Incannex

Company Overview

ASX Ticker: IHL | NASDAQ Ticker: IXHL

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Incannex is a global biotech company developing cannabinoid and psychedelic compound medicines.

Our mission is to create premier pharmaceutical drugs and therapies, restoring the health and transforming the lives of patients with unmet medical needs. We are developing targeted and scientifically validated products, creating long term value for our patients and shareholders.

– Listed on the ASX in 2016

Leadership Team

Joel Latham
Managing Director and CEO

Joel Latham is the CEO and Managing Director of Incannex Healthcare and is responsible for the Company's commercial operations, strategic decision-making, and oversight of all clinical development assets.

Troy Valentine
Chairman of the Board of Directors

Troy Valentine has been Chairman of the Board of Directors since December 2017. Troy is a finance professional with extensive managerial and Board experience.

Dr Sud Agarwal
CMO and Non-Executive Director

Dr Sud Agarwal has been the Chief Medical Officer of Incannex since June 2019, responsible for conceptualizing the Company's pipeline of proprietary cannabinoid products and regulatory strategies.

Peter Widdows
Non-Executive Director

Peter Widdows is a Fellow Chartered Accountant with extensive experience in Australian and international consumer goods markets, and has worked as a senior executive in numerous countries around the world.

Madhukar Bhalla
CFO and Company Secretary

Madhukar "Madhu" is an experienced company secretary who has previously worked with multiple ASX-listed companies and is proficient in corporate governance, company administration, financial management and corporate law.

Dr Mark Bleackley
Chief Scientific Officer

Dr Bleackley has a PhD in Genetics from the University of British Columbia with post-doctoral training at La Trobe University and Australian biotechnology company Hexima Ltd. He oversees all research and development activities at Incannex, from proof-of-concept to commercialization.

Rosemarie Walsh
Clinical Research Manager

Rosemarie Walsh has a degree in Applied Biology from RMIT University and over 20 year's experience in clinical trials including concept/design, start-up, conduct and close out, having worked for global and local contract research organizations and global pharma. As clinical research manager, Rosemarie oversees all aspects of Incannex's clinical trials.

Pia Kroner
Clinical Research Coordinator

Pia Kroner works on design and development of clinical trials for Incannex's new drugs. She has a bachelor's degree in Biomedical Science with Honours from La Trobe University and experience in running phase I clinical trials in the clinical unit.

Problem

Around the world there are millions of people with a range of conditions, who have unmet medical needs.

These include:

- Obstructive Sleep Apnea
- Traumatic Brain Injury
- Inflammatory Lung Conditions
- Rheumatoid Arthritis
- Inflammatory Bowel Disease
- Generalized Anxiety Disorder

The total addressable market for the treatment of these unmet medical needs is *$US110 billion+.

*Aggregate of indications referenced within

A treatment for any one of these conditions has massive potential, as the markets we are targeting are huge. Success in just one development program provides significant investor value.

Solution

Incannex is undertaking six clinical programs guided by its advisory board, targeting conditions for patients with unmet medical needs.

Development Pipeline

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-42X Obstructive Sleep Apnea*			Completed →					Open IND Q4 2022
Psilocybin ("Psi-GAD") Generalized Anxiety Disorder+			Completed →					Australian CT complete Q4 2022
IHL-675A Inflammatory Lung Disease#			Completed →					Australian CT complete Q3 2022
IHL-675A Rheumatoid Arthritis#								Australian CT complete Q3 2022 FDA pre-IND Q3 2022
IHL-675A Inflammatory Bowel Disease#								Australian CT complete Q3 2022 FDA pre-IND Q3 2022
IHL-216A TBI/Concussion								FDA pre-IND Q3 2022

*Incannex has been able to use historical data from an existing body of work to bypass traditional pre-clinical activities for IHL-42X and Psi-GAD.

* IHL-42X	Australian clinical trial investigating safety and efficacy in OSA patients.
+ PSI-GAD	Australian clinical trial investigating safety and efficacy in GAD patients.
# IHL-675A	Australian clinical trial investigating safety and pharmacokinetics in healthy volunteers.

Partnerships

Camargo
A Division of Premier Research

A regulatory and development partner with expertise in the FDA 505(b)2 drug registration.

labcorp

Extensive experience and services list across drug development ranging from preclinical services to post-marketing solutions.

PROCAPS

World leaders in commercial pharmaceutical-grade soft gel capsule manufacturing.

BrainPark
DAVID W. TURNER RESEARCH CLINIC

A world-first neuroscience research clinic dedicated to improving the physical, mental and brain health.

THE UNIVERSITY OF WESTERN AUSTRALIA

The UWA Centre for Sleep Science is a world-class academic facility at the forefront of sleep research.

NOVOTECH
The Asia Pacific CRO

Internationally recognized as a leading regional full-service contract research organization (CRO).

VECTURA

A state-of-the-art contract development and manufacturing organization (CDMO) that specializes in the development and manufacture of inhaled drugs and their associated delivery products.

AVANCE CLINICAL

The largest full service Australian CRO specializing in delivering clinical trials, with globally accepted data.

MONASH University

An Australia university consistently ranked in the world's top 100. The Monash University School of Medicine is ranked number 36 of medical schools globally (QS Top Universities Rankings 2021).

FDA Authorization Strategy

To achieve our goals, we intend to:

01.

Advance our novel investigational drug candidates towards approval in the United States and elsewhere.

- Undertake FDA compliant clinical trial programs
- Pursue New Drug Applications with the FDA
- Applications to be made in EU, Japan, Australia and Israel

02.

Take advantage of accelerated commercialization pathways for our drug candidates.

- 505(b)(2) NDA pathway pursued where applicable public data on compounds exists
- Expedited review program potential

03.

Develop future clinical products targeting unmet medical needs.

- Continual assessment of additional candidates

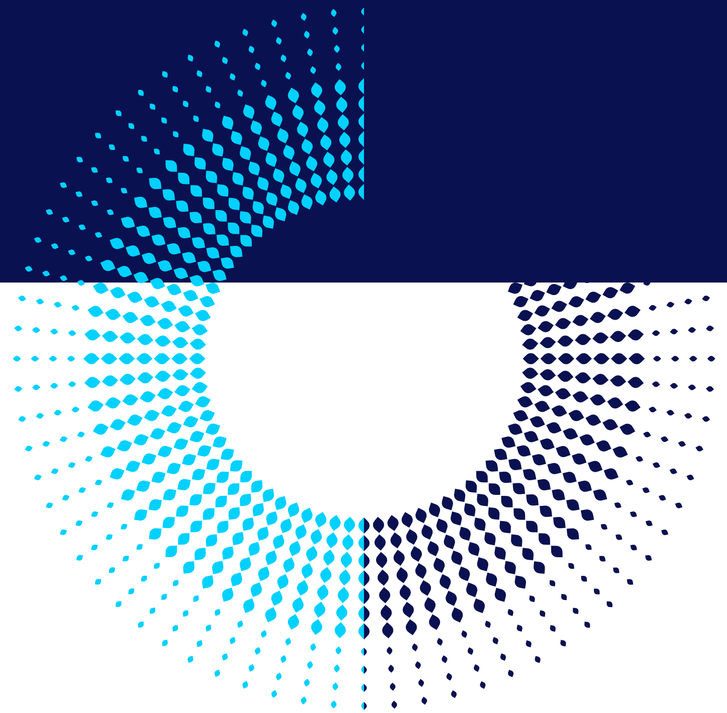
Competitive MOAT Strategy

Market Leaders

First to combine cannabinoids with established medicines for enhanced research outcomes and receive approval to investigate psilocybin in combination with psychotherapy for Generalized Anxiety Disorder.

Regulatory Exclusivity

We are pursuing FDA registration and marketing approval for each product and therapy under development.



Patents

IHL drug candidates are considered novel and inventive due to the synergy between cannabinoid and off-patent medicines.

Economic Potential

With 6 active programs, there is significant value creation for our shareholders in both the near and long term.

IHL-42X Obstructive Sleep Apnea

Program 1 of 6

Problem

People suffering from OSA (Obstructive Sleep Apnea) have interrupted breathing while asleep. It's a highly prevalent condition and current treatments have poor patient compliance. There are no approved pharmacotherapies for OSA.

Solution

IHL-42X has two active pharmaceutical ingredients (Dronabinol and acetazolamide) that target OSA through different pathways. Dronabinol binds to cannabinoid receptors, modulates signalling, and activates muscles that dilate the airway whereas acetazolamide induces metabolic acidosis which signals to the body that there is excess CO2 in the blood, inducing the taking of a breath. IHL-42X is intended to decrease the required dose of each of the component drugs by targeting the two mechanisms for reducing AHI simultaneously.

Addressable Market

US$10B[1]

Estimated sleep apnea device market

6.2%[1]

Annual Growth Rate

(1) https://www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market

* IHL-42X Australian clinical trial investigating safety and efficacy in OSA patients.

Clinical development status

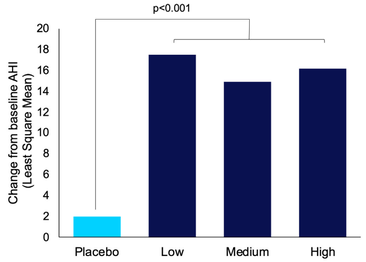
Unblinded and confidential interim clinical data provided to the patent examiner.

Patent application considered novel and inventive.

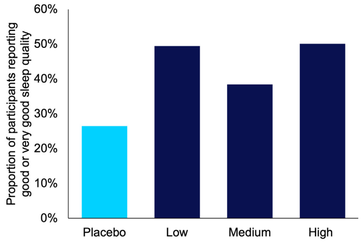
Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-42X Obstructive Sleep Apnea*			Completed →					Open IND Q4 2022

IHL-675A OSA proof of concept clinical trial results

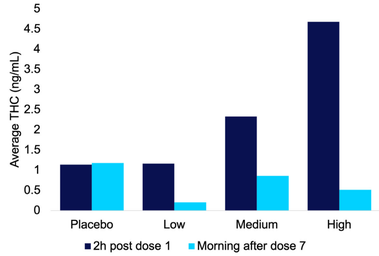
Participants completed a single blind placebo treatment period followed by three double blind IHL-42X treatment periods, each with a different dose strength of IHL-42X. Each treatment period was seven days with an overnight sleep study on night seven to determine AHI and other secondary endpoint data. Blood samples were collected the morning after the sleep study and analyzed for THC content.



IHL-42X reduced AHI at all three dose strengths with the low dose being most effective, reducing AHI by 50.7 % relative to baseline with 25% of subjects' AHI reduced by >80%.



Subjects reported improved sleep quality during IHL-42X treatment periods compared to placebo.



With low dose IHL-42X, THC was cleared below the common threshold for impaired driving (1 ng/mL) by the morning after dosing.

- IHL-42X also improved oxygen desaturation index and sleep efficiency.
- There were less adverse events reported during low dose IHL-42X treatment periods than placebo, which indicates that IHL-42X was well tolerated.
- Low dose IHL-42X performed the best in this clinical trial. It yielded the greatest reduction in AHI, the greatest improvement in sleep quality, the fewest number of adverse events and THC levels were below the threshold for impaired driving the morning after dosing.

Psi-GAD Generalized Anxiety Disorder

Program 2 of 6

Problem

GAD is diffuse, excessive, uncontrollable anxiety that is not restricted to any specific environmental circumstances. Treatment of GAD remains inadequate, with less than half of patients achieving remissions with currently accepted treatments.

Solution

Psilocybin works by facilitating access to fundamental causes of anxiety and providing a remarkable opportunity for patients to make real and lasting changes via psychotherapy.

Addressable Market

US & AUS COMBINED

8M people[2]

An estimated 7M people in the US and 1M in Australia have moderate to severe GAD at any point in time

(2) https://www.prnewswire.com/news-releases/global-generalized-anxiety-disorder-market-is-estimated-to-grow-at-25-cagr-to-reach-75-billion-by-2023-679279763.html

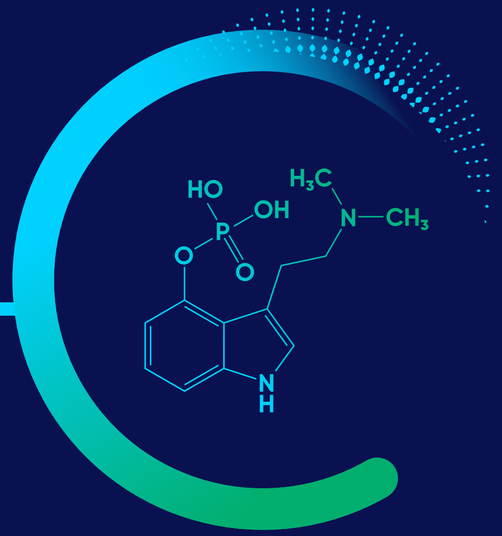
Clinical development status

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
Psilocybin ("Psi-GAD") Generalized Anxiety Disorder+			Completed →					Australian CT complete Q4 2022

+ PSI-GAD Australian clinical trial investigating safety and efficacy in GAD patients.

Psi-GAD: Psilocybin-assisted psychotherapy

A new mental health treatment paradigm



Psilocybin is a naturally-occurring psychedelic molecule produced by more than 100 species of mushrooms. It is a well-tolerated serotonergic psychedelic that produces therapeutically useful altered states of consciousness, and possibly greater neuroplasticity, providing a "window of opportunity" for more successful psychotherapy.

Lead by a world class multi-disciplinary team of experts

Dr Liknaitzky

Head of Clinical Psychedelic Research Lab, Turner Institute and Dept of Psychiatry, Monash University.

Professor Yücel

Professor of clinical neuropsychology and lead director of BrainPark - neuroscience research clinic.

Professor Sundram

Head of Dept Psychiatry, Monash University.

IHL-675A Novel multi-use drug candidate

Pulmonary inflammation model

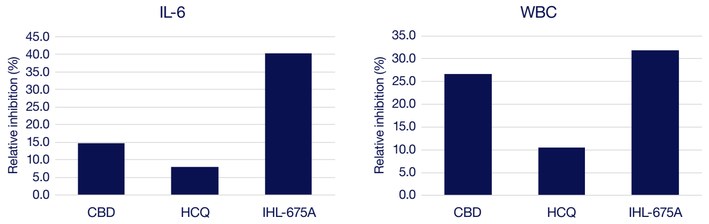
Mice were treated with IHL-675A, CBD or Hydroxychloroquine (“HCQ”) prior to induction of pulmonary inflammation. Lung fluid was collected and analyzed for inflammatory markers.

Rheumatoid arthritis model

Rheumatoid arthritis was induced in rats for 17 days followed by treatment with IHL-675A, CBD or HCQ for 14 days. Joints were monitored for swelling during the treatment period and at the end of the study the joint tissue was analyzed for damage via microscopy.

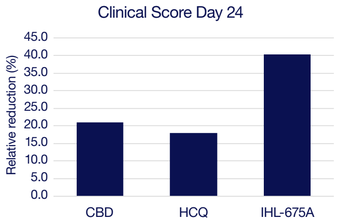
Inflammatory bowel disease model

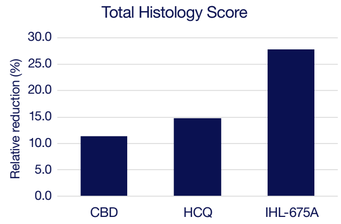
To assess the potential for IHL-675A in treatment of inflammatory bowel disease an mouse ulcerative colitis model was used. Colitis was induced prior to treatment with IHL-675A, CBD or HCQ. On day 5, the mice were sacrificed and the colon removed for analysis.



IHL-675A treated animals had a greater reduction in inflammatory markers in lung fluid, including white blood cells and the cytokine IL-6, than animals treated with either CBD or HCQ alone. This pattern was observed for other inflammatory cytokines.

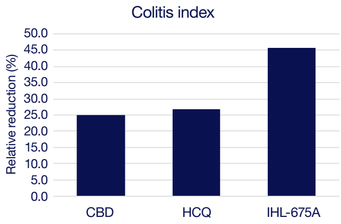
This indicates IHL-675A has the potential to treat lung inflammation.

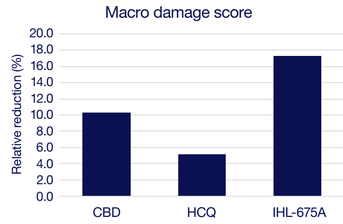




IHL-675A treated animals had a greater reduction in clinical score, a composite based on joint swelling and the histology score, which is a composite based on post-mortem analysis of joint tissue, than animals treated with either CBD or HCQ alone.

This indicates IHL-675A has the potential to treat rheumatoid arthritis.





Animals treated with IHL-675A had a greater reduction in macroscopic damage score and colitis index, a composite measure of the microscopic damage indicative of colitis severity, than animals treated with either CBD or HCQ.

This indicates IHL-675A has the potential to treat inflammatory bowel disease.

IHL-675A Lung Inflammation

Program 3 of 6

Problem

Inflammation is a major contributing factor to a range of lung diseases. Many patients don't respond, or experience side-effects, with current drug treatments.

Solution

IHL-675A targets two components of the inflammatory pathway by combining two anti-inflamamtory drugs, CBD and hydroxychloroquine sulfate. Incannex has demonstrated that CBD and hydroxychloroquine sulfate synergistically reduce inflammatory markers in an animal model of lung inflammation.

Addressable Market

US$50.4B[3]

Projected global COPD & asthma drugs market by 2022

3.7%[3]

Projected annual growth rate from 2016 to 2022[3]

(3) https://www.alliedmarketresearch.com/asthma-COPD-drug-market

Clinical development status

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-675A Inflammatory Lung Disease#			Completed →					Australian CT complete Q3 2022

IHL-675A Australian clinical trial investigating safety and pharmacokinetics in healthy volunteers.

IHL-675A Rheumatoid Arthritis

Program 4 of 6

Problem

Inflammation is a major contributing factor to rheumatoid arthritis.
Many patients do not respond to current drug treatments.

Solution

IHL-675A targets two components of the inflammatory pathway by combining two anti-inflamamtory drugs, CBD and *hydroxychloroquine sulfate. Incannex has demonstrated that IHL-675A reduce disease severity in an animal model of rheumatoid arthritis to a greater extent than either CBD or hydroxychloroquine sulfate alone.

Addressable Market

US$57B[4]

Rheumatoid arthritis drugs market

(4) https://www.alliedmarketresearch.com/rheumatoid-arthritis-RA-drugs-market#:~:text=The%20global%20rheumatoid%20arthritis%20drugs,pain%20and%20inflammation%20in%20joints

*Hydroxychloroquine was politicized in 2020 due to misconceptions about its use as an anti-viral treatment for Covid-19, however, anti-inflammatory and other properties of hydroxychloroquine are well established and it is shown to act synergistically with CBD as described in an Incannex patent application

Clinical development status

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-675A Rheumatoid Arthritis#								Australian CT complete Q3 2022 FDA pre-IND Q3 2022

IHL-675A Australian clinical trial investigating safety and pharmacokinetics in healthy volunteers.

IHL-675A Inflammatory Bowel Disease

Program 5 of 6

Problem

Inflammation is a major contributing factor to inflammatory bowel disease. Many patients do not respond to current drug treatments.

Solution

IHL-675A targets two components of the inflammatory pathway by combining two anti-inflamamtory drugs, CBD and hydroxychloroquine sulfate. Incannex has demonstrated that IHL-675As reduce disease severity in an animal model of inflammatory bowel disease to a greater extent than either CBD or hydroxychloroquine sulfate alone.

Addressable Market

US$20B+ [5]

Global market size in 2021

4.8% [5]

Projected annual growth rate from 2021 to 2028

(5) https://www.grandviewresearch.com/industry-analysis/inflammatory-bowel-disease-ibd-treatment-market#:~:text=The%20global%20inflammatory%20bowel%20disease,market%20over%20the%20forecast%20period

Clinical development status

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-675A Inflammatory Bowel Disease#								Australian CT complete Q3 2022 FDA pre-IND Q3 2022

IHL-675A Australian clinical trial investigating safety and pharmacokinetics in healthy volunteers.

IHL-216A Concussion

Program 6 of 6

Problem

Concussion and minor TBI (Traumatic Brain Injury) have major long term effects include cognitive deficits, depression and anxiety. Current recommendations are simply to avoid strenuous activities.

Solution

IHL-216A aims to improve recovery time by combining CBD and isoflurane to target inflammatory, oxidative and excitative components of the secondary injury mechanism of TBI.

Addressable Market

US$2.9B[6]

Global TBI market size in 2019

8.3%[6]

Projected annual growth rate from 2020 to 2027

(6) https://www.grandviewresearch.com/industry-analysis/traumatic-brain-injuries-tbi-assessment-management-devices-market

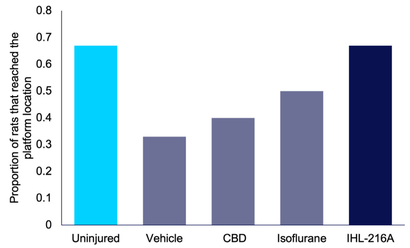
Clinical development status

Asset	Preclinical	Australian Phase 1/2	FDA Pre-IND	FDA IND	FDA Phase 1	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-216A TBI/Concussion								FDA pre-IND Q3 2022

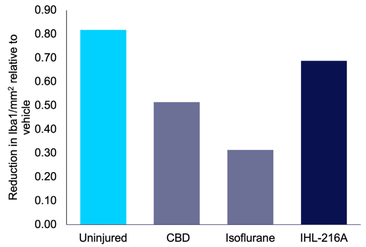
IHL-216A TBI animal model study results

Study 1

Rat controlled cortical impact model
Represents severe TBI



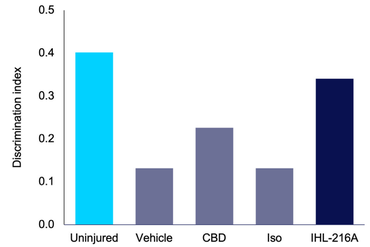
IHL-216A restored the spatial learning and memory deficit that occurs with TBI as assessed using the Morris water maze. The effect of IHL-216A was greater than either CBD or isoflurane monotherapy.



IHL-216 reduced neuroinflammation, assessed by determining levels of the neuroinflammatory marker Iba1 relative to the vehicle treated group, to a greater extent than either CBD or isoflurane monotherapy.

Study 2

Rat sports concussion model
Represents mild TBI



IHL-216A restored the spatial memory deficit that occurs with mTBI as assessed using the Y-maze. CBD only partially restored the deficit and isoflurane had no effect.

IHL-216A also restored the motor deficit and reduced neuronal cell death in rodents with TBI. These effects were greater than those observed with CBD and isoflurane monotherapies.

This model was developed by TBI researchers in collaboration with the NFL and NFLPA to accurately represent the types of TBI that occur during contact sports,

Acquisition of APIRx Pharmaceuticals USA, LLC

- Binding share purchase agreement executed to acquire 100% of APIRx Pharmaceutical USA, LLC ‘(APIRx’), subject to shareholder vote at Extraordinary General Meeting In June 2022. Acquisition of APIRx made by all scrip transactions, with a lock-up period of 12 months.
- The acquisition of APIRx delivers a strong portfolio of patented drug candidates, with 22 development programs covering a total addressable market of US$400B per annum.
- Together, Incannex and APIRx will form the world’s largest portfolio of patented medicinal cannabinoid drug formulations and psychedelic treatment protocols.
- Drug candidates are expertly designed to target irritable bowel syndrome, addiction disorders, spasticity and pain in multiple sclerosis, nausea and vomiting in chemotherapy, inflammatory bowel disease, periodontal disease and gingivitis, skin conditions, ophthalmic conditions, dementia, Parkinson’s disease, restless legs syndrome, among others.
- The APIRx integration to Incannex is anticipated to be seamless, as the development of assets is congruent with current operational capabilities and FDA pharmaceutical

Key Benefits of the APIRx Acquisition

01.

Substantial IP portfolio covering active pharmaceutical ingredients, formulations and methods of use to secure commercial exclusivity.

- Developed technologies and IP at all stages of cannabinoid drug development from extraction to therapeutic uses.

02.

Clinical stage: Proof of concept and formulations have been established for APIRx drug products.

- Multiple completed pre-clinical, phase 1 and phase 2 clinical trials.
- Favorable interactions with the FDA and other major regulators.
- Several pre-IND meetings completed and INDs open.
- Drug formulations to combat topical afflictions (addiction, dementia and pain)

03.

Potential for short runways to market by leveraging public data on existing FDA or EMA registered pharmaceutical cannabinoid products Sativex and Marinol. (owned by Jazz Pharmaceuticals, formerly GW Pharmaceuticals, and AbbVie Inc respectively)

- Short pathway to registration and commercial launch for MedChew™ Rx and MedChew™ Dronabinol, as the active pharmaceutical ingredient is the same as approved products but with a novel dosage form (medicated chewing gum for increased bioavailability and extended release).
- **Discussions with regulatory agencies for registration will focus on a request for a single bridging clinical trial for MedChew™ Rx and MedChew™ Dronabinol.**

04.

Commercially exclusive patented drug delivery technologies expand potential applications for established compounds and IHL-675A multi-use anti-inflammatory cannabinoid combination drug. Some of these technologies include:

- Medicated chewing gums and chewable tablets.
- High bioavailability oral mucosa delivery mechanisms.
- Super slow-release delivery formulations.
- Topical and ophthalmic formulations.

Key Benefits of the APIRx Acquisition

05.

Over-the-counter (OTC) patented CBD chewable tablet relevant to a range of ailments being planned for the CheWell high-bioavailability oral mucosa dosage form.

- Therapeutic Goods Administration (TGA) limits on daily CBD dosage for OTC cannabinoid products necessitate high bioavailability formulation such as CheWell being acquired by Incannex.
- Generic CBD oils have low bioavailability, due to low solubility, gastrointestinal loss, first pass metabolism and potentially low effectiveness.
- Opportunity to leverage favourable phase 1 and phase 2 trial data to expedite the TGA approval process.

06.

All research and development of APIRx assets in Australia will be eligible for the R&D tax rebate of 43.5% for R&D spend.

The progress of existing Incannex development programs will not be affected by the addition of new projects resulting from the APIRx acquisition.

Competitive Advantage

- The first ASX listed company to investigate psychedelics in combination with psychotherapy.
- A robust patent filing strategy and diversified drug portfolio including 6 drug development programs, creating long term benefits for our patients and shareholders.
- Highly credentialed and experienced specialist medical and scientific team including global key opinion leaders.

- Simplified FDA registration strategy to shorten time to commercialization.
- Multiple income streams; immediate revenue via SAS sales and future drug sales post-registration.

Corporate Information

Shares on issue	1,208,528,003
Director's interest	175,876,390 (14.6%)
Market Capitalization (A$0.42 per share)	A$524M (US$372M)

ASX share code: IHL | **NASDAQ code: IXHL**

Investment Highlights

Multiple clinical programs addressing unmet medical needs

- *28 clinical programs guided by a world class advisory board and group of partners
- Targeting conditions for patients with unmet needs
- Multiple INDs open with accelerated FDA registration strategy

Large Market Opportunities

- The combined annual global market size of the indications we are targeting is over *US$420 billion
- Combination cannabinoid drugs facilitate patent opportunities
- Dually listed on the ASX NASDAQ

*28 programs post the finalisation of the APIRx acquisition

*US $420b post APIRx acquisition

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