Incannex

Company Overview

ASX Ticker: IHL | NASDAQ Ticker: IXHL

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Company Overview

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

Our mission is to deliver novel drugs and therapies that transform the lives of patients currently experiencing unmet medical needs. We aim to develop targeted medicines at the cutting edge of biomedical science and cultural acceptance, creating long term benefit for both our targeted patients and shareholders who co-invest in our vision.

- Listed on the ASX in 2016
- Listed on the NASDAQ in 2022

Our mission *in action*

01 **World leaders**

Incannex Healthcare (NASDAQ: IXHL, ASX: IHL) is a world leader in the development of novel cannabinoid pharmaceuticals and psychedelic therapies.

02 **Diversified portfolio**

Diversified portfolio of candidates: clinical and pre-clinical studies have established proof of concept over 28 drug candidates for a broad range of under-met medical conditions representing major economic opportunities. Incannex is not a “one trick pony”.

03 **Backed by patents**

Pharmaceuticals backed by patents: recently completed acquisition strategically expands intellectual property portfolio; Incannex owns 19 patents and 27 provisional applications. Granted patents offer 20 years of commercial exclusivity.

04 **Purposefully distinct**

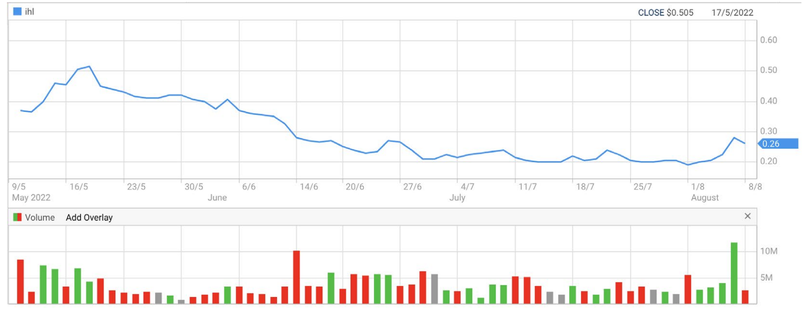
Purposefully distinct from other medicinal cannabis companies: combination cannabinoid drugs (CBD or THC combined with existing expired-patent pharmaceutical compounds) observed to have superior therapeutic outcomes to cannabinoids and the partner compound alone in sleep apnoea, traumatic brain injuries and various inflammatory conditions.

05 **Commercial focus**

Focus on commercialisation: project ideation is completed, and we are now working towards FDA and EMA development programs for drug registration and marketing approval, as well as over the counter sales opportunities in the near term.

Corporate Information

Shares on issue	1,523,593,695
Top 40 Shareholders	720,170,447 shares 47.27%
Market Capitalization (A0.28 per share / USD $4.89 per ADS)	$426M AUD / $294M USD



75.5¢ ↑

All time high

03/03/2022

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

Cash position

A$37.5M

as of 30th June 2022

Incannex is funded for the foreseeable future after raising $24M at A$0.35 in May of 2022.

Global markets have changed suddenly, but Incannex continues to strengthen.

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. Joel has over 15 years commercial management and executive experience, working for a range multi-national publicly traded companies.

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.

Peter Widdows
Non-Executive Director

Peter Widdows is the former CEO covering a large part of Asia and Australasia for the H. J. Heinz Co. He is also the Non-Executive Chairman of Sunny Queen Australia, Australia's largest egg and egg based meal producer and a Non-Executive Director of Youi - a general insurance company. Peter has extensive experience as a senior executive/CEO in many geographies including the UK, USA, Asia and Australasia. He is also a Fellow Chartered Accountant.

George Anastassov, MD DDS, MBA
Non-Executive Director

Dr. Anastassov is one of the developers of the first-in-the-world cannabinoid-containing chewing gum-based delivery system among a number of other systems and formulations. Previously, he was CEO and Co-founder of AXIM Biotechnologies, driving market capitalization to over USD $1.2 billion.

Lekhram Changoer, MSc
Chief Technical Officer

Mr. Changoer is responsible for the Company's R&D, clinical and product development, commercial operations, quality assurance, Sales and Marketing of technical, consumer healthcare and pharmaceutical products. He has co-developed several cannabinoid patents.

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.

Madhukar Bhalla
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.

Rosemarie Walsh
Vice President, Clinical Operations

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 VP clinical operations, Rosemarie oversees all aspects of Incannex's clinical trials.

28 Projects

over which proof of concept has been established in either pre-clinical, phase 1 or phase 2 clinical studies.

Established drug formulations with data packages necessary for regulatory applications.

Proof of concept data from pre-clinical and clinical studies supporting the proposed therapeutic applications.

Regulatory filings for multiple drug products.

Granted and pending patents for manufacturing methods, drug formulations and methods of use to treat a range of conditions.

– *Covers the entire drug development process from raw materials to patient dosing.*

Different cannabinoid development strategy than IHL's current programs.

– *Recently completed acquisition of APIRx adds unique cannabinoid formulations and delivery mechanisms protected by patent.*

Clinical Project	Addressable Market Opportunity (in US$)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
IHL-42X Obstructive Sleep Apnoea	$10.4B (U.S.)	Phase 2A completed	FDA Pre-IND completed	IND opening study	1x Pending Deemed novel & inventive
IHL-675A Inflammatory Lung Disease	$50.4B (U.S.) by 2022	Pre-clinical completed	FDA Pre-IND completed	Phase 1 CT	2x Pending Deemed novel & inventive
IHL-675A Rheumatoid Arthritis	$57B (U.S.) by 2022	Pre-clinical completed		Phase 1 CT	2x Pending Deemed novel & inventive
IHL-675A Inflammatory Bowel Disease	$20B (U.S.) by 2021	Pre-clinical completed		Phase 1 CT	2x Pending Deemed novel & inventive
IHL-216A TBI/Concussion	$2.9B in 2019	Pre-clinical completed	FDA Pre-IND scheduled (Sept. 2022)	IND opening study	2x Pending Deemed novel & inventive
Psi-GAD Generalized Anxiety Disorder	8M people (U.S. & AUS)	Phase 2A ongoing	FDA Pre-IND completed	Phase 1	Drafting
MedChew™-1401 Pain and Spasticity in Multiple Sclerosis	$62B (Global) in '21 (a)	Pre-clinical	Pre-IND completed in NL and Switzerland	Phase 1	Granted
MedChew™ GB Post-herpatic Neuralgia	$3.7B (U.S.) by '27 (n)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™-1502 Parkinson's Disease	$8.05B (Global) by '27; 6.5% CAGR (l)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™-1503 Dementia	$23.9B (Global) by '28; 7.9% CAGR (m)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™ RL Restless Legs Syndrome	12.1.% prevalence of U.S. pop. (j)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™ Dronabinol Nausea and Vomiting in Chemotherapy	$3.1B (Global) by '24 (e)	Phase 1A completed	FDA Pre-IND completed	Phase 1B	Granted
APIRx 1505 Flotex Gastro: Chrohn's Disease	$12.6B (Global) by '24 (k)	Pre-clinical	Pre-regulatory	Phase 1	Drafting

(a) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021

(d) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Irritable Bowel Syndrome / Disease

(e) Healdkeepers, "Chemotherapy Induced Nausea and Vomiting (CINV) Drugs Market Research Report, History and Forecast 2022-2027", Jan. 2, 2022

(j) Straits Research: Home Care Sleep Screening Devices Market

(k) Heraldkeepers,"Crohn's Disease Drugs Market Research Report 2022: Prospects, Trends Analysis, Market Size and Forecasts to 2027", Jan. 2, 2022

(l) Global Market Insights,"Parkinson's Disease Therapeutics Market", Base Year 2020

(m) Accurize Market Research,"Dementia Drugs Treatment Market", Nov. 27, 2021

(n) Comserve,"U.S. Shingles Vaccine Market", Jan. 4, 2022

(r) Coherent Market Insights "Inflammatory Bowel Disease Market Analysis", Sept. 2021.

Clinical Project	Addressable Market Opportunity (in US$)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
CanChew Plus Gastro: IBS	$40B (U.S.) in '21 (d)	Phase 2A Completed	Pre-IND, ethical approval	Phase 2B	Granted
CanChew RX Gastro: IBD	$2.78B (U.S.) by '28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
SuppoCan (Suppository) Gastro: IBD	$2.78B (U.S.) by 28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
Oraximax Gingivitis and Periodontitis	$42B (U.S. and Europe) in '21 (a)	Clinical Stage	510(k) pre-market submission to FDA	Phase 2	Granted
CheWell Addiction: Cannabis Dependence	$64B (U.S.) in '21 (c)	Pre-clinical	Pre-IND ready for submission	Phase 1	Drafting
CanQuit Addiction: Tobacco Smoking Cessation	$47.75B (Global) by '24, 17.3% CAGR (o)	Pre-clinical	Pre-regulatory	Phase 1	Granted
CanQuit O Addiction: Opioid Addiction	$64B (U.S.) in '21 (c)	Pre-clinical	Pre-regulatory	Phase 1	Granted
APIRx-1601 Skin: Vitiligo	$0.1B (Global) in '21 (b)	Phase 2 completed	Pre-IND drafting	Phase 1	2x Granted, 1x Pending
APIRx-1602 Skin: Psoriasis	$0.5B (Global) in '21 (b)	Phase 2A completed	Pre-IND drafting	Phase 1	2x Granted, 1x Pending
APIRx-1603 Skin: Atopic Dermatitis	$1.1B (Global) in '21 (b)	Phase 2A completed	Pre-IND drafting	Phase 1	2x Granted, 1x Pending
APIRx-1701 Opth: Glaucoma	$10.4B (Global) by '26, 6.3% CAGR (g)	Pre-clinical	Pre-regulatory	in vitro studies	Granted
APIRx-1702 Opth: Dry Eye Syndrome	$6.6B (Global) by '27, 6.4% CAGR (p)	Pre-clinical	Pre-regulatory	in vitro studies	Granted
APIRx-1801 Ultrapure THC	$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1802 Ultrapure CBD	$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1803 Ultrapure CBG	$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted

(b) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is medications and other, where other includes visits to physicians, in/out patient costs

(c) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Adolescent Substance Abuse

(g) ResearchandMarkets, "Outlook on the Glaucoma Therapeutics Global Market", 2020-2026", Oct. 22. 2021

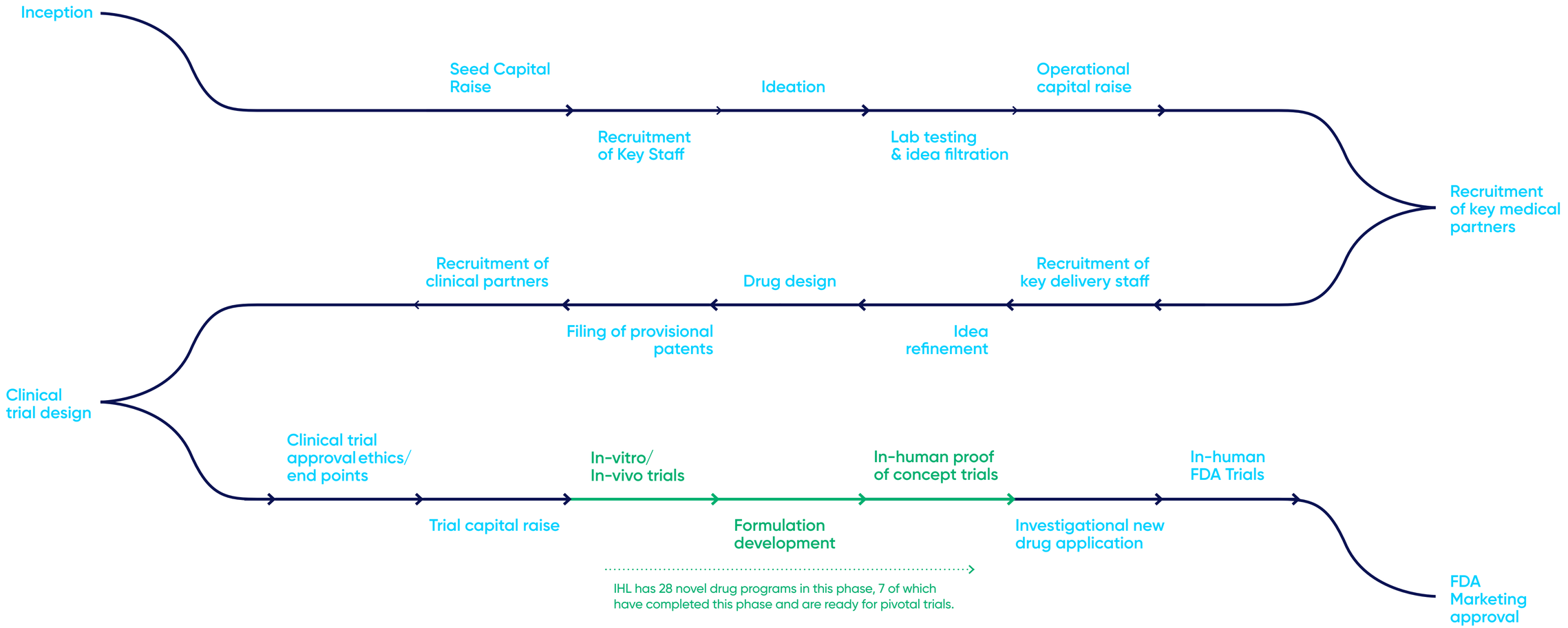
(o) Worldwide Market Reports,"Smoking Cessation and Nicotine De-Addiction Products Market", May 2018

(p) Future Market Insights,"Dry Eye Syndrome Treatment Market", July 2017

(q) Precedence Research "Cannabis Extract Market", Mar. 2020; includes THC, CBD, CBG and other

Our growth and where we are heading.

The typical biopharma life stages:



6 The six categories of opportunity

Incannex intellectual property

15
Lead Drug Candidates

Addressable Market Estimate
$290bn
per year

13
Secondary Drug/treatment Candidates

Addressable Market Estimate
$120bn
per year

3
Near Term Revenue Opportunities

Potential Revenue Estimate
$100m
per year

3
Novel Drug Delivery Systems

Potential Revenue Estimate
$150m
per year

3
Commercial, Agricultural & Industrial Technology

Potential Revenue Estimate
$40m
per year

2
Psychedelic Treatment Therapies

Potential Revenue Estimate
$2bn
per year

Partnerships

Camargo
A Division of Premier Research

labcorp

PROCAPS

BrainPark
DAVID W. TURNER RESEARCH CLINIC

THE UNIVERSITY OF WESTERN AUSTRALIA

NOVOTECH
The Asia Pacific CRO

VECTURA

AVANCE CLINICAL

VU UNIVERSITY AMSTERDAM

University of St Andrews

Universität Basel

MONASH University

NYU

UBC THE UNIVERSITY OF BRITISH COLUMBIA

Icahn School of Medicine at Mount Sinai

curia

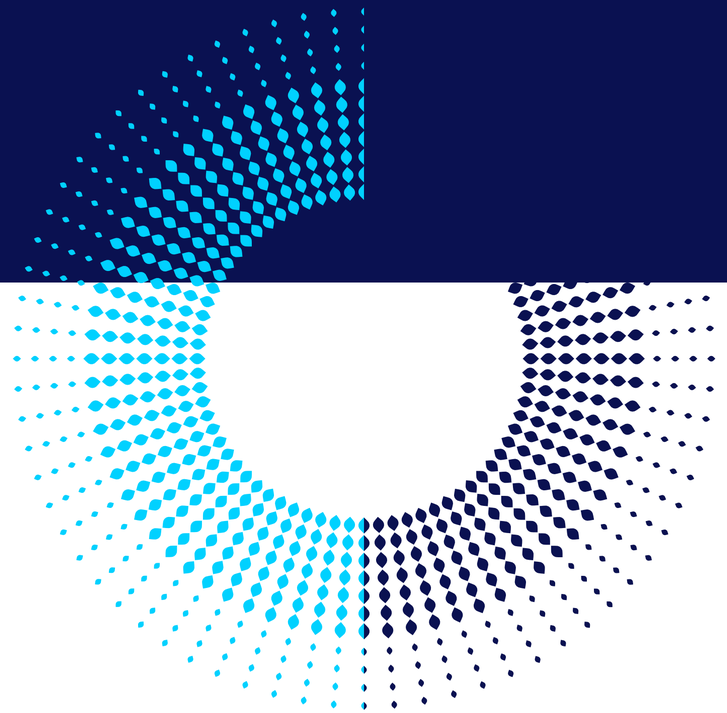
Competitive MOAT Strategy

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. Regulatory approvals for commercialization in other jurisdictions to be sought e.g. EU, Canada, Australia, Japan, etc.



Patents

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

Acquisition of APIRx completed in June adds 19 granted patents and 23 pending.

Economic Potential

With 28 active development programs within 6 active economic initiatives, there is significant value creation for our shareholders in both the near and long term.

APIRx Intellectual Property Families

19 granted and 23 pending patents to secure commercial exclusivity and our R&D investment.
Some patents meet more than one of the categories below:

Extraction

3 Granted
2 Pending

API modification

4 Pending

Formulation

17 Granted
15 Pending

Methods of use

3 Granted
5 Pending

Cannabinoid drug development pipeline

Formulation/Extraction

- Chewing gum (also combo products)
- Ultra-high bioavailability chewing gum / chewable tablet
- Oral care
- Ophthalmic solutions
- Suppositories
- Extraction of THC, CBD, CBG
- Cannabinoid sugar alcohol
- Microencapsulation of cannabinoids
- Sustained release technology

Methods of use

- Treat glaucoma and conjunctivitis
- Treat atopic dermatitis
- Antimicrobial
- Treat Vitiligo
- Treat Osteonecrosis of the jaw
- Treat psoriasis

Cannabinoid delivery methods with increased bioavailability and altered release profiles which provide opportunity to develop unique cannabinoid products and or products with advantages over established cannabinoid medicines.

Patent lawyers engaged for all psychedelic programs.

IHL-42X Obstructive Sleep Apnea

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 CO_2 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

Lead Assets ●○○○○○○○○○

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.

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

Patent application considered novel and inventive.

Clinical development status

Asset	Preclinical	Phase 2a CT	FDA Pre-IND	FDA IND	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-42X Obstructive Sleep Apnea*							Open FDA IND Q4 2022 Commence IND opening clinical trial

Strategic composition of dronabinol and acetazolamide makes IHL-42X an exciting novel potential treatment for OSA.

Dronabinol

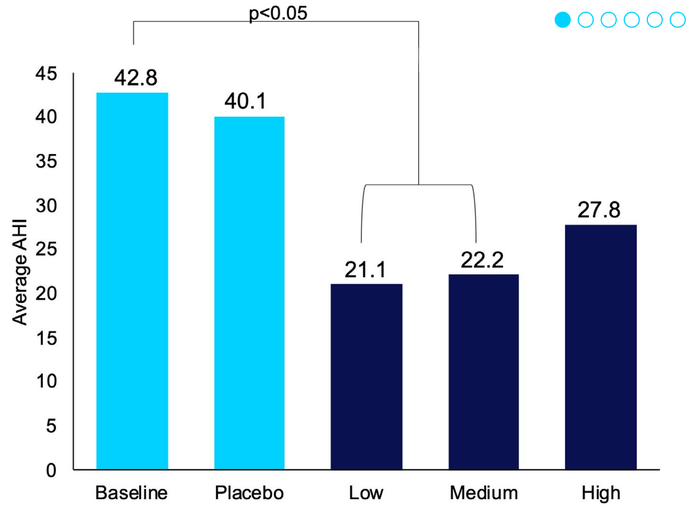
- Synthetic form of (-)-trans-Δ9-tetrahydrocannabinol (THC).
- Approved in US for treatment of HIV/AIDS induced anorexia and chemotherapy induced nausea and vomiting.
- Dampens afferent vagal feedback, stabilizes respiratory patterns and dilates upper airway.
- Two clinical trials to demonstrate effectiveness in reducing AHI in patients with OSA.

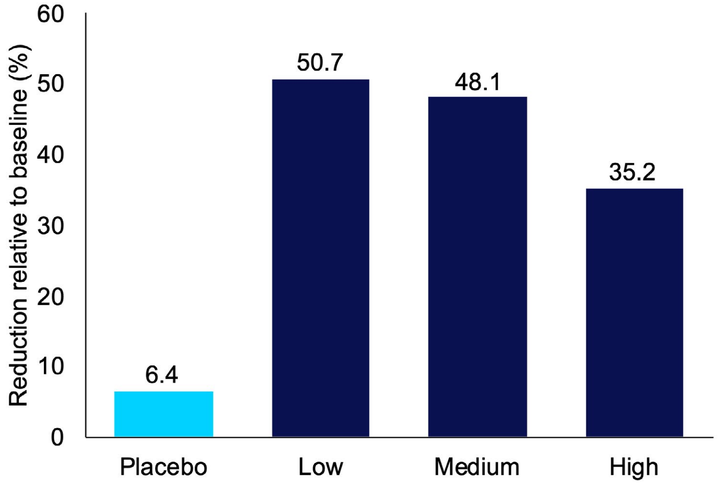
Acetazolamide

- Carbonic anhydrase inhibitor.
- Used to treat glaucoma, altitude sickness, epilepsy and other indications.
- Increases the difference between prevailing PCO_2 and apnoeic PCO_2.
- Demonstrated as an effective treatment for OSA in 14 clinical studies.

IHL-42X ⟶ reduced AHI at a group level.

- Low dose IHL-42X (2.5mg dronabinol, 250mg acetazolamide) was the most effective dose strength with an average reduction in AHI of 50.7% compared to the baseline.
- When comparing the means of the treatment groups, the difference observed for both low and medium dose compared to baseline was statistically significant (p<0.05).

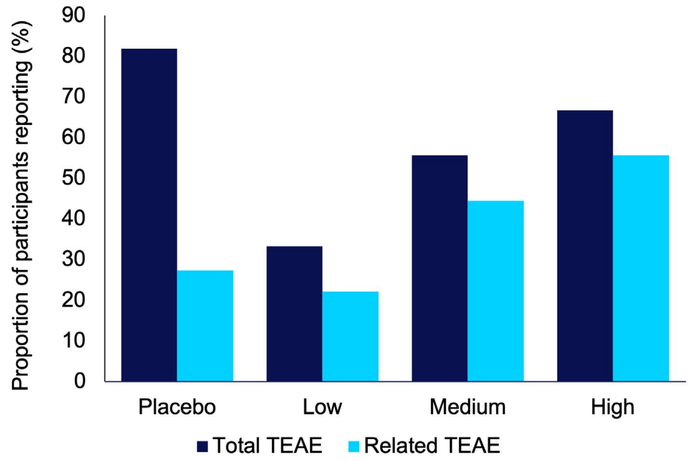


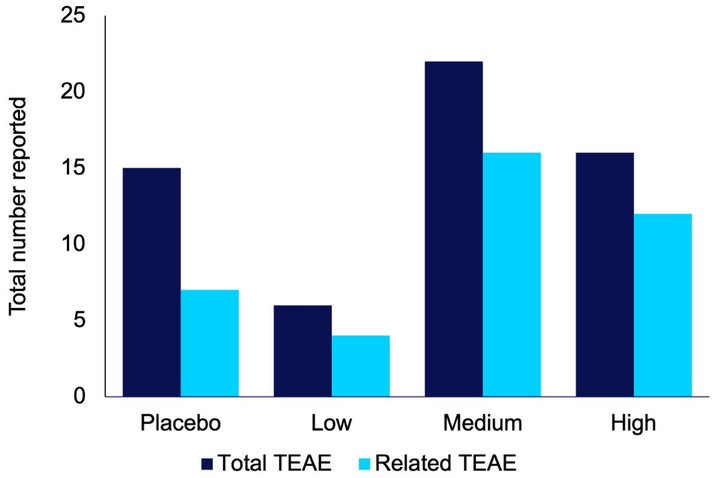


Results

IHL-42X ⟶ was well tolerated.

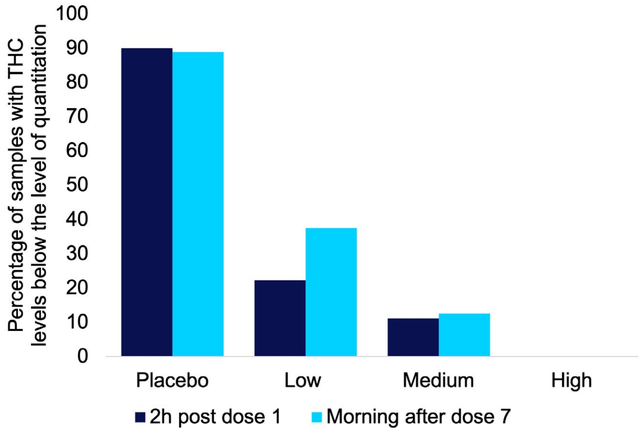
- No serious treatment emergent adverse events (TEAE) were reported during the study.
- Low dose IHL-42X had the lowest proportion of participants reporting TEAEs and the fewest number of total TEAEs compared to other treatment groups including placebo.
- One participant on high dose IHL-42X had a TEAE that caused them to be withdrawn from the study. However, they tested positive for illicit substances other than cannabis.
- One participant on placebo had a severe TEAE that was not linked to the study drug.

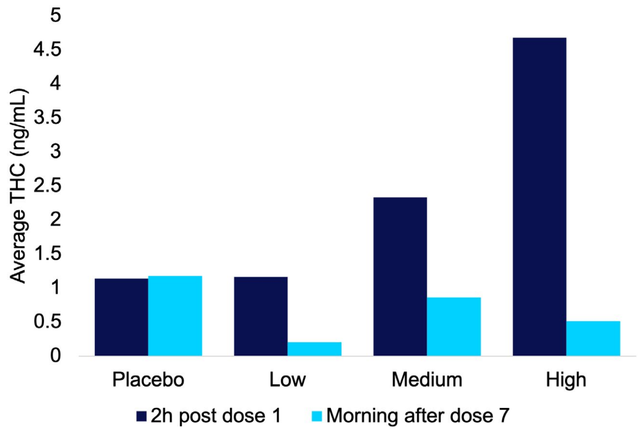




Results

IHL-42X THC clearance





- THC levels in blood samples collected the morning after dose 7 were below the limit of detection (0.1 ng/mL) in 37.5% of low dose IHL-42X samples.
- The average THC concentration in blood samples from the morning after night 7 in the low dose IHL-42X treatment period was 0.20 ng/mL.
- The highest THC concentration detected in a sample from the low dose group was 0.45 ng/mL.

1. https://www.justice.gc.ca/eng/cj-jp/sidl-rlcfa/qa2-qr2.html

2. Vindenes, V., et al., (2012) Impairment based legislative limits for driving under the influence of non-alcohol drugs in Norway, Forensic Science International 219(1-3,)1-11

3. Wolff, K, et al., Driving Under the Influence of Drugs: Report from the Expert Panel on Drug Driving, Department of Transport, London, 2013.

4. https://www.vifm.org/wp-content/uploads/VIFM-Annual-Report-2019-2020.pdf

The blood concentration of THC was below the impairment limit to drive

Country	THC blood concentration above which driving is prohibited
Canada[1]	2 ng/mL
Norway[2]	1.3 ng/mL
UK[3]	2 ng/mL
Ireland[4]	1 ng/mL
Germany[4]	1 ng/mL

IHL-42X Conclusions

01.

Data from phase 2 proof of concept clinical trial supports the potential of IHL-42X as an effective and well tolerated treatment for OSA, meeting the unmet needs of millions of people.

02.

IHL-42X reduced AHI, improved sleep quality with respect to both patient reported outcome and actigraphy, and did not lead to any adverse events beyond those expected based on what was expected from dronabinol and acetazolamide.

03.

Low dose IHL-42X was the most effective of the doses tested in this study.

- It reduced AHI by over half (on average) in trial participants and 25% of participants saw an 80% reduction in AHI.
- Low dose IHL-42X has the lowest number of reported adverse events, even lower than placebo.
- Low observed THC blood concentration amongst participants below limits for impairment to drive.

04.

Patent application for IHL-42X considered "novel and inventive" by international patent examiner.

05.

Pre-IND meeting completed with FDA and the next major development milestone for IHL-42X will be the commencement of the IND opening clinical trial.

IHL-675A Novel multi-use drug candidate

Pulmonary inflammation model

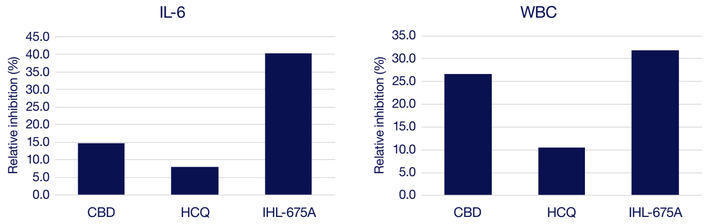
Mice were treated with IHL-675A, CBD or Hydroxychloroquine ("HCQ") prior to induction of pulmonary inflammation. Lung fluid was collected and analyzed for inflammatory markers.

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.

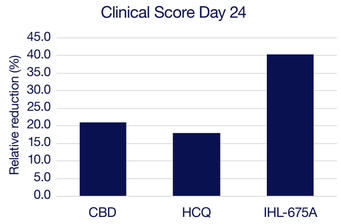
Inflammatory bowel disease model

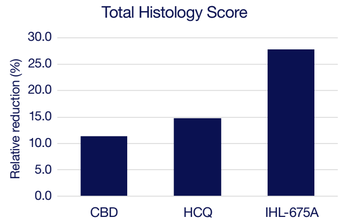
To assess the potential for IHL-675A in treatment of inflammatory bowel disease an mouse ulcerative colitis model was used. Colitis was induced prior to treatment with IHL-675A, CBD or HCQ. On day 5, the mice were sacrificed and the colon removed for analysis.



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.

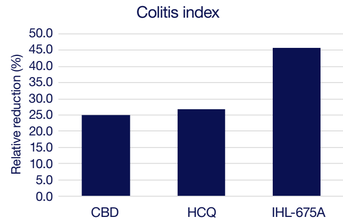
This indicates IHL-675A has the potential to treat lung inflammation.

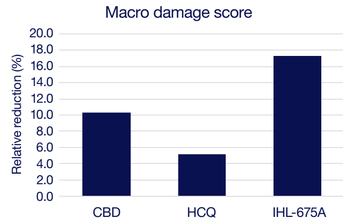




IHL-675A treated animals had a greater reduction in clinical score, a composite based on joint swelling and the histology score, which is a composite based on post-mortem analysis of joint tissue, than animals treated with either CBD or HCQ alone.

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

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

Lead Assets ●●○○○○○○○○

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	FDA Pre-IND	Phase 1 CT	FDA IND	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-675A Inflammatory Lung Disease#							Complete Phase 1 CT Open FDA IND Phase 2 CT 2023

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

IHL-675A Rheumatoid Arthritis

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 reduced disease severity in an animal model of rheumatoid arthritis to a greater extent than either CBD or hydroxychloroquine sulfate alone.

Addressable Market

Lead Assets ●●●○○○○○○

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	Phase 1 CT	FDA IND	FDA Phase 2	FDA Phase 3	Anticipated Milestones	
IHL-675A Rheumatoid Arthritis#						Complete Phase 1 CT FDA Pre-IND meeting	FDA IND Phase 2 CT 2023

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

IHL-675A Inflammatory Bowel Disease

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-675A reduced disease severity in an animal model of inflammatory bowel disease to a greater extent than either CBD or hydroxychloroquine sulfate alone.

Addressable Market

Lead Assets ●●●●○○○○○○

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	Phase 1 CT	FDA IND	FDA Phase 2	FDA Phase 3	Anticipated Milestones	
IHL-675A Inflammatory Bowel Disease#						Complete Phase 1 CT FDA Pre-IND meeting	FDA IND Phase 2 CT 2023

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

IHL-216A Concussion

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

Lead Assets ●●●●●○○○○○

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

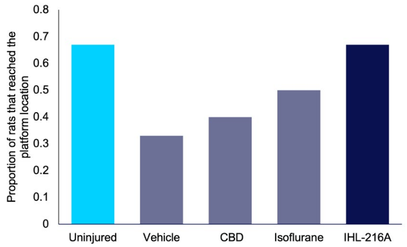
Clinical development status

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

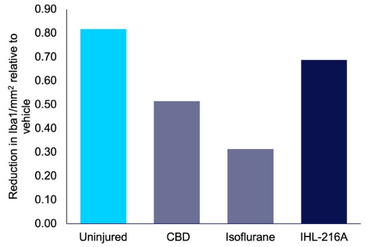
IHL-216A TBI animal model study results

Study 1

Rat controlled cortical impact model
Represents severe TBI



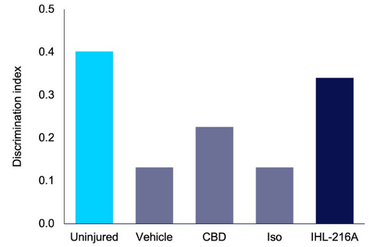
IHL-216A restored the spatial learning and memory deficit that occurs with TBI as assessed using the Morris water maze. The effect of IHL-216A was greater than either CBD or isoflurane monotherapy.



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,

Why cannabinoid oral delivery via medicated chewing gum and chewable tablets

Medicated chewing gum and chewable tablets ('MCGT') is a drug delivery system growing in favour amongst the medical community due to widespread potential applications as an extended-release dosage form that provides a continuous release of the medicine contained. MCGTs are fast acting as they release the active ingredients into the oral mucosa, reducing the potential for gastric intolerance amongst patients. These qualities, amongst others, make MCGTs an excellent delivery system for medicinal combinations designed to treat sustaining pain and addiction disorders.

Extended release of cannabinoid and other pharmaceutical ingredients while chewing.

APIRx have a patented procedure for conversion of cannabinoids to their hydrophilic form.

Well tolerated by patients. No capsules to swallow or messy liquids to administer.

Cannabinoid absorbed via oral mucosa (mouth)

- Avoids first pass metabolism in the liver, a major factor that reduces the oral bioavailability of cannabinoids.
- Avoids gastrointestinal intolerance of pharmaceutical ingredients.
- Increased bioavailability leads to increased therapeutic effect and/or reduced cost of goods due to reduced dose.

Benefits of Mastication*

- Improved cerebral circulation
- Anxiety reduction effect: De-stress or "eustress"
- Hypothalamic-hypophyseal-adrenal axis (HPA) coordination/ attenuation
- Memory coordination/ improvement
- Neuroprotection
- Analgesic effect
- "Physical exercise" effect

** Weijenberg, Roxane Anthea Francesca, and Frank Lobbezoo. "Chew the pain away: oral habits to cope with pain and stress and to stimulate cognition." BioMed research international 2015 (2015).*

Canchew and Chewell patented MCGTs
for Over-the-Counter ('OTC') and Prescription markets

Lead Assets

01.
MCGTs, using APIRx patented formulation technology, with potential to develop as OTC products in Australia and other jurisdictions (U.S., EU, UK, et cetera).

02.
Phase 1 Pharmacokinetic (PK) study demonstrated that the patented CheWell formulation led to >10x increase in CBD bioavailability compared to the standard CBD chewing gum delivery mechanisms.

03.
Therapeutic effect and commercial considerations will dictate whether to administer CBD via CheWell chewable tablet or CanChew chewing gum dosage forms.

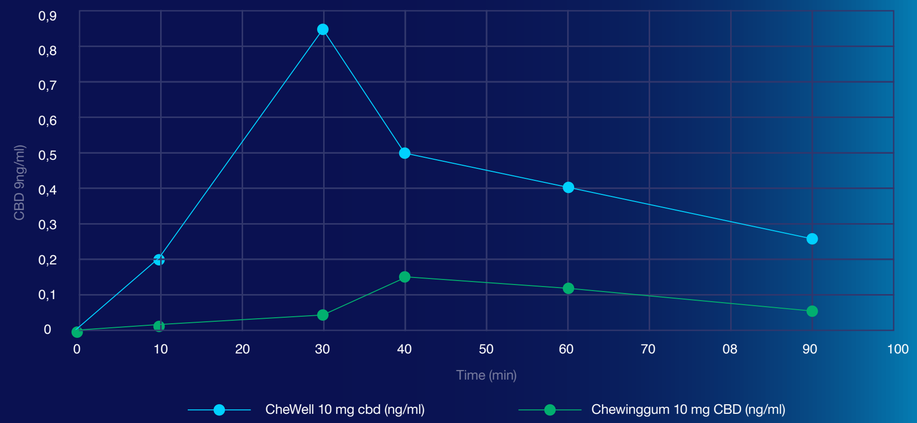
04.
Data from 36 patient phase 2 proof of concept trial observed a 50% reduction in abdominal pain in CheWell treated Irritable bowel syndrome (IBS) patients, supporting a therepeutic effect in IBS.

05.
Therapeutic claims from the phase 2 clinical trial and proven high bioavailability increases marketability.

06.
International regulatory analysis being undertaken to identify what is required for commercial launch.

07.
Potential to develop CheWell for treatment of pain and cannabis addiction.

Bioavailability CheWell vs Chewingum



1) Analysis of CheWell shows an early onset and 10-fold higher CBD bioavailability than in a non-microencapsulated chewing gum.

Improved bioavailability means that even small doses of CBD within MCGTs could be highly effective even without a prescription from a doctor. That is, they would meet the TGA requirements for an OTC product.

Increased bioavailability also reduces cost of goods, which increases margins.

First marketing claim could be for IBS, however, could be suitable for a range of indications for which CBD may currently assist patients.

Cannabinoid Chewing Gums and chewable tablets for Treatment of Addiction

APIRx has multiple patents for cannabinoid based drug candidates designed for treatment of addiction to different drug classes.

Marijuana addiction

CheWell for Cannabis Dependence

APIRx has a patented CBD chewable tablet high-bioavailability that can be used in treatment of marijuana addiction.

- Cannabis dependence is predicted to to be the fastest growing segment of drug dependence market.
- Preliminary data suggest a possible beneficial impact of CBD on mitigating the craving effect of cannabis; while a case report has shown positive outcomes for one patient treated with CBD during the withdrawal and relapse phase of cannabis dependence.
- Pre-IND with FDA is pending.

Smoking cessation

CanQuit – Nicotine Addiction

APIRx patented chewing gum that combines cannabinoids with reducing doses of nicotine.

- OTC product to be trialled for effectiveness against existing nicotine medicated chewing gums.
- A more-effective and cost effective cannabinoid + nicotine gum may disrupt the incumbent global nicotine gum market, which had sales of US$ 5.2B in 2020.
- By combining nicotine and cannabinoids, patented APIRx product CanQuit is designed to better assist addicted smokers to quit smoking.

Opioid addiction

CanQuit O – Opioid Addiction

APIRx patented chewing gum that combines cannabinoids with opioid agonists and/or antagonists.

- A prescription product to combat the opioid addiction for which the annual market size in the United States alone is expected to reach US$ 64B by 2028.
- The act of mastication (chewing) aids neuroprotection, has an analgesic and anti-anxiety effect, which should also assist to suppress opioid cravings.

Lead Assets

Opioid use disorder addressable market

US$ 64B*

Nicotine chewing gum market sales of

US$ 5.2B in 2020**

MCGs for nicotine addiction already accepted in the real world.

* Frost & Sullivan Market Report as commissioned by APIRx; and other publicly available information

** https://www.imarcgroup.com/nicotine-gum-market

MedChew™ Rx (CBD and THC)
for Pain and Spasticity in Multiple Sclerosis (MS)

Problem

Up to 84% of people suffering from MS also experience spasticity, which causes involuntary muscle stiffness and spasms. Pain is also a common symptom in MS, with up to two-thirds of people with MS reporting pain in worldwide studies.

Solution

MedChew™ Rx is absorbed through the oral mucosal membrane and bypasses the liver, and first pass metabolism. No cannabinoid-based drug approved for pain management in MS or other pain producing conditions.

Patents

1) Granted: Chewing gum comprising cannabinoids.
2) Granted: Process to extract and purify delta-9-THC.

Competitive Advantage

MedChew™ Rx contains the same constituents as Sativex, however provides extended dosing, reducing the need to readminister, which for Sativex is up to 12 times per day, MedChew™ Rx does not contain alcohol, which Sativex does, and will not exacerbate the dry mouth that is ofter associated by MS pharmacotherapy.

Addressable Market

Lead Assets ●●●●●●●●○○

US$ 62B*
Associated Total Global Direct Healthcare Costs in '21

50%
Increase in Global MS Prevalence 2013 to 2020

** Frost & Sullivan Market Report as commissioned by APIRx, Oct. 2021*

Sativex (nabiximols, THC+CBD)

- Approved for use in Europe and Canada.
- Oromucosal spray approved in multiple jurisdictions in Europe and Canada (not U.S. currently) for treatment of spasticity associated with MS.
- Although it targets oral mucosa, it has recently been suggested that the drug is partially washed away by saliva and absorbed in the GI tract.
- Administered too frequently - up to 12 times per day.
- Alcohol in formulation exacerbates dry mouth symptoms associated with MS pharmacotherapy.

MedChew™ Rx (THC+CBD)

- MedChew™ Rx is absorbed in oral mucosa, bypassing first pass metabolism, increasing bioavailability.
- Increased bioavailability may also mean that MedChew™ Rx is effective at treating pain associated with MS.
- The MedChew™ Rx formulation has been developed and patented by APIRx.
- MedChew™ Rx provides extended dosing, reducing need to readminister frequently.
- MedChew™ Rx does not contain any alcohol.
- Pre-IND meetings completed with Swiss-Medic (Switzerland) and CBG-MEG (Netherlands).

Next Steps:

- Step 1 - Potential fastrack to EMA drug approval with bioequivalent phase 1 bridging study* to bridge to Sativex CBD/THC oral spray safety and efficacy data.
- Step 2 - Additional late stage (phase 3 or 4) clinical trials to support extension of label claims to additional indications where THC+CBD is reported to have a therapeutic benefit.

*a bridging study is a study designed to demonstrate that an investigational product is sufficiently similar to an approved product and establish a bridge to data, safety and/or efficacy, that is already accepted by the regulatory authority for the approved drug product

MedChew™ Dronabinol

Nausea and Vomiting in Chemotherapy

Problem

According to the WHO, cancer is one of the leading causes for death. Chemotherapy is utilized by 10 million cancer patients each year. This number will grow by 53% by 2040. Nausea and vomiting are two of the most dreaded cancer treatment-related side effects.

Solution

MedChew™ Dronabinol treatment for Chemotherapy-related nausea and vomiting.

Clinical Trial Results

1) All subjects showed a release of dronabinol starting at 10 minutes, providing evidence of oro-mucosal absorption.
2) In most of the study's subjects, the dronabinol Pharmacokinetic (PK) profile reflected a sustained released effect for four to eight hours after administration.
3) No serious side effects reported.

Competitive Advantage

- Product fully formulated.
- Completed IND with the FDA.
- Completed Pharmacokinetic (PK)/ Pharmacodynamic (PD) studies.

Addressable Market (a)

Lead Assets

US$ 3.1B

Chemotherapy Induced Nausea and Vomiting Drugs (Global) by '24

7.5%

CAGR from 2018 - 2024

a) Brisk Insights, "Chemotherapy Induced Nausea And Vomiting Treatment Market, 2018-2026", Sept. 8, 2021

Dronabinol

- Approved for treatment of chemotherapy associated nausea and vomiting as well as anorexia associated with HIV/AIDS.
- Oral dronabinol is taken up slowly, 1-2.5 h to reach peak plasma concentration, and subject to first pass metabolism, which means that only 10-20% of the dose reaches the circulation.
- Global dronabinol market was US$ 147.2M in 2020. CAGR of 4.5% during 2021-2026 leading to projected market of US$ 191.9M by 2026.

MedChew™ Dronabinol

- Absorption through the oral mucosa bypasses first pass metabolism, increasing bioavailability.
- The formulation has been developed and is patented by APIRx.
- In a phase 1A study THC appears in circulation within 10 min and a sustained release profile was observed in most study subjects so that the product is more useful in the time in which it is required.
- IND open with FDA.

Next Steps:

- Step 1 - Conduct Bioavailability/Bioequivalence clinical study to support application for approval by bridging to publicly available data on Marinol.
- Step 2 - Additional late stage (phase 3 and 4) clinical trials to support additional indications where THC is reported to have a therapeutic benefit.

Psi-GAD Generalized Anxiety Disorder

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

Lead Assets

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

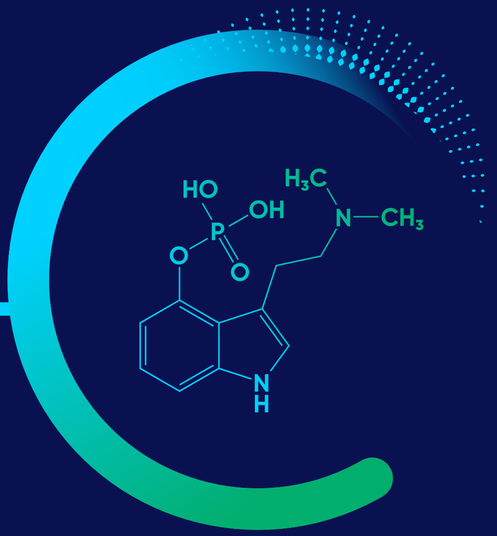
Clinical development status

Asset	Preclinical	FDA Pre-IND	Phase 2a CT	FDA IND	FDA Phase 2	FDA Phase 3	Anticipated Milestones
Psilocybin ("Psi-GAD") Generalized Anxiety Disorder+							Phase 2a mid trial results "readout" Q4 2022 Open FDA IND

+ 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.

Psi-GAD Phase 2a trial design

World-first clinical trial prioritising scientific independence and rigour for the best patient outcomes

The Study

A phase 2 randomised triple-blind active-placebo-controlled clinical trial

Safety and Efficacy

The safety, efficacy and tolerability of psilocybin-assisted psychotherapy

Participants

72 participants that will experience two psilocybin or active-placebo dosing sessions

Psychotherapy

Up to 11 non-drug, specialist psychotherapy sessions over a period of 10 weeks

Primary Outcomes

Reduction in anxiety as measured using the Hamilton Anxiety Rating Scale

Secondary Outcomes

Quality of life, functional impairment and comorbidities

Analysis

A preliminary analysis of patient data will be conducted after 30 patients, full analysis at 72 patients

2B Planning

Preliminary analysis will inform the second part of the trial (n=42) and/or facilitate commencement of the phase 2b pivotal clinical trial

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
- Dual listed on the ASX and NASDAQ

Short term priorities and value drivers

Program	Value driver	Next steps
CheWell for treatment of IBS	– OTC product for Australia with potential to extend to global markets	– Meeting with TGA to discuss clinical data requirements for CheWell™ to become an OTC CBD product in Australia
CanQuit (addiction products)	– Step change on established market for use of chewing gum for treatment of addiction	– Pre-IND meeting with FDA and clinical trial preparations
MedChew™ Rx	– Fast path to market by bridging to Sativex regulatory data	– Regulatory approval application following bridging clinical trial
MedChew™ Dronabinol	– Fast path to market by bridging to Dronabinol regulatory data	– Regulatory approval application following bridging clinical trial
CanChew Rx/SuppoCan for treatment of IBD	– Unique route of delivery for treatment of gastrointestinal disorders	– Phase 1 clinical trial to understand bioavailability of CBD suppository
Oraximax for treatment of periodontal disease and gingivitis	– Fast path to market due to regulation of mouthwash products as a “medical device”	– Phase 2 clinical trial to support efficacy and potentially product registration
Topical CBD formulation	– Patented formulation with proof of concept clinical trial data – No approved cannabinoid products with a similar delivery route	– Pre-IND meeting with FDA
Opthalmic formulation	– Patented formulation – No approved cannabinoid products with a similar delivery route	– Phase 1 and proof of concept clinical trials
IHL-42X for treatment of obstructive sleep apnoea	– Patented drug product that treats a condition for which there are no approved pharmacotherapies – Proof on concept clinical trial supports safety and efficacy of IHL-42X	– Open IND, IND opening clinical trial
IHL-675A for treatment of rheumatoid arthritis	– Patented drug product that provides evidence-based cannabinoid product to rheumatoid arthritis market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in rheumatoid arthritis
IHL-675A for treatment of inflammatory bowel disease (IBD)	– Patented drug product that provides evidence-based cannabinoid product to IBD market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in IBD
IHL-675A for treatment of lung inflammation	– Patented drug product that provides evidence-based cannabinoid product to lung inflammation market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in lung inflammation
IHL-216A for treatment of traumatic brain injury	– Patented drug product for treatment of a condition for which there are no approved pharmacotherapies	– Pre-IND meeting with FDA and clinical trial preparations
Psilocybin assisted psychotherapy for treatment of generalized anxiety disorder	– Combination of a unique psychotherapy with psilocybin to address underlying cause of disorder and build new mental connections reduce disease severity	– Completion of Phase 2 clinical trial at Monash University

Development of IHL’s six current programs will continue as previously described. Progress will not be disrupted by the APIRx acquisition.

Incannex

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