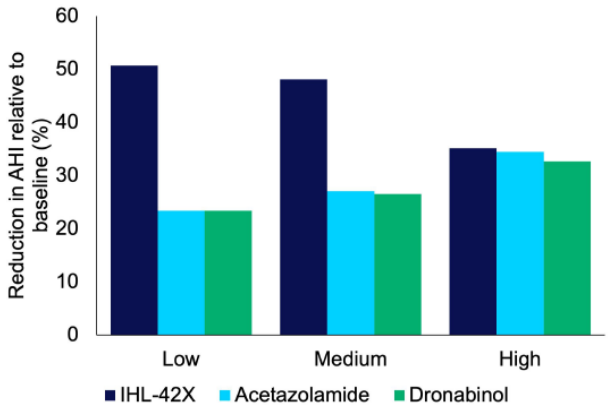
Exhibit 2: IHL-42X Phase II trial design



Source: Incannex corporate presentation, June 2022

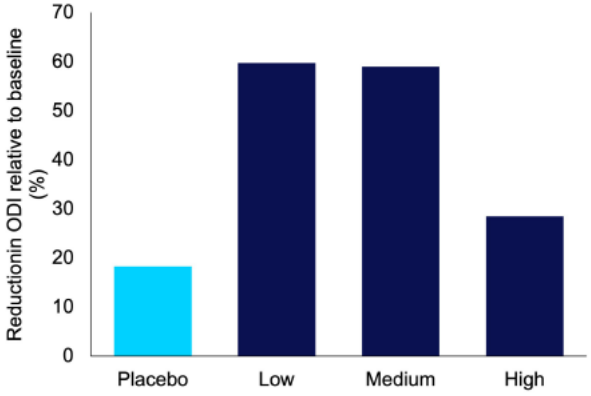
Two important metrics used to evaluate efficacy were the apnea hypopnea index (AHI), used to indicate the severity of sleep apnea, and the oxygen desaturation index (ODI), a measure of the reduction in blood oxygen levels. The AHI measures the average number of partial or complete breathing interruptive events a patient experiences per hour with individuals having AHI readings between 5 to 15 considered as mild apnea, 15 to 30 moderate, and >30 severe. For the ODI, normal blood oxygen levels are typically 96–97% (saturated), with ranges from 80–90% considered moderate desaturation and less than 80% severe. Patients in the Phase II IHL-42X trial (n = 11) completed a single-blind placebo treatment period, followed by three double-blind treatment periods with IHL-42X at randomized doses (low, medium, high). Treatment periods were seven days long and were separated by a seven-day 'wash out' period. AHI and ODI data were collected during sleep studies on night seven at the end of each treatment period.

Exhibit 3: AHI measurements



Source: Incannex corporate presentation, June 2022

Exhibit 4: Changes in ODI



Source: Incannex corporate presentation, June 2022

At low doses (2.5mg dronabinol, 125mg acetazolamide) IHL-42X was found to reduce AHI by an average of 50.7% compared to baseline, with 25% of patients experiencing a reduction in AHI of greater than 80% (Exhibit 3). Additionally, IHL-42X displayed a synergistic effect at low doses, compared to acetazolamide or dronabinol monotherapies, at reducing AHI. ODI was also reduced by 59.7% (Exhibit 4) at low doses with patients reporting improved overall sleep quality and reduced number of treatment-related adverse events relative to placebo. We believe these data provide encouraging signs that IHL-42X will meet the FDA's combination criteria, where both drugs must provide therapeutic benefit.

The use of low-dose IHL-42X formulations allows dronabinol to be cleared from the patients' bodies overnight, meaning they are below driving impairment limits the morning after administration. In the United States, the limit ranges between states from 2–5ng/mL. We note that some US states operate a zero-tolerance limit with regards to THC blood levels and driving, making the hurdle for patient uptake more difficult, in our view.

Towards IND approval

Following positive results from the proof-of-concept Phase II trial, management intends to use the data gathered to support an IND application, which we expect will be filed with the FDA in Q422. The company has engaged the regulators to discuss IHL-42X's long-term development strategy, including the parameters required to demonstrate safety and efficacy in pivotal Phase II and/or III trials. Management expects results from the proof-of-concept Phase II study in Australia will provide sufficient quality data to progress straight to Phase II FDA studies in the United States, should an IND be granted. We expect future clinical trial protocols will be tailored to ensure they generate sufficient data to pursue a 505(b)(2) NDA pathway for IHL-42X, allowing the company to submit the product for FDA review by including data or clinical results originally collected by another party. In our view, this could significantly expedite the development process for IHL-42X.

Psi-GAD Phase II ongoing

An underserved patient population

The company's second clinical program, Psi-GAD, is investigating the use of the naturally occurring psychoactive compound psilocybin in combination with psychotherapy for the treatment of GAD, a mental health condition characterized by persistent and extensive worry. It is estimated that c 6.8 million US adults suffer from GAD (c 3% of the US population), representing a significant patient population. First-line treatment for GAD is often psychotherapy followed by medications, including

anti-depressants, pregabalin (an anxiolytic) and benzodiazepines (tranquilizers). However, c 50% of patients treated for GAD will not respond to first-line treatment and long-term use of existing medications may result in adverse side effects including dependence, irritability and dizziness.

Psilocybin in the clinic

The ongoing Australian Phase II Psi-GAD study (ACTRN12621001358831) is a triple-blind, active-placebo controlled trial to assess the safety, efficacy and tolerability of psilocybin-assisted psychotherapy in patients with GAD. The study aims to recruit a total of 72 patients (30 in Phase IIa, 42 in Phase IIb). Preliminary analysis of patient data from the Phase IIa study will be conducted by an independent monitoring board and will inform investigators on the design and protocol for Phase IIb. Participant recruitment began in Q122 and, as of the last clinical update, 22 patients have been recruited into Phase IIa. We expect recruitment to complete in Q322, shortly followed by preliminary readouts in Q422, which we believe represents a near-term catalyst for the company. Again, we expect management's intention is to use the results of this trial, assuming they are positive, to support potential Phase II FDA-approved studies in FY23.

Interest in the use of psychedelics to treat mental illnesses has gained significant momentum over recent years, however we note that the field is still in its infancy and the clinical utility of these compounds is not yet concrete. As part of academic sponsored clinical trials (NCT00465595, NCT00957359), psilocybin has previously been investigated for the treatment of cancer patients suffering from anxiety. In these, psilocybin was shown to have a positive effect on patients, with low toxicity and no serious adverse events reported. This is a positive foundation for Incannex's Psi-GAD study, in our opinion, however clinical efficacy will need to be demonstrated in addition to an acceptable safety profile.

IHL-675A and IHL-216A provide diversification

Phase I recruitment begins

In August 2022, Incannex began recruiting patients into its Phase I Australian study, investigating the safety and pharmacokinetics of IHL-675A for the treatment of inflammatory conditions. IHL-675A is a combinational therapy comprised of CBD and HCQ. CBD is the non-psychoactive active ingredient found in cannabis plants. Both drugs have well characterized anti-inflammatory activity as monotherapies. It is believed that both CBD and HCQ play a role in downregulating the autoimmune response by interfering with immune system activation. Preclinical studies have demonstrated a positive synergistic effect of IHL-675A in three indications: rheumatoid arthritis, inflammatory bowel disease and pulmonary lung inflammation. The Phase I study aims to demonstrate the bioavailability and safety of IHL-675A and data will be applicable in the development of all three inflammatory indications. Subject to positive readouts, Incannex intends to use the data to pursue IND filings for each indication.

The immunosuppressant market (which includes anti-inflammatory drugs) is huge and growing. In 2021, global sales of immunosuppressive drugs reached c US$36bn, with the market expected to grow to c US$90bn by 2028 (EvaluatePharma). If approved in the anti-inflammatory setting, we expect IHL-675A would be competing with several multi-billion-dollar drugs for market share. For example, Sanofi's Dupixent (2021 global sales US$6.2bn), AbbVie's Rinvoq (2021 global sales US$1.7bn) and Johnson & Johnson's Stelara (2021 global sales US$9.1bn). Owing to this, we believe it will be exceptionally important for Incannex to differentiate IHL-675A in the anti-inflammatory market possibly through long-term safety and/or use in highly specific subsets of patients.

IHL-216A approaching the clinic

In addition, Incannex is conducting preclinical evaluation of IHL-216A, a combination of CBD and isoflurane, for the treatment of TBIs. IHL-216A has been assessed in two separate animal models representing both mild and severe TBI, with results demonstrating the combination reduced neuroinflammation and restored spatial memory. We see the company's preclinical assets as positive diversification from IHL-42X and Psi-GAD, potentially providing multiple paths to an approved therapeutic.

APIRx Pharmaceuticals acquisition

In August 2022, Incannex announced the completion of its acquisition of APIRx Pharmaceuticals, a US biotechnology company focused on the development and manufacture of cannabinoid formulations. In an all-share transaction (A$125.0m at A$0.573 per share), Incannex has acquired 100% of the issued share capital in APIRx and the company's full pipeline, consisting of 22 cannabinoid-based development programs and an extensive IP portfolio (19 granted patents and 23 patents pending). The bid was part of a competitive process. The APIRx stakeholders (sellers) have also entered into a 12-month voluntary escrowed share agreement, restricting the disposal of any shares issued. The deal strengthens Incannex's market position and provides it with what we believe is one of the sector's most diversified portfolios of medicinal cannabinoid drug formulations and psychedelic treatment regimes. The transaction offers synergies, in terms of both portfolio alignment and route to market strategy for products and offers Incannex near- and longer-term opportunities. The acquisition expands and diversifies Incannex's global portfolio of cannabinoid and psychedelic medicines with APIRx specializing in cannabinoid formulations, manufacturing and drug delivery platforms. While management does not expect its current development programs to be affected by new projects from the acquisition, we expect the expanded development platform will require additional capital.

Incannex's development strategy involves pursuing the FDA 505(b)(2) regulatory pathway for its assets and we expect the company to employ a similar strategy with products from APIRx's portfolio. The MedChew Rx (pain in multiple sclerosis) and MedChew Dronabinol (nausea from chemotherapy) programs, we believe, represent the most immediate commercial opportunities. These products are cannabinoid-based chewing gums or chewable tablets, designed to increase bioavailability over existing oral formulations. The deal brings with it APIRx's substantial IP portfolio covering active pharmaceutical ingredients, formulations, methods of use and drug delivery technologies. This provides Incannex with commercial exclusivity across all stages of clinical development, while, in our view, offering opportunities for the company to identify synergies with the existing programs. Incannex will continue to use synthetic cannabinoids in its core programs, whereas the APIRx programs will primarily use botanically extracted cannabinoids. We believe, however, there may be beneficial overlap between programs in terms of manufacturing and formulation.

Sensitivities

Incannex is subject to the regular sensitivities associated with drug research and development. The company's prospects will be affected by development delays or failures, regulator risks, competitor successes, partnering successes and financing risks. While Incannex is utilizing drugs that are either already marketed or that have pre-existing clinical data, this does not ensure clinical success. Failure to receive IND approval for IHL-42X represents the most significant near-term risk, which we believe would have significant implications on the company's strategy. As a cannabinoid company, Incannex may also be sensitive to commercial risk. While regulatory sentiment towards

cannabinoids and psychedelics has progressed, consumer sentiment may still need to evolve, with some populations potentially still perceiving cannabinoids as recreational drugs as opposed to therapeutics. This could, in our view, affect the ability of cannabinoid-based products to penetrate certain markets.

As a drug developer, Incannex is subject to highly capital-intensive developmental costs so the company may need to raise capital beyond our forecasts. We model future fund-raises as illustrative debt. However, the company may need to issue equity instead, at a price that may not be favorable for current shareholders and could lead to potentially significant dilution.

Valuation

We value Incannex at US$695.7m or US$11.42 per ADR. Our valuation is based on a risk-adjusted NPV for IHL-42X in OSA (peak sales US$3,065m, rNPV of US$665.5m) and psilocybin in GAD (peak sales US$187m, rNPV of US$4.0m). We include an unaudited net cash position of US$26.1m ($A37.5m) at 30 June 2022. We have excluded IHL-675A and IHL-216A from our valuation pending further clinical development. Our model applies a discount rate of 12.5%. Currently, Incannex has not entered any licensing deals; however, the company is open to partnering if the deal economics are beneficial. Therefore, our rNPV assumes Incannex will develop and commercialize IHL-42X and the Psi-GAD protocol (anticipated launch 2027) in the United States without a partner or licensing deal. In line with management's strategy, we have solely included the US market in our model. The assumptions used in our valuation are presented in Exhibit 5.

Exhibit 5: Risk-adjusted NPV assumptions for IHL-42X and psilocybin

Indication	Assumptions
Obstructive sleep apnea (OSA)	■ **Target population**: We assume a prevalence of moderate to severe OSA in the United States of 11% in men and 5% in women, 20% of whom are diagnosed and 50% are prescribed CPAP devices. We assume the company will gain 30% share of existing patients using CPAP devices, which represents 0.1% of the overall US population.
	■ **Pricing**: US$3,000 per patient per year in the United States, peak sales reached in five years.
	■ **Trial timelines and R&D cost:** A$5.6m in FY23 to begin Phase II FDA studies with IHL-42X and A$14m in both FY24 and FY25 for Phase III studies.
Generalized anxiety disorder (GAD)	■ **Target population**: We assume a prevalence of GAD in the United states of 5% and, of these, 43% are prescribed therapeutic treatment. 50% of patients are also resistant to first-line treatment. We assume a peak penetration of 0.5%.
	■ **Pricing**: US$7,500 per patient per year in the United States, peak sales reached in five years.
	■ **Trial timelines and R&D cost:** A$5.6m in FY24 to begin Phase II FDA studies with IHL-42X and A$14m in both FY25 and FY26 for Phase III studies.

Source: Edison Investment Research

The therapeutic cannabinoid and OSA markets are currently underdeveloped and thus few comparative products to IHL-42X exist. Therefore, our pricing assumption of US$3,000 per patient per year in OSA is based on a comparison of the price per patient per year of Sunosi (a wake-promoting agent for the symptomatic treatment of OSA) in the United States (c US$5,000), and current prices of CPAP devices (c US$1,000). IHL-42X is being developed as a prophylactic where no existing therapies exist. We have therefore assumed that the drug could command a premium to CPAP machines, should positive results be demonstrated in US clinical trials. Our pricing assumption in GAD (c US$7,500 per patient per year) is based on the average price of three top 10 selling benzodiazepines and the estimated costs and number of recommended psychotherapy sessions for patients in the United States.

A breakdown of our rNPV for Incannex Healthcare can be found in Exhibit 6. We estimate peak sales for IHL-42X in OSA of US$3,065m in the US in 2032 after approval in 2026. Further, we forecast peak sales for psilocybin/psychotherapy treatment in GAD of US$187m in the US in 2032 after approval in 2027. As the cannabinoid-based therapeutic market is highly underdeveloped, and, in the US, uptake may only be observed in more liberal states, we assume a peak market penetration for IHL-42X of 30% of existing CPAP users (0.1% of the US population). We attribute a

higher penetration to IHL-42X due to the extensive patient compliance issues associated with CPAP devices, with IHL-42X offering a simpler oral formulation alternative. To our knowledge, the closest competitor in the clinic is atomoxetine, Strattera (NCT05071612). The drug is currently approved for the treatment of attention-deficit hyperactivity disorder (ADHD) and is being investigated for treating OSA. However, a side effect observed in patients who receive Strattera is insomnia and we therefore believe IHL-42X is positioned well within the market against this competitor. We expect the Psi-GAD treatment protocol will require specialist therapist training and as such we anticipate a more conservative clinical uptake. We therefore estimate a peak penetration of 0.5% of addressable patients in GAD. While IHL-42X has demonstrated efficacy in the clinic, the therapy is still to undergo FDA-approved clinical trials. In addition, the Psi-GAD treatment protocol has not yet demonstrated clinical proof-of-concept. Hence, we have assigned a probability of success of 20% to IHL-42X and 10% to the Psi-GAD protocol. The probability of Incannex's lead asset IHL-42X is based upon the anticipated benefits the company will face in pursuing the FDA 505(b)(2) regulatory pathway by utilizing safety pre-existing data for marketed therapies. Additionally, through management's pre-IND meetings with the FDA, the company anticipates that the data package from the Australian Phase II clinical data will support it straight to Phase II FDA studies. Our 20% probability is conservative and below industry average success rates for Phase II trials.

We will revisit our model once the APIRx product line and developmental strategy has been fully integrated into the group. We ascribe 92% of the company's valuation to IHL-42X, 1% to psilocybin and 7% to cash. We have not included the earlier-stage assets IHL-675A or IHL-216A in our valuation; however, we will revisit our valuation following clinical progression of these therapies.

Exhibit 6: 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	3,213.1	20%	665.5	10.93
Psilocybin (Psi-GAD) in generalized anxiety disorder	2027	2032	186.6	115.3	10%	4.0	0.07
Net cash at 30 June 2022 including proceeds from fund-raise in H122 (unaudited)				26.1	100%	26.1	0.43
Valuation				**3,354.5**		**695.7**	**11.42**

Source: Edison Investment Research

Pricing and market penetration represent the two critical assumptions that our valuation is most sensitive to. The immature nature of the cannabinoid therapeutics market means that both parameters are challenging to predict. Therefore, Exhibit 7 provides a two-dimensional sensitivity analysis of peak sales to pricing and market penetration. We assume initial cost of goods sold of 50% in our model, benchmarked against analogous pre-commercial cannabinoid manufacturing gross margins.

Exhibit 7: IHL-42X peak sales (US$m) – sensitivity to price and market penetration

		Market penetration									
		5%	10%	15%	20%	25%	30%	35%	40%	45%	50%
Pricing (US$)	1,000	170	341	512	682	853	1023	1194	1364	1535	1705
	2,000	340	681	1022	1362	1703	2043	2384	2724	3065	3405
	3,000	510	1022	1533	2044	2555	3066	3577	4088	4599	5110
	5,000	850	1703	2555	3406	4258	5109	5961	6812	7664	8515
	8,000	1363	2725	4088	5450	6813	8175	9538	10900	12263	13625

Source: Edison Investment Research. Note: Pricing is per patient per year.

Financials

Incannex recorded pharmaceutical cannabinoid oil sales in FY21 of A$1.9m; however, the company has now halted manufacturing to focus on the development of drugs targeting regulatory approval.

The company currently receives other income through contractual arrangements and government grants. Of note, Incannex is eligible to receive an annual cash rebate equivalent to c 43.5% of R&D expenses in Australia as part of the Australian government's R&D rebate scheme.

The company's total operational costs for FY21 were A$9.2m, higher than in FY20 (A$4.3m), largely due to an increase in research and development expenditure (FY21: A$4.7m, FY20: A$2.1m) as the company stepped up clinical trial activities for IHL-42X. Excluding R&D expenses, the remaining operating costs for FY21 consisted mainly of regulatory (FY21: A$1.2m), advertising and promotion (FY21: A$1.1m) and staff costs (FY21: A$1.3m). The company's operating expenses for H122 (the six months ending 31 December 2021) came to A$5.8m. Based on these figures, we estimate total FY22 operating expenses will reach A$10.1m and that c 50% of this cost will be associated with R&D activities (c A$5.2m). This figure incorporates estimated costs associated with the IHL-42X Phase II trial in H122 and the ongoing Phase II Psi-GAD study.

We expect R&D expenses to rise to A$9.8m in FY23 following the initiation of Phase II FDA studies with IHL-42X and to significantly increase to A$21.6m in FY24 and A$30.0m in FY25 respectively as a result of Phase III trials for both the IHL-42X and Psi-GAD programs. We base our R&D estimates upon clinical trial costs per patient of c A$70,000 (US$50,000), which we derive from management's communication and our anticipated number of patients in each trial. We also attribute A$2m to ongoing annual pharmaceutical research, in line with historical figures. The company received A$0.8m in R&D tax rebates in H122, however had no recorded sales of cannabinoid oils (H121: A$1.2m) as the company has now halted production.

In FY22 Incannex completed two option exercise programs in Q122 and Q422 raising a total of A$41.2m. The raise in Q122 saw the issuance of 159m new shares raising a total of A$17.66m. A portion of the options exercised (exercise price: A$0.08) were primarily owned by Incannex directors and existing shareholders (118m shares). A further 40.99m options were exercised by Incannex's chief medical officer (exercise price: A$0.20). The raise in Q422 raised a total of A$23.6m (exercise price: A$0.35) with a total of 67.3m new shares issued. This financing will help fund the Phase II Psi-GAD program and the initiation of FDA trials of IHL-42X, anticipated in CY23.

Incannex reported a cash position of A$37.5m at end-June 2022 and a CY Q222 burn rate of A$3.9m. With the anticipated increased in R&D spending corresponding to the initiation of FDA Phase II studies in OSA and the continuation of the Australian Phase II Psi-GAD study, we estimate a cash runway into H2 CY23 (H1 FY24). In our model, we project that Incannex will launch its first product (IHL-42X) in FY26. We estimate the company will need to raise an additional A$50m in FY24 to completely fund Phase III trials for IHL-42X and Psi-GAD in FY24 and FY25 before reaching profitability in FY26. We note that the potential signing of a licensing deal or any delays or changes to clinical timelines may shorten or lengthen our runway estimates. Cash figures are taken from the company's Appendix 4C, which is an unaudited financial statement.

Exhibit 8: Financial summary

Accounts: IFRS, year-end 30 June; A$000s	2020	2021	2022e	2023e
PROFIT & LOSS				
Total revenues	822	1,973	860	77
Cost of sales	(450)	(912)	(434)	(39)
Gross profit	372	1,061	426	38
Total operating expenses	(4,301)	(9,225)	(10,117)	(14,973)
Research and development expenses	(2,111)	(4,750)	(5,224)	(9,848)
SG&A	(864)	(1,236)	(1,392)	(1,627)
EBITDA (normalized)				
Operating income (reported)	(3,929)	(8,164)	(9,691)	(14,935)
Operating margin %	-	-	-	-
Finance income/(expense)	0	0	0	0
Exceptionals and adjustments	0	0	0	0
Net loss from discontinued operations	(768)	0	0	0
Profit before tax (reported)	(4,698)	(8,164)	(9,691)	(14,935)
Profit before tax (normalised)	(4,698)	(8,164)	(9,691)	(14,935)
Income tax expense (includes exceptionals)	0	0	0	0
Net income (reported)	(4,698)	(8,164)	(9,691)	(14,935)
Net income (normalised)	(4,698)	(8,164)	(9,691)	(14,935)
Basic average number of shares, m	684.0	978.0	1,182.8	1,472.0
Basic EPS (c)	(0.69)	(0.83)	(0.82)	(1.01)
Adjusted EPS (c)	(0.69)	(0.83)	(0.82)	(1.01)
Dividend per share (c)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Tangible assets	0	0	0	0
Intangible assets	0	0	0	0
Right-of-use assets	0	0	0	0
Other non-current assets	0	0	0	0
Total non-current assets	0	0	0	0
Cash and equivalents	3,603	9,124	39,110	24,206
Current tax receivables	0	0	0	0
Trade and other receivables	413	169	178	186
Inventory	183	0	0	0
Other current assets	36	36	36	36
Total current assets	4,236	9,329	39,324	24,428
Non-current loans and borrowings	0	0	0	0
Non-current lease liabilities	0	0	0	0
Other non-current liabilities	0	0	0	0
Total non-current liabilities	0	0	0	0
Accounts payable	(955)	755	793	832
Illustrative debt	0	0	0	0
Current lease obligations	0	0	0	0
Other current liabilities	(117)	0	0	0
Total current liabilities	(1,072)	755	793	832
Equity attributable to company	3,164	8,574	38,531	23,596
CASH FLOW STATEMENT				
Operating income	(4,698)	(8,164)	(9,691)	(14,935)
Depreciation and amortisation	37	0	0	0
Share based payments	565	1,172	0	0
Other adjustments	97	91	0	0
Movements in working capital	91	(10)	29	31
Cash from operations (CFO)	(3,907)	(6,910)	(9,662)	(14,904)
Capex	13	0	0	0
Acquisitions & disposals net	0	0	0	0
Other investing activities	0	0	0	0
Cash used in investing activities (CFIA)	13	29	0	0
Capital changes	7,469	12,401	39,648	0
Debt Changes	(65)	0	0	0
Other financing activities	0	0	0	0
Cash from financing activities (CFF)	7,404	12,401	39,648	0
Cash and equivalents at beginning of period	93	3,603	9,124	39,110
Increase/(decrease) in cash and equivalents	3,510	5,520	29,986	(14,904)
Effect of FX on cash and equivalents	0	0	0	0
Cash and equivalents at end of period	3,603	9,124	39,110	24,206
Net (debt)/cash	3,603	9,124	39,110	24,206

Source: Incannex Healthcare, Edison Investment Research. Note: FY22 are estimates pending release of the full financials.

Contact details	Revenue by geography
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Management team

Managing director and CEO: Mr Joel Latham	Non-executive director: Mr Robert B Clark
Mr Latham brings with him significant experience in management and operations and has 14 years' experience with large firms such as Mars Foods, Tabcorp and Philip Morris International. He has already played a key role in the execution of Incannex's drug development and regulatory strategy.	Mr Clark is a senior-level strategic regulatory affairs expert with over 38 years of US and global regulatory experience, including with large corporates including Pfizer and Novo Nordisk. He is an internationally recognized expert on US Food and Drug Administration (FDA) and European Medicines Agency (EMA) liaison interactions, US pharmaceutical advertising practices and regulatory aspects related to healthcare professionals and salesforce activities.
Chief scientific officer: Dr Mark Bleackley	**CFO and company secretary: Madhukar Bhalla**
Dr Mark Bleackley has a PhD in genetics from the University of British Columbia, and post-doctoral experience at La Trobe University and Hexima. Dr Bleackley oversees all matters of clinical development and research at the company.	Mr Bhalla is an experienced company secretary, and has worked at multiple ASX-listed companies in corporate governance, financial management and corporate law. Prior to Incannex he held the position of managing director at Colortype Press for eight years.

Principal shareholders	(%)
Agarwal Sudhansu	7.04
Carrol Raymond Laurence	2.97
ETF Managers Group LLC	2.94
Valentine Troy	2.22
Vanguard Group Inc/The	2.20
CANNVALATE PTY LTD	2.10
MICHAEL MALIYNAK ANTHONY	1.68

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