Incannex

2022
Annual report

Limitless Potential

Incannex Healthcare Limited
ASX: IHL | NASDAQ: IXHL

Our Mission is to create first-in-class pharmaceutical drugs and therapies for patients with unmet medical needs.

Corporate Information

Incannex Healthcare Limited

ABN 93 096 635 246

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Directors

Mr Joel Latham (Managing Director & CEO)

Mr Troy Valentine (Non-Executive Chairman)

Mr Peter Widdows (Non-Executive Director)

Dr George Anastassov (Non-Executive Director)

Mr Robert B. Clark (Non-Executive Director)

Company Secretary

Madhukar Bhalla

Registered Office

Level 39, South Tower Rialto
525 Collins Street
Melbourne Victoria 3000

Principal Place of Business

105/8 Century Circuit
Norwest 2153

Share Register

Automic Pty Ltd
Level 5 126 Phillip Street
Sydney NSW 2000
T +61 2 9698 5414

Auditors

PKF Brisbane Audit
Level 6, 10 Eagle St
Brisbane 4000, Queensland

Securities Exchange Listing

ASX Limited (Australian Securities Exchange)
Home Exchange: Melbourne Victoria
ASX Codes: IHL

Contents

Chairman's Message

On behalf of the Board of Directors, I am pleased to present the Annual Report of Incannex Healthcare Limited ("Incannex" or "IHL") for the financial year ended 30 June 2022.

The year has presented Incannex with major opportunities and good fortunes in our research endeavours despite challenging conditions for capital markets in the second half of the year.

The hard work and dedication of our broader team has culminated in Incannex becoming an ASX300 company, an outstanding achievement that puts our business in an echelon that all emerging public companies strive for, and we have a lot more to look forward to in the coming year.

Our CEO, Joel Latham has continued to provide outstanding leadership for the team, which has been bolstered by new staff appointments of highly experienced people in key roles for our company.

Operationally we've seen significant advancements in clinical development across the entire portfolio.

In our IHL-42X program to treat obstructive sleep apnoea, patients in our phase 2 trial were dosed safely and successfully and the clinical trial results in fact exceeded the expectations of our scientific team. We're now looking forward to working on our FDA IND opening trial, which marks the commencement of the pivotal studies required to obtain drug registration and marketing approval in the United States.

It was also an important year for IHL-675A, our multi-use cannabinoid drug candidate for inflammatory disorders. Various pre-clinical assessments of IHL-675A have demonstrated superior outcomes to CBD alone, which is encouraging to us from a marketability and economic perspective.

A significant body of work has been undertaken to produce GMP grade soft gel capsules incorporating our drug candidate, these capsules are being used in our phase 1 clinical trial being conducted in Adelaide, South Australia.

We're also very pleased with progress in our IHL-216A program to treat traumatic brain injury and concussion. In May of 2022, we reported to ASX that IHL-216A demonstrated a neuroprotective effect in a rodent model of sports concussion, restoring spatial memory post-concussion more rapidly than untreated animals. Following these and other positive pre-clinical observations, we are now liaising with the FDA on an appropriate clinical program to demonstrate our product's safety and efficacy.

Our partnership with Monash University continues to flourish as we work with world renowned Dr Paul Liknaitzky to undertake clinical trials in the psychedelic therapy space. The phase 2 Psi-GAD clinical trial that combines psilocybin and psychotherapy to treat patients with generalised anxiety disorder has been led with the utmost professionalism and enthusiasm. Psychedelic therapies continue to garner attention from the psychiatric field globally and we are delighted to be working with Monash University to build this highly innovative mode of treatment.

From a corporate perspective, we are excited to have finalised the acquisition of APIRx Pharmaceuticals. Integrating with APIRx has significantly enhanced our intellectual property position and has diversified our pipeline of drug candidates with a suite of projects with major economic potential. I'd like to welcome Dr George Anastassov and Mr Lekhram Changoer, the founders of APIRx, to the Incannex team.

Financially, the company remains in a strong position with a long cash runway, reinforced by our $24 million option exercise program completed in April. Moreover, completing our listing on Nasdaq has opened us to a whole new market of stakeholders in the United States.

Our strong financial position and having strong investor visibility in Australia and the United States gives us the necessary comfort to conduct our research programs unimpeded and at pace as we focus on delivering our novel pharmaceutical products and therapies to patients in need.

Finally, I would like to thank CEO and managing director Mr Joel Latham and the entire Incannex team for their energy and commitment they bring to Incannex on a daily basis. I thank our shareholders - we very much appreciate your support and look forward to our exciting journey together throughout FY2023.

Troy Valentine
Chairman

Integrating with APIRx has significantly enhanced our intellectual property position and has diversified our pipeline of drug candidates with a suite of projects with major economic potential.

Directors' Report

Your directors submit the annual financial report of Incannex Healthcare Limited ("IHL" or "the Company") and its wholly owned subsidiary ('the Group") for the financial year ended 30 June 2022. In order to comply with the provisions of the Corporations Act 2001, the Directors report as follows:

Directors

The names of directors who held office during or since the end of the year and until the date of this report are as follows. Directors were in office for this entire period unless otherwise stated. No director served as a director of any other listed company during the period of three years immediately before the end of the financial year.

Mr Joel Latham
Managing Director & Chief Executive Officer

Appointed 24 July 2019

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.

Mr Troy Valentine
Non-Executive Chairman

B. Comm
Appointed 11 December 2017

Troy Valentine has been Chairman of the Board of Directors since December 2017. Mr. Valentine is a finance professional with managerial and Board experience spanning over 27 years. He commenced his career with Australian brokerage firm Hartley Poynton (now Euroz Hartley's Limited) in 1994 before moving to Patersons Securities (now Canaccord Genuity) in 2000 and subsequently became an Associate Director. During his time at Patersons, he was responsible for managing both retail and institutional accounts. Mr. Valentine has significant corporate and capital raising experience, especially with start-ups and small to mid-cap size companies.

He is currently a director of Australian boutique corporate advisory firm Alignment Capital Pty Ltd, which he co-founded in 2014.

Mr Peter Widdows
Non-Executive Director

ACA (ICAEW), BTec, MAICD
Appointed 1 March 2018

Peter Widdows is the former Regional CEO of the H.J. Heinz corporation, with responsibility for a large portion of Asia and Australasia. He has extensive experience in Australian and international consumer goods markets and has worked as a senior executive/CEO in numerous geographies, including Europe, the USA and Asia/Pacific. Mr Widdows has a strong track record of driving profitable growth in both small and large companies and turning around poor performing businesses.

He is the current Non-executive Chair of Sunny Queen Australia Ltd – Australia's largest shell egg and egg based meal producer and a Non-Executive Director of Youi Holdings Ltd – A general insurance company.

Dr George Anastassov
Non Executive Director

Appointed 28 June 2022

Dr Anastassov is responsible for APIRx commercial operations, strategic decision-making, and oversight of all clinical development assets. He 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, which achieved an all-time-high market capitalization of approximately US$1.2B.

Director's Report

Company Secretary

Robert Clark
Non Executive Director

Appointed 17 August 2022

Robert Clark is currently the Vice President, Regulatory Affairs for Novo Nordisk in the United States. He joined Novo Nordisk in 2012 after spending over 20 years at Pfizer in roles of increasing responsibility in the regulatory field. Robert has over 35 years of US and global regulatory experience. Under his leadership, his regulatory teams have received US FDA approvals for a large number of medicines across various therapeutic areas.

Madhukar Bhalla

Appointed 7 July 2021

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. Madhu also has significant business and management experience having previous job titles including general manager and corporate administrator. Madhu was the managing director of Colortype Press for a period of 8 years until 2004. There, he was responsible for the overall management of the business, including marketing, contracting, procurement and directing over 30 employees.

Director's Meetings

The number of meetings of Directors held during the year, and the number of meetings attended by each director were as follows:

Name	Number of meetings eligible to attend	Number of meetings attended
Troy Valentine	11	11
Peter Widdows	11	11
Dr Sud Agarwal	10	10
Joel Latham	10	10

Principal Activities

During the financial year, the principal activity of the Company was research and development associated with medicinal cannabinoid and psychedelic pharmaceutical products and therapies.

Review of operations and significant changes in state of affairs

Operating result for the year

The Group's loss for the year to 30 June 2022 after income tax was $14,903,909 (2021: Loss of $8,163,590).

Cash resources

At 30 June 2022, the Group had total funds, comprising cash at bank and on hand of $37,500,931 the majority of which is held in Australian dollars. Total current assets at year-end stand at $37,879,608.

Business activities and outlook

Our mission is to create premier ethical pharmaceutical drugs and therapies for patients with unmet medical needs, in all instances fulfilling regulatory requirements of the Food and Drug Administration (“FDA”) and other relevant regulatory agencies (EMA, TGA).

Business activities and outlook

Additionally, we seek to secure patents on our drug candidates in conjunction with our medical and scientific staff, advisors and the investigators of our research studies that constitute our advisory board. Our advisory board is comprised of industry and academic experts familiar with our business, and we meet with the advisory board regularly.

The current members of our advisory board are Dr. Sud Agarwal (our Chief Medical Officer and Director), Dr. Mark Bleackley (our Chief Scientific Officer), Rosemarie Walsh (our Clinical Research Manager), Dr. Ron Jithoo (neurosurgeon and advisor for IHL-216A), and Dr. Paul Liknaitsky (psychedelic principal investigator from Monash University). Our advisory board also comprises our collaborative partners, in particular Monash University. Clinical trials are being conducted at The Alfred Hospital and the University of Western Australia Centre for Sleep Science with Prof Terence O'Brien (Alfred Hospital), Dr Jennifer Walsh (University of Western Australia) as principal investigators.

To achieve our goals, we intend to:

01. Advance

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

We are pursuing FDA approval of all our drug candidates currently in development. All preclinical and clinical trials are structured to ensure that each program is FDA compliant. We will be pursuing a New Drug Application ("NDA") with the FDA with respect to each of our drug candidates. If the NDA is approved, the product may be marketed in the United States. Once an NDA for one of our drug candidates is approved in the United States, we plan to pursue marketing approval of our drug candidates in other regions including Europe, Japan, Australia and Israel.

02. Accelerate

Take advantage of accelerated commercialisation pathway options for our drug candidates.

We and our regulatory consultants believe that each of our drug candidates will qualify for one or more FDA expedited review programs (breakthrough designation, accelerated approval, priority review and/or fast track), as there are limited pharmaceutical treatments approved in the U.S. for the indications that we are targeting with our drug candidates, and the pharmaceutical treatments that do exist have limited efficacy and/or are expensive. These expedited review programs often result in accelerated and less-costly pathways to approval compared with traditional regulatory pathways.

03. Develop

Develop future clinical products targeting unmet medical needs.

We intend to develop clinical products that treat unmet medical conditions or conditions where current treatment options are limited. As a result, we may have opportunities to accelerate commercialisation of such products.

04. Maintain IP

Maintain a strong intellectual property portfolio.

We have developed a global intellectual property strategy to support our commercial objectives. We are monitoring the results of our research and development programs to identify new intellectual property that aligns with those commercial objectives. We intend to take a global approach to our intellectual property strategy and we intend to pursue patent protection in key global markets, including the United States, Europe, Japan and Israel. We have pending patent applications relating to our drug candidates IHL-42X, IHL-216A and IHL-675A.

05. Approach

Clinical Approach

We are pursuing FDA approval of all our drug candidates currently being developed. The graphic on page 16 represents our clinical development pipeline and estimated timelines until the receipt of FDA pre-IND advice and the opening of INDs for each research program.

06. Opportunity

Market Opportunity

The combined annual global market size of the indications we are targeting is over US$110 billion, which is derived from the total addressable market for the treatment of OSA, TBI, concussion, rheumatoid arthritis, inflammatory bowel disease, inflammatory lung conditions (ARDS, COPD, Asthma, Bronchitis) and GAD. Thus, there is significant economic potential to shareholders, as well as benefit to patients suffering from untreated medical conditions.

Drug Candidates

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

(a) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021
(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
(d) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Irritable Bowel Syndrome/Disease
(e) Heraldkeepers, "Chemotherapy Induced Nausea and Vomiting (CINV) Drugs Market Research Report, History and Forecast 2022-2027", Jan. 2, 2022
(g) ResearchandMarkets, "Outlook on the Glaucoma Therapeutics Global Market", 2020-2026", Oct. 22. 2021
(j) Straits Research: Home Care Sleep Screening Devices Market

28 Projects

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

Clinical Project	Addressable Market Opportunity (in US$)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
APIRx 1505 Flotex Gastro: Chrohn's Disease	$12.6B (Global) by '24 (k)	Pre-clinical	Pre-regulatory	Phase 1	Drafting
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

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

Our mission

Incannex Healthcare Limited was incorporated in Australia in April 2001. Incannex listed its ordinary shares on the ASX under the symbol "IHL" in November 2016 and, in the form of American Depositary Shares under the symbol "IXHL" on Nasdaq in February 2022. Since 2019, we have been conducting research and development for synthetic cannabinoid pharmaceutical products and psychedelic medicine therapies for treatment of a range of indications.

Strategy

Our mission is to create premier ethical pharmaceutical drugs and therapies for patients with unmet or undermet medical needs, in all instances fulfilling regulatory requirements of the FDA and other relevant regulatory agencies. We aim to be recognized as a leading specialty drug development company, committed to restoring health and transforming the lives of patients through the development of novel pharmaceutical products and treatments.

We develop targeted and scientifically validated fixed-dose combinations of synthetic cannabinoids and psychedelic agents, applying proprietary insights in an effort to create long term value for our patients and shareholders. We focus on clinical indications that we believe represent unmet or inadequately addressed medical needs and also represent compelling commercial opportunities. In particular, we are developing three unique pharmaceutical compositions to target five indications: obstructive sleep apnea ("OSA"), traumatic brain injury and concussion ("TBI"), rheumatoid arthritis ("RA"), inflammatory bowel disease ("IBD") and inflammatory lung conditions ("ARDS", "COPD", Asthma, Bronchitis). We are also developing a treatment for generalized anxiety disorder ("GAD") utilising psilocybin combined with innovative psychotherapy methods. We are pursuing FDA registration and marketing approval for each product and therapy under development.

Additionally, we seek to secure patents on our drug candidates in conjunction with our medical and scientific staff, advisors and the investigators of our research studies that constitute our advisory board. Our advisory board is comprised of industry and academic experts familiar with our business, and we meet with the advisory board regularly. The current members of our advisory board are Mark Bleakley (our Head of Programs), Rosemarie Walsh (our Clinical Research Manager), Terrance O'Brien (principal investigator of the IHL-42X from Alfred Hospital), Dr Jennifer Walsh (professor at University of Western Australia), Ron Jithoo (neurosurgeon and advisor for IHL-216), and Paul Liknaitsky (psychedelic principal investigator from Monash University). Our advisory board also comprises our collaborative partners, and in particular Monash University, The Alfred Hospital and the University of Western Australia Centre for Sleep Science.

To achieve our goals, we intend to:

- Advance our novel investigational drug candidates towards approval in the United States and elsewhere. We are pursuing FDA approval of all our drug candidates currently in development. All preclinical and clinical trials are structured to ensure that each program is FDA compliant. We will be pursuing a New Drug Application ("NDA") with the FDA with respect to each of our drug candidates. If the NDA is approved, the product may be marketed in the United States. Once an NDA for one of our drug candidates is approved in the United States, we plan to pursue marketing approval of our drug candidates in other regions including the European Union, Japan, Australia and Israel.
- Take advantage of accelerated commercialization pathway options for our drug candidates. We and our regulatory consultants believe that each of our drug candidates will qualify for one or more FDA expedited review programs (breakthrough designation, accelerated approval, priority review and/or fast track), as there are a limited amount of pharmaceutical drug treatments approved in the U.S. to treat the indications that we are targeting with our drug candidates, and the pharmaceutical treatments that do exist provide limited treatment and are costly. These expedited review programs often result in accelerated and less-costly regulatory pathways to approval compared with traditional regulatory pathways. We have not yet approached the FDA about the suitability of our products for these accelerated approval pathways and such designations do not guarantee accelerated review by the FDA.
- Develop future drug candidates targeting unmet medical needs. We intend to only develop drug candidates that treat unmet or undermet medical conditions. As a result, we may have opportunities to accelerate commercialization of such products.
- Maintain a strong intellectual property portfolio. We have developed a global intellectual property strategy to support our commercial objectives. We are monitoring the results of our research and development programs to identify new intellectual property that aligns with those commercial objectives. We intend to take a global approach to our intellectual property strategy and intend to pursue patent protection in key global markets, including the United States, Europe, Japan and Israel. We have pending patent applications relating to our drug candidates IHL-42X, IHL-216A and IHL-675A and we own a further 19 granted and 23 pending patents resulting from the APIRx acquisition. Our patents approach aligns with our regulatory strategy, including the proposed submission of Pre-Investigational New Drug Application ("pre-IND") meeting requests to the FDA for our clinical programs.

Clinical Approach

We are pursuing FDA approval for all our drug candidates currently being developed. We will continue to work with FDA to ensure each clinical program is structured to meet regulatory requirements. FDA approval will be sought following the completion of successful phase 3 studies. Once we receive FDA approval for our drug candidates, we will be able to commercialize our drug candidates in the United States and pursue regulatory approval for the drug to be made available in other jurisdictions, including the Europe, Japan, Australia and Israel. The graphic below represents our clinical development pipelines.

Market Opportunity

The combined annual global market size of the indications we are targeting is over US$420 billion, which is derived from the total addressable market for the treatment of all indications over which we are developing drug candidates. The indications being pursued include: OSA, TBI, concussions, rheumatoid arthritis, inflammatory bowel disease, inflammatory lung conditions (ARDS, COPD, Asthma, Bronchitis), GAD, pain, spasticity, addiction disorders, dementia, Parkinson's Disease, restless leg syndrome, gastrointestinal diseases, periodontitis, skin conditions and ophthalmic conditions. Thus, there is significant economic potential to shareholders, as well as benefit to patients suffering from these medical conditions.

IHL-42X
Obstructive Sleep Apnoea

Obstructive sleep apnea is characterized by a narrowing or obstruction of the upper airway during sleep, interfering with breathing and interrupting sleep. This relatively common and chronic disorder is underdiagnosed and inadequately treated.

It is understood to contribute to a wide range of serious long-term outcomes, including cardiovascular disease, cognitive impairments such as memory loss, poor concentration and judgment, depression and death or injury due to traffic accidents resulting from excessive daytime sleepiness. The costs associated with OSA are substantial, relating to lost productivity, workplace and motor vehicle accidents.

A 2019 article published by the Lancet premised on literature-based analysis of 17 studies across 16 countries, estimated that OSA affects some 936 million adults worldwide. This alarming statistic is also thought to be increasing due to growing prevalence of obesity and an ageing global population. Many people with OSA develop high blood pressure (hypertension), which can increase the risk of cardiovascular disease. The more severe the OSA, the greater the risk of coronary artery disease, heart attack, heart failure and stroke.

There are no registered drugs for OSA. Current treatment options include: continuous positive airway pressure ("CPAP") in which an external device pneumatically splints the airway open to prevent disruptions in breathing; oral appliances to advance the mandible or to retain the tongue, putting the mouth in a position more conducive to breathing; surgery to remove physical obstructions to air flow; and implantable electronic stimulators to activate muscles at the base of the tongue, opening the airway in synchrony with respiration. However, all of these therapies are inadequate, expensive, and for implantable stimulators and surgery, invasive.

The standard treatment option is the mechanical CPAP device, however, we believe patient compliance to CPAP devices is low due to discomfort and claustrophobia resulting from pressurized air being pumped into the patient's nose and/or mouth during sleep. Despite these discomforts, the global annual market for OSA detection and treatment using CPAP devices is over US$10 billion and growing. The estimated compound annual growth rate ("CAGR") for OSA detection and treatment using CPAP devices from 2021 to 2028 is 6.2%.

IHL-42X in Obstructive Sleep Apnea

IHL-42X is a fixed-dose combination of acetazolamide, a registered pharmaceutical, and dronabinol, a synthetic form of -Delta-9-tetrahydrocannabinol (THC); both agents have been shown to reduce the apnea hypopnea index ("AHI"). We believe that the activity of dronabinol on cannabinoid receptors causes dilation of the airway, and acetazolamide induces modest metabolic acidosis, signalling to the body that there is excess CO2 in the blood, thus increasing respiration. By exploiting two mechanisms that both reduce AHI in one pharmaceutical formulation, we believe that IHL-42X has a therapeutic benefit at doses of each constituent drug that are safe and tolerable.

Phase 2 Clinical Trial for IHL-42X for Obstructive Sleep Apnea ("OSA")

We have completed our proof-of-concept Phase 2 clinical trial in Australia to support our IND application with FDA and to inform the clinical design of our future pivotal Phase 2 clinical trial, which will be conducted under the IND to assess the safety and efficacy of IHL-42X in patients with Obstructive Sleep Apnea. The IND for IHL-42X in treatment of OSA has not yet been submitted and although we have incorporated multiple facets into this study, including full monitoring by a CRO and CDISC data formatting, there is no guarantee that the FDA will accept data from the Australian trial and further testing may be required prior to opening the NDA.

We received approval from The Alfred Hospital Human Research Ethics Committee in September 2020 to proceed with the trial in Australia. In December 2020, we recruited the first patients to the randomized, double-blind, placebo-controlled clinical trial that assesses the therapeutic benefit of IHL-42X at three different doses. The primary endpoint of the trial is the change in AHI relative to baseline and the secondary endpoints are change in oxygen desaturation index ("ODI"), daytime somnolence measured by the Epworth Sleepiness Scale, improvement in mood as measured by the POMS (Profile of Moods State), and well-being as measured by the Short Form 36 and the safety of the IHL-42X combination will be established through adverse event monitoring.

The study was undertaken at the Alfred Hospital in Melbourne Australia and the University of Western Australia Centre for Sleep Science in Perth. Novotech, a global contract research organization, managed and monitored the study. In July 2021, a confidential interim analysis of the data from the phase 2 double blind randomized placebo-controlled clinical trial was performed, and these results were utilized to support a patent application regarding the methods for the treatment of obstructive sleep apnea. In December 2021, we completed the dosing of participants in the phase 2 clinical trial.

In March 2022, we announced the completion of a preliminary analysis of the full patient data set from the phase 2, proof-of-concept clinical trial. The study assessed three doses of IHL-42 at reducing AHI compared to placebo in patients who suffered from the disease. Trial participants received each of the three doses of IHL-42X, low, medium and high, and placebo across four seven-day treatment periods, separated by one week washout periods. A total of eleven participants were recruited to the study and ten participants competed treatment periods. Because the trial assessed low, mid and high doses of IHL-42X and the placebo in all ten trial participants with one week washout periods, the trial data is effectively as useful to us as a 40 participant trial.

At baseline, the average AHI was 42.84. For all IHL-42X treatment periods (using low, mid, and high doses), the average AHI was 23.81, a 44.4 % reduction (p-value 0.0067) compared to baseline AHI. During placebo treatment periods, the average IHI was 40.08, a 6.4 % reduction (p-value 0.75) compared to baseline. In total, 60% of participants experienced a reduction in AHI of greater than 50% (range: 55.0% to 91.5%) and a resulting AHI of less than 20 during at least one treatment period of one dose strength of IHL-42X. In addition, 20% of participants experienced a reduction in AHI of greater than 80% (range: 82.7% to 91.5%) relative to baseline during at least one treatment period of one dose strength of IHL-42X.

In May 2022, following a pre-IND meeting, the FDA confirmed that we do not need to conduct studies in animals to have an IND application approved for IHL-42X. This decision by the FDA will save Incannex time and cost. The FDA provided guidance on our proposed long-term development strategy, including specific parameters to demonstrate the safety and efficacy in phase 2 and 3 pivotal studies, which will ensure that we can generate the data we need for a new drug application with FDA, subject to ongoing clinical success.

Table 1. Average AHI data for baseline and each treatment period

	Baseline	Placebo	Low	Medium	High
Average AHI	42.84	40.08	21.13	22.22	27.78
Standard deviation	20.33	18.16	15.92	15.52	17.61
% Reduction relative to baseline	N/A	6.44	50.69	48.13	35.16
p value compared to baseline	N/A	0.76	0.029	0.031	0.12

Table 2. Change in AHI from baseline within subject (least square mean)

	Average change in AHI from baseline	p-value relative to placebo (Bonferroni adjusted)	Proportion of subjects with AHI reduction >50% relative to baseline (%)	Proportion of subjects with AHI reduction >80% relative to baseline (%)
Placebo	1.95	N/A	10	0
Low	17.51	<0.001	62.5	25
Medium	14.86	<0.001	33.3	11.1
High	16.18	<0.001	22.2	11.1

In June 2022, we announced the full and complete analysis of data from the phase 2 proof-of-concept clinical trial investigating IHL-42X for treatment of OSA:

- All doses of IHL-42X reduced AHI in patients with sleep apnoea compared to baseline (Table 1). This reduction was substantially greater than observed for placebo.
- At the group level the difference relative to baseline with low dose and medium dose was statistically significant ($p<0.05$)
- When comparing directly to baseline within patients the difference in AHI compared to baseline between all three doses and placebo was statistically significant ($p<0.001$) (Table 2)
- Low dose IHL-42X reduced AHI by >50% relative to baseline in 62.5% of patients and by >80% in 25% of patients
- Low dose IHL-42X reduced AHI to the greatest extent at both the group level and when comparing the within patient reduction relative to baseline
- Low dose IHL-42X reduced AHI to a greater extent than predicted based on published data for dronabinol and acetazolamide alone (Table 3)

The reduction in AHI observed during IHL-42X treatment periods means that when treated with our proprietary drug, patient's breathing was interrupted less frequently during sleep. This supports our hypothesis that IHL-42X is an effective treatment for OSA. Furthermore, greater reduction in AHI with low dose IHL-42X compared to dronabinol and acetazolamide at equivalent doses supports our hypothesis that the two drugs are acting synergistically to produce a superior outcome than would be expected from dronabinol and acetazolamide as monotherapies.

With respect to the oxygen desaturation index ('ODI'), the data from the phase 2 proof-of-concept clinical trial supported the following:

- all three doses of IHL-42X reduced ODI compared to baseline to a greater extent than placebo.
- For low and medium dose IHL-42X the difference in reduction in ODI relative to baseline compared to placebo was statistically significant ($p<0.05$)

Table 3. Comparison of reduction in AHI relative to baseline with low dose IHL-42X and the predicted reduction with component drugs as monotherapies at equivalent doses based on reported data

	Reduction in AHI compared to baseline (%)
2.5 mg dronabinol (1)	23.4
125 mg acetazolamide (2)	23.4
Low dose IHL-42X	50.7

Table 4. Reduction in ODI compared to baseline during each treatment period

	Reduction in ODI relative to baseline (least squares mean)	Reduction in ODI relative to baseline (%)	p value compared to placebo (Bonferroni adjusted)
Placebo	1.8	18.3	N/A
Low	11.7	59.7	0.021
Medium	12	59.0	0.012
High	8.32	28.5	0.162

The study also measured the Plasma THC levels in patients' blood. Plasma samples were collected 2 hours post dose 1 and the morning after dose 7 for each treatment period. The morning after dose 7, THC levels in the low dose IHL-42X samples had an average of 0.20 ng/ml and a maximum of 0.45 ng/ml, both of which are below the thresholds for impaired driving imposed in countries that have set limits for THC. With medium and high dose IHL-42X the average THC concentrations the morning after dose 7 were 0.86 and 0.52 respectively.

During the IHL-42X treatment periods patients more frequently reported that their sleep quality was good or very good when compared to placebo. The highest level of patient reported sleep quality was observed with low and high dose IHL-42X (Table 5).

For the duration of the clinical trial, patients wore an Actiwatch, a watch-like device that uses actigraphy to capture data on activity and sleep. IHL-42X at all doses improved sleep efficiency (the percentage of time in bed a patient is asleep), the number of awakenings per night, and the total minutes every patient was awake during the night (WASO) compared to placebo (Table 6). These improvements were greatest for low and high dose IHL-42X. This means that while taking IHL-42X, trial participants were asleep for a greater proportion of time they were in bed and woke up less often.

Adverse events were recorded from the time the patients enrolled in the trial until their end of study visit. After recording treatment emergent adverse events (TEAE), the study team, including investigators and medical monitors, reviewed the TEAEs to determine whether they were likely related to the investigational product. The TEAEs were consistent with what has been reported for dronabinol and acetazolamide alone. For each treatment period the proportion of patients reporting one or more TEAEs (Table 7) as well as the total number of TEAEs (Table 8) were extracted from the clinical study report. Low dose IHL-42X had a similar proportion of patients reporting TEAEs and a lower number of total TEAEs than placebo. This indicated that low dose IHL-42X is well tolerated and in fact was more tolerable to trial participants than placebo.

Table 5. Patient reported sleep quality during each treatment period

	Proportion of subjects reporting good or very good sleep quality
Placebo	26.50%
Low	49.49%
Medium	38.47%
High	50.13%

Table 6. Sleep metrics captured by actigraphy

		Placebo	Low	Medium	High
Sleep efficiency	average	76.83	84.81	81.34	84.17
	p value compared to placebo	N/A	0.0048	0.058	0.0078
Awakenings per night	average	49.31	35.8	41.44	37.33
	p value compared to placebo	N/A	0.0053	0.055	0.012
WASO (min)	average	62.59	37.55	47.22	38.55
	p value compared to placebo	NA	0.00011	0.0031	0.0010

IHL-42X lowered apnoea hypopnea index score in OSA sufferers during clinical study.

Table 7. Proportion subjects of TEAEs reported for each treatment period

	Placebo	Low	Medium	High
Total TEAE (%)	81.8	33.3	55.6	66.7
Related TEAE (%)	27.3	22.2	44.4	55.6

Table 8. Total number of TEAEs reported during each treatment period

	Placebo	Low	Medium	High
Total TEAE	15	6	22	16
Related TEAE	7	4	16	12

IHL-216A for Concussion/Traumatic Brain Injury and Chronic Traumatic Encephalopathy

Concussion/Traumatic Brain Injury ('TBI') are caused by a rapid acceleration/ deceleration of the brain caused by a direct blow to the head or sudden impact to the body that jolts the skull. This causes the brain to compress against the skull. The impact of the brain against the skull causes both macro and micro scale damage to the brain which sets of a series of physiological events called secondary injury cascades. These secondary injury cascades are what cause many of the neurocognitive deficits seen in TBI patients.

Falls, vehicle collisions, violence, sports and combat injuries are the main activities leading to TBI and concussion. The signs and symptoms of a concussion can be subtle and may not show up immediately. Symptoms can last for days, weeks or even longer. Common symptoms after a concussive traumatic brain injury are headache, loss of memory (amnesia) and confusion. The amnesia usually involves forgetting the event that caused the concussion. Other symptoms include nausea, vomiting, fatigue, blurry vision and ringing in the ears.

Complications can occur immediately or soon after a traumatic brain injury. Severe injuries increase the risk of a greater number of and more-severe complications. Moderate to severe traumatic brain injury can result in prolonged or permanent changes in a person's state of consciousness, awareness or responsiveness. Many people who have had a significant brain injury will experience changes in their cognitive ability, have executive functioning problems and or communication, emotional and behavioral problems. Some research suggests that repeated or severe traumatic brain injuries might increase the risk of degenerative brain diseases, but this risk cannot be predicted for an individual.

Chronic traumatic encephalopathy ("CTE") is the term used to describe brain degeneration likely caused by repeated head traumas. CTE is a diagnosis made only at autopsy by studying sections of the brain. CTE is a rare disorder that is not yet well understood. CTE is not related to the immediate consequences of a late-life episode of head trauma. CTE has a complex relationship with head traumas such as persistent post-concussive symptoms and second impact syndrome that occur earlier in life.

Experts are still trying to understand how repeated head traumas, including how many head injuries and the severity of those injuries, and other factors might contribute to the changes in the brain that result in CTE.

CTE has been found in the brains of football players, boxers and other athletes that play contact sports, along with military personnel who were exposed to explosive blasts. Some signs and symptoms of CTE are thought to include difficulties with thinking (cognition) and emotions, physical problems and other behaviors. Symptoms of CTE often manifest decades after head trauma occurs.

CTE cannot be made as a diagnosis during life except in those rare individuals with high-risk exposures. Researchers do not yet know the frequency of CTE in the population and do not understand the causes. There is no cure for CTE. Researchers are currently developing diagnostic biomarkers for CTE, but none have been validated yet.

The total global addressable market for TBI was estimated to be US$2.9 billion in 2020 and the anticipated CAGR for the market from 2021 to 2028 is 8.3%. There are currently no pharmalogical treatments for the secondary neurological effects of TBI.

IHL-216A Formulation development for clinical trials

IHL-216A is a fixed dose combination of isoflurane, a registered pharmaceutical, and CBD, intended for administration in the immediate period after primary blunt head injury to prevent development of brain injuries. Isoflurane is approved in the United States for induction and maintenance of anaesthesia. CBD is approved for use in seizure disorders and has shown effects on

neuroinflammatory responses to brain injury. Isoflurane is a registered pharmaceutical, and also has demonstrated neuroprotective activity (neuroprotective activity, or neuroprotection, is defined as reduced neuronal cell death or disruption) in animal studies of TBI and is thought to act by modulating glutamate release and calcium uptake as well as via effects on mitochondrial membrane depolarization and excitatory neurotransmission. Thus, we believe that IHL-216A may affect neuroexcitation, neuro-inflammation, cerebral blood flow and cerebral oxygen consumption resulting in overall neuroprotection. We are also assessing its ability to protect the brain against secondary injury mechanisms that cause neuronal cell death and raised intracranial pressure in the days and weeks following head trauma in sports, and all other applicable scenarios resulting in head trauma (falls, vehicle collisions, violence, combat, among other causes). Reducing secondary brain injury may improve positive outcomes for long term neurological sequelae, including CTE, a major health risk associated with contact sports.

The formulation of IHL-216A presents a unique research and development opportunity. We have formulated IHL-216A as a combined inhalational product with nebulized drug delivery that involves using air pressure or ultrasonic vibrations to turn a liquid drug solution into an aerosol. We engaged Vectura, a UK based contract development and manufacturing organization, to develop the nebulised CBD formulation and device for delivery of the CBD to the isoflurane anaesthetic circuit. Vectura specializes in the development of inhaled drugs and has an excellent track record of bringing products to market and have formulated pharmaceutical drugs for multinational pharmaceutical companies including Bayer, Sandoz and Novartis. Development of the nebulized formulation was an iterative process starting with three steps of refinement based on properties of the solution, generated aerosol and dose delivery.

On August 2, 2022, we announced that we have engaged Curia Global, Inc. (‘Curia’) to further develop and manufacture GMP-grade IHL-216A. Curia, formerly AMRI, is a leading contract research, development and manufacturing organization providing products and services from R&D through commercial manufacturing to pharmaceutical and biopharmaceutical customers. Curia’s 3,700 employees at 29 locations across the U.S., Europe and Asia help its customers advance from curiosity to cure.

Their engagement represents substantial progress in the development of IHL-216A and follows pleasing results from extensive proof-of-concept and optimisation studies undertaken at Vectura. Curia is engaged to scale-up the fill-finish manufacture of IHL-216A in compliance with Current Good Manufacturing Practice (‘cGMP’).

Curia will also generate data on the quality and stability of IHL-216A to support future regulatory filings, including a FDA pre-IND package and subsequent IND application. The first cGMP batch manufactured at Curia will be used in a phase 1 clinical trial, which will commence once feedback on the proposed IHL-216A development plan is received from FDA in a pre-IND meeting that Incannex is aiming to set with FDA in Q3 2022.

Due to the product’s potential therapeutic utility in contact sports, IHL-216A has been developed to satisfy the World Anti-doping Authority (“WADA”) specifications for use by elite and amateur athletes at risk of TBI and CTE.

Stage 1 pre-clinical study for IHL-216A for TBI and CTE

In December 2020, we completed an animal study to formally assess the neuroprotective capability of IHL-216A. The study introduced rodents to head trauma in a highly controlled manner to inflict a reproducible injury. Various doses of IHL-216A or its active pharmaceutical ingredients were administered to eight cohorts of rodents soon after traumatic head injury. Behavioral tests were used to assess the neurocognitive and motor function over time. We also monitored secondary injury cascades, and performed micro-scale cellular analysis post-mortem to discern and compare neuronal damage across the cohorts.

As detailed below, we found that the IHL-216A components, CBD and isoflurane, act synergistically to reduce indicators of neuronal damage, neuroinflammation and behavioral deficits that are consequences of TBI, as IHL-216A had a greater effect than the predicted effect of CBD and isoflurane combined. The predicted result is determined by analyzing the results of isoflurane and CBD independently, and then based on those results predicting how well the drugs would do in combination; to the extent IHL-216A exceeds the predicted result, we can conclude that the drugs strengthen the effectiveness of one another and synergy exists. The study also found that IHL-216A reduced neuronal damage, neuroinflammation and cognitive deficits in a rodent model of TBI to a greater extent than either CBD or isoflurane applied on a standalone basis. These results have not been assessed for statistical significance.

Post-mortem analysis of rat brains also detected synergy between CBD and isoflurane. Brains were fixed and sectioned prior to Nissl staining to identify neuronal damage. Nissl staining is a microscopy technique to visualise Nissl bodies. Healthy neurons typically have more Nissl bodies than damaged ones. Neuronal damage is indicated by the ratio of Nissl bodies to neurons across different sections of the hippocampus with a lower Nissl/neuron ratio indicative of increased neuronal damage.

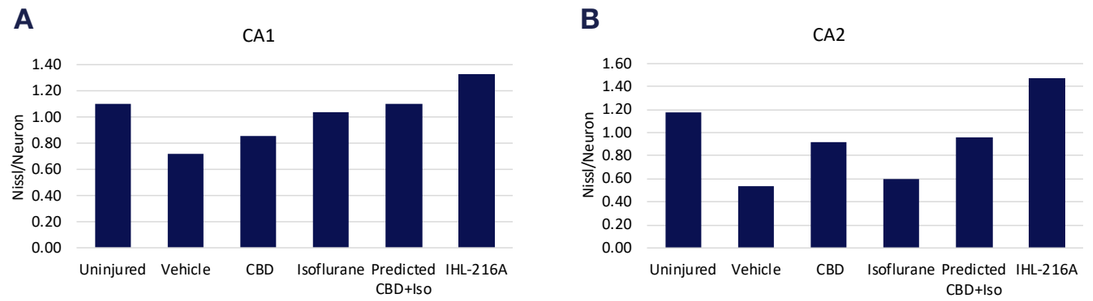

Figure 1. Synergistic activity of CBD and isoflurane (IHL-216A) in neuronal damage as assessed by Nissl staining.

Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for neuronal damage by post-mortem analysis of fixed brain sections by Nissl staining. Nissl staining permits the quantitation of the ratio of Nissl bodies to total neurons, a lower ratio being indicative of increased neuronal damage. The Nissl/neuron ratio observed in hippocampal regions (A) CA1 and (B) CA2 contralateral to the site of injury in the group treated with IHL-216A was greater than that predicted based on the groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=6, CBD n=6, isoflurane n=5, IHL-216A n=6. Neuroinflammation Marker — Iba1.

Synergy between CBD and isoflurane was detected in hippocampal regions *cornu ammonis* 1 (CA1) and *cornu ammonis* 2 (CA2). These regions of the brain are known to be important in the formation and storage of memories. In the study, the improvement in Nissl/Neuron ratio observed for IHL-216A treated animals was increased by 53% for CA1 and 60% for CA2 relative to CBD alone, 28% for CA1 and 145% for CA2 relative to isoflurane alone, and by 20% for CA1 and 53% for CA2 relative to the predicted effect of CBD and isoflurane combined. These results demonstrated that less neuronal damage was observed in the rats treated with IHL-216A relative to the predicted value.

A post-mortem analysis of the rat brains also determined that CBD and isoflurane were synergistic in reducing levels of the neuroinflammation marker Iba1 as detected using immunofluorescence. Iba1 is a protein expressed in microglia, a type of innate immune cell in the brain, that is an established marker of microglial activation and neuroinflammation. The levels of Iba1 in the brain are detected using immunofluorescence, which is a microscopy technique that employs antibodies specific to Iba1 which are detected using a fluorescent tag. Increased levels of Iba1 are indicative of increased neuroinflammation. In groups treated with IHL-216A, levels of the Iba1 neuroinflammation marker were reduced by 35% more relative to CBD alone and 123% more relative to isoflurane administered alone. IHL-216A also reduced the Iba1 neuroinflammation marker by 10% more than the predicted value of the combined CBD and isoflurane treatments.

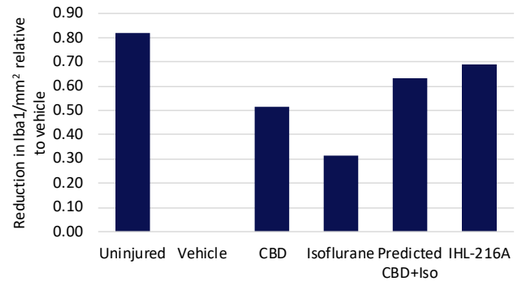

Figure 2. Synergistic activity of CBD and isoflurane (IHL-216A) in reducing levels of the neuroinflammatory marker Iba1.

Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for neuroinflammation through immunofluorescence analysis of the neuroinflammatory marker Iba1. Iba1 levels increase after TBI and a reduction in Iba1 is indicative of a reduction in neuroinflammation. Iba1 levels in brain sections ipsilateral to the site of injury in the group treated with IHL-216A were reduced more than would be predicted based on the reduction observed in groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=5, CBD n=6, isoflurane n=3, IHL-216A n=5.

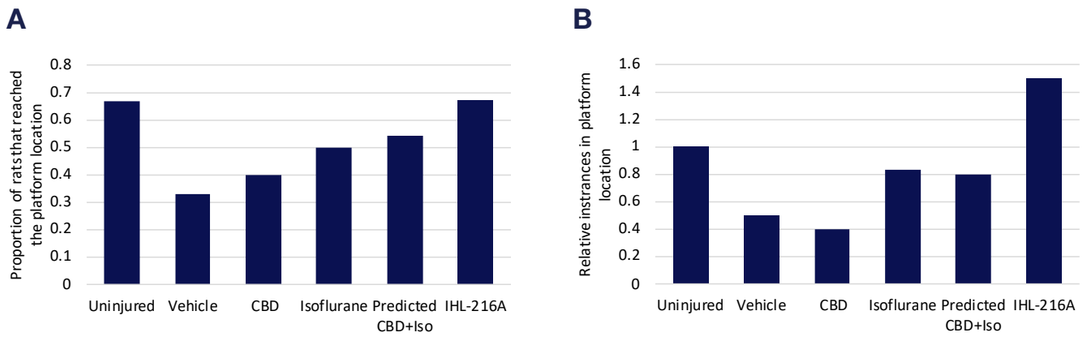

Figure 3. Synergistic activity of CBD and isoflurane (IHL-216A) in the Morris Water Maze assessment.

Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for spatial learning and memory using the Morris Water Maze. The observed performance with respect to both (A) relative instances of animal in platform location and (B) proportion of animals in that reached the platform location was better in the group treated with the CBD isoflurane combination (IHL-216A) than what was predicted based on the performance of the groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=6, CBD n=5, isoflurane n=6, IHL-216A n=6.

Table 1. Values used to determine synergy between CBD and isoflurane

	Relative instances in platform location	Proportion of rats that reached the platform location	Rotarod Latency (s)	Nissl/Neuron CA1	Nissl/Neuron CA2	Reduction in Iba1 count/ mm2 relative to vehicle
Uninjured	1.00	0.67	23.39	1.10	1.18	0.82
Vehicle	0.50	0.33	17.83	0.72	0.54	0.00
CBD	0.40	0.40	17.60	0.86	0.92	0.51
Isoflurane (ISO)	0.83	0.50	17.33	1.03	0.60	0.31
Predicted CBD+ISO	0.80	0.54	17.08	1.10	0.96	0.63
IHL-216A	1.50	0.67	19.33	1.32	1.47	0.69
EOB	0.70	0.13	2.25	0.22	0.51	0.06
% Outperform CBD	275%	67%	10%	53%	60%	35%
% Outperform ISO	81%	34%	12%	28%	145%	123%
% outperform Pred	87%	24%	13%	20%	53%	10%

Calculation definitions for Table 1:
- EOB = IHL-216A – Predicted CBD+ISO
- % Outperform CBD = (IHL-216A/CBD) - 1
- % Outperform ISO = (IHL-216A/ISO) – 1
- % Outperform Pred = (IHL-216A/Predicted CBD+ISO) - 1

Synergy between CBD and isoflurane was detected in the behavioral outcomes assessed using the Morris Water Maze. In the Morris Water Maze animals are trained to find a platform in a pool of water. After a number of training sessions, the platform is removed and the mice are monitored to determine whether they return to the location of the platform, which is a measure of spatial learning and memory. The number of animals treated with IHL-216A that returned to the location of the platform per group and the proportion of rats in the group that returned to the location of the platform was greater than that predicted based on the effect of CBD and isoflurane by 87 % and 24 % respectively. The improved performance of IHL-216A treated rats compared to the predicted effect demonstrated the synergistic effect of CBD and isoflurane.

Stage 2 pre-clinical study for IHL-216A

We have finalized a second and more-extensive animal study on the protective effect of IHL-216A in sports concussion with the Monash Trauma Group at the Department of Neuroscience, Monash University, Australia.

The Monash Trauma Group consists of a team of leading scientists within their respective fields. Their research focuses on the effects, underlying pathophysiological mechanisms, biomarkers, and treatments of trauma related conditions including TBI and concussion as well as other types of neurological diseases, including CTE.

The study was coordinated by Dr Stuart McDonald, an expert in fluid biomarker development for monitoring TBI, Associate Professor Richelle Mychasiuk, an expert in animal models of TBI and their clinical relevance, and Associate Professor Sandy Shultz, an expert in the pathological mechanisms, biomarkers and treatments of TBI and related conditions.

The model of TBI used in the study was developed by Monash University in collaboration with the US National Football League (“NFL”). The results of the study will be used as a precursory data set to inform the pivotal clinical trials required for drug registration. Assessments in this study include neurocognitive performance, levels of blood biomarkers associated with traumatic brain injury, and postmortem analysis of brain tissue using both MRI and immunohistochemistry.

In May 2022, we announced that the stage 2 study had been completed and that IHL-216A was observed to have a strong neuroprotective effect in a widely known model of sports concussion developed in collaboration with the NFL to accurately represent the type of brain injury that occurs in sports-related concussion. This study compared six groups of twenty-four Sprague Dawley rats When animals

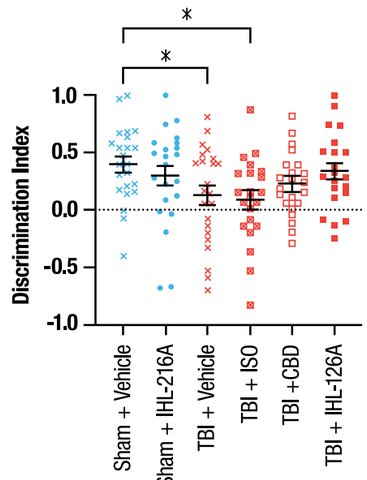

Figure 4. IHL-216A restores the deficit in Y-maze novel/familiar arm discrimination index assessment 24 h post TBI.

A Y-maze was used to assess spatial memory 24 h after induction of TBI. Sham + Vehicle treated animals displayed a clear preference for the novel arm. This preference was reduced in TBI + vehicle animals, indicating that there is a deficit in novel arm discrimination associated with TBI. 10 Each group consisted of 24 rodents.

were tested in a Y-maze task, which assesses spatial memory by determining the animal’s ability to discriminate between a novel (new) and familiar arm, twenty-four hours after injury, animals treated with IHL-216A were found to have no difference in discrimination index compared sham (uninjured) animals (mean difference= 0.0598, p=0.5855) (Figure 4). In contrast, injured animals treated with either vehicle or isoflurane alone after injury, the discrimination index was significantly reduced compared to sham animals (mean diff=0.2704, p=0.0498 and mean diff=0.3095, p=0.0245 respectively). The group treated with CBD alone had intermediate performance in the Y-maze between sham and vehicle treated animals (mean diff.0.1745, p==0.2933). These findings indicate that the defect in spatial memory observed at 1 day post injury is restored in animals treated with IHL-216A.

Following current and previous positive preclinical observations, Incannex has commenced preparation of a pre-IND meeting package for IHL-216A. The study team is targeting a pre-IND meeting with FDA in Q3 2022 to discuss our intention to conduct an expedited clinical trial program required for a new drug application and marketing approval.

IHL-675A

IHL-675A multi-use anti-inflammatory drug targeting rheumatoid arthritis, inflammatory bowel disease and lung inflammation (COPD, asthma, bronchitis, and ARDS)

IHL-675A comprises a combination of hydroxychloroquine, a registered pharmaceutical, and CBD. Hydroxychloroquine (HCQ) is a disease modifying anti-rheumatic drug that regulates the activity of the immune system, which may be overactive in some conditions. HCQ can modify the underlying disease process, rather than simply treating the symptoms. We have demonstrated that IHL-675A components, cannabidiol and hydroxychloroquine, act synergistically to inhibit production of key inflammatory cytokines in an in vitro study and in 4 distinct successful in vivo experiments using established models of inflammation. We are able to determine whether synergies exist in IHL-675A studies by comparing the predicted result of CBD and HCQ acting together to the actual IHL-675A results. The predicted result is determined by analyzing the results of HCQ and CBD independently in the study, and then based on those results predicting how well the drugs would do on a combined basis; to the extent IHL-675A exceeds the predicted result, we can conclude that the drugs strengthen the effectiveness of one another and synergies exist.

We have evaluated the results of these experiments and believe IHL-675A to be a multi-use drug candidate for the prevention and treatment of inflammatory lung conditions (ARDS, COPD, asthma, and bronchitis), rheumatoid arthritis and inflammatory bowel diseases. Potentially, this could mean that IHL-675A is a better alternative to CBD based products for certain inflammatory diseases, subject to further examination.

We have completed a pre-IND meeting with the FDA to discuss the regulatory pathway for the development of IHL-675A for lung inflammation in the United States and plan to open INDs for each of the three indications. FDA agreed that marketing applications for IHL-675A should be 505(b)(2) applications due to the existence of certain safety and efficacy information on the active ingredients of IHL-675A originating from historical studies that we are entitled to use in a new drug application. In the context of the IHL-675A development program, this means that we do not have to perform many of the nonclinical toxicology studies that are required for approval of a new chemical entity because there is adequate toxicology data for both CBD and HCQ available in pre-existing scientific literature or in regulatory submissions for the respective reference listed drugs. However, we still need to demonstrate IHL-675A is safe and effective in the target indications via a series of randomized, controlled clinical trials.

In July 2022, we received approval from the Bellberry Human Research Ethics Committee (“HREC”) for a phase 1 clinical trial investigating the proprietary multi-use of IHL-675A. The trial will measure the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ). Three cohorts of 12 participants (n = 36) will receive either IHL-675A, CBD or HCQ and the assessments will be identical across the three arms of the trial. Patient recruitment is anticipated to commence in August 2022. Subject to clinical success, the results of the phase 1 clinical trial will form part of three IND applications with the FDA for each of the initial three indications the Company is pursuing for IHL-675A. These indications are rheumatoid arthritis, inflammatory bowel disease and lung inflammation, representing major markets for Incannex to pursue with IHL-675A. Once the IND applications are evaluated and approved, we intend to conduct clinical trials partly or wholly in the United States.

Lung Inflammation (COPD, Asthma, ARDS and Bronchitis)

Chronic obstructive pulmonary disease (“COPD”) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs. Symptoms include breathing difficulty, cough, mucus (sputum) production and wheezing. It is typically caused by long-term exposure to irritating gases or particulate matter, most often from cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions.

Asthma is a condition in which inflammation causes the airways to narrow and swell and which may cause the patient to produce extra mucus. This can make breathing difficult and trigger coughing, a whistling sound (wheezing) during breathing and shortness of breath. For some people, asthma is a minor nuisance. For others, it can be a major problem that interferes with daily activities and may lead to a life-threatening asthma attack. According to Allied Market Research, the Global COPD and asthma drug market is expected to reach US$50.4 billion by 2022, growing at a CAGR of 3.7% from 2016 to 2022.

Acute respiratory distress syndrome (“ARDS”) occurs when fluid builds up in the air sacs (alveoli) located in the lungs. The fluid prevents oxygen from reaching the bloodstream. This deprives organs of the oxygen they need to function. ARDS typically occurs in people who are already critically ill or who have significant injuries. Severe shortness of breath (the main symptom of ARDS) usually develops within a few hours to a few days after the primary injury or infection. It is the one of the main causes of death resulting from COVID-19 and many people who develop ARDS do not survive. The risk of death increases with age and severity of illness. People who survive ARDS may experience lasting damage to their lungs.

Bronchitis is an inflammation of the lining of the bronchial tubes of the lungs. Bronchitis may be either acute or chronic. While acute bronchitis is common, chronic bronchitis, a more serious condition, is a constant irritation or inflammation of the lining of the bronchial tubes.

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory disorder that can affect joints, skin, eyes, lungs, heart and blood vessels. As an autoimmune disorder, rheumatoid arthritis is caused by attacks to body tissues by one’s immune system. Unlike the wear-and-tear damage caused by osteoarthritis, rheumatoid arthritis causes a painful swelling that can eventually result in bone erosion and joint deformity. The total global addressable market for the pharmaceutical treatment of rheumatoid arthritis is estimated at US$57 billion.

HCQ is approved for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate and marketed as Plaquenil. HCQ has risks of ocular toxicity and cardiac effects including cardiomyopathy and QT prolongation amongst long term users, as listed in the prescribing material.

Similarly, long term use of HCQ in rheumatoid arthritis patients was associated with increased cardiovascular mortality. Therefore, there is a medical benefit to reducing the dose of HCQ in these arthritis patients. To understand the capacity for the combination of CBD with HCQ to permit reduction of the HCQ dose, in an animal study, low dose IHL-675A (1 mg/kg CBD + 2.5 mg/kg HCQ) was compared to a standard dose of HCQ (25 mg/kg HCQ). The 25 mg/kg HCQ dose in rats is equivalent to a 243 mg HCQ dose in a 60 kg human based on the FDA body surface area dose equivalence of 6/37.

In a rheumatoid arthritis animal disease model study, low dose IHL-675A reduced disease severity scores across multiple assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels to a greater extent than the equivalent of a standard dose of HCQ. The reduction in disease severity scores in animals treated with low dose IHL-675A was 1.06-3.52 times that observed in animals treated with HCQ alone at the standard dose equivalent.

This indicates that the combination of CBD and HCQ in IHL-675A has the potential to permit a ten-fold reduction in HCQ dose, when combined with CBD, without sacrificing efficacy in treatment of arthritis.

We have broadened claims within initial patent filings to cover rheumatoid arthritis as an indication. We are continuously monitoring the results of our research and development program, with a view to identifying and protecting new IP that aligns with our commercial objectives.

Inflammatory Bowel Disease

Inflammatory Bowel Disease (“IBD”) is an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract. Significant types of IBD include:

- Ulcerative colitis. This condition involves inflammation and sores (ulcers) along the superficial lining of the large intestine (colon) and rectum.
- Crohn’s disease. This type of IBD is characterized by inflammation of the lining of the digestive tract, which often can involve the deeper layers of the digestive tract.

Both ulcerative colitis and Crohn’s disease are usually characterized by diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss. IBD can be debilitating and sometimes leads to life-threatening complications.

The precise cause of inflammatory bowel disease remains unknown. Previously, diet and stress were suspected. However, currently medical practitioners acknowledge that these factors may aggravate, but are not the cause, of IBD. One possible cause is an immune system malfunction. When the immune system attempts to defeat an invading virus or bacterium, an abnormal immune response can cause the immune system to attack the cells in the digestive tract. The total global addressable market for IBD is estimated at US$20 billion in 2021 and the IBD global market is anticipated to grow at a CAGR of 4.8% from 2021 to 2028.

Preclinical in vitro study of IHL-675A against inflammation

On November 5, 2020, we released the results of our first in vitro study to investigate the synergistic activity of IHL-675A to inhibit inflammation. To test the anti-inflammatory potential of IHL-675A, human peripheralblood mononuclear cells (“PBMCs”) were stimulated with bacterial lipopolysaccharide (“LPS”). PBMCs were incubated with a range of concentrations of CBD and HCQ in combination or each drug alone and then stimulated with LPS to induce an inflammatory response. The inflammatory response was assessed by measuring cytokine levels in the culture medium after 24 hours. A reduction in cytokine levels in response to drug treatment is indicative of anti-inflammatory activity.

Cytokine levels were averaged across three replicates from two donors and normalized to maximum values to yield a relative inhibition value. A relative inhibition of 1 is complete inhibition of cytokine release whereas a value of 0 is no inhibition of cytokine release. Anti-inflammatory synergy was determined using the standard scientific “Excess over Bliss” (“EOB”) method where the predicted inhibition, as calculated using the formula $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$, is subtracted from the observed inhibition to yield an EOB score. An EOB score of greater than zero indicates that the combination is synergistic. None of the below data has been analysed for statistical significance.

The study demonstrated that CBD and HCQ act synergistically to inhibit production of the assessed inflammatory cytokines IL-1β, IL-6, TNF-α, IL-1aα, and MIP-1α by PBMCs from the donors. The average EOB scores ranged from 0.32-0.57. The reduction in levels of the five cytokines (relative to vehicle treated PBMCs) observed in PBMCs treated with IHL-675A was 436% to 1320% greater relative to those treated with HCQ alone, 109% to 767% greater relative to those treated with CBD alone and 87% to 767% greater relative to the predicted combinatorial effect of CBD and HCQ. The results in Figures A, B, C, D and E presented below, display the optimal fixed dose IHL-675A combination assessed for each cytokine. The bars noted as Predicted CBD+HCQ represent what our expectation was based on the activity of each drug individually. The observed inhibition of cytokine release upon treatment with the CBD HCQ combination was greater than predicted based on the activity of each drug alone for each cytokine analyzed.

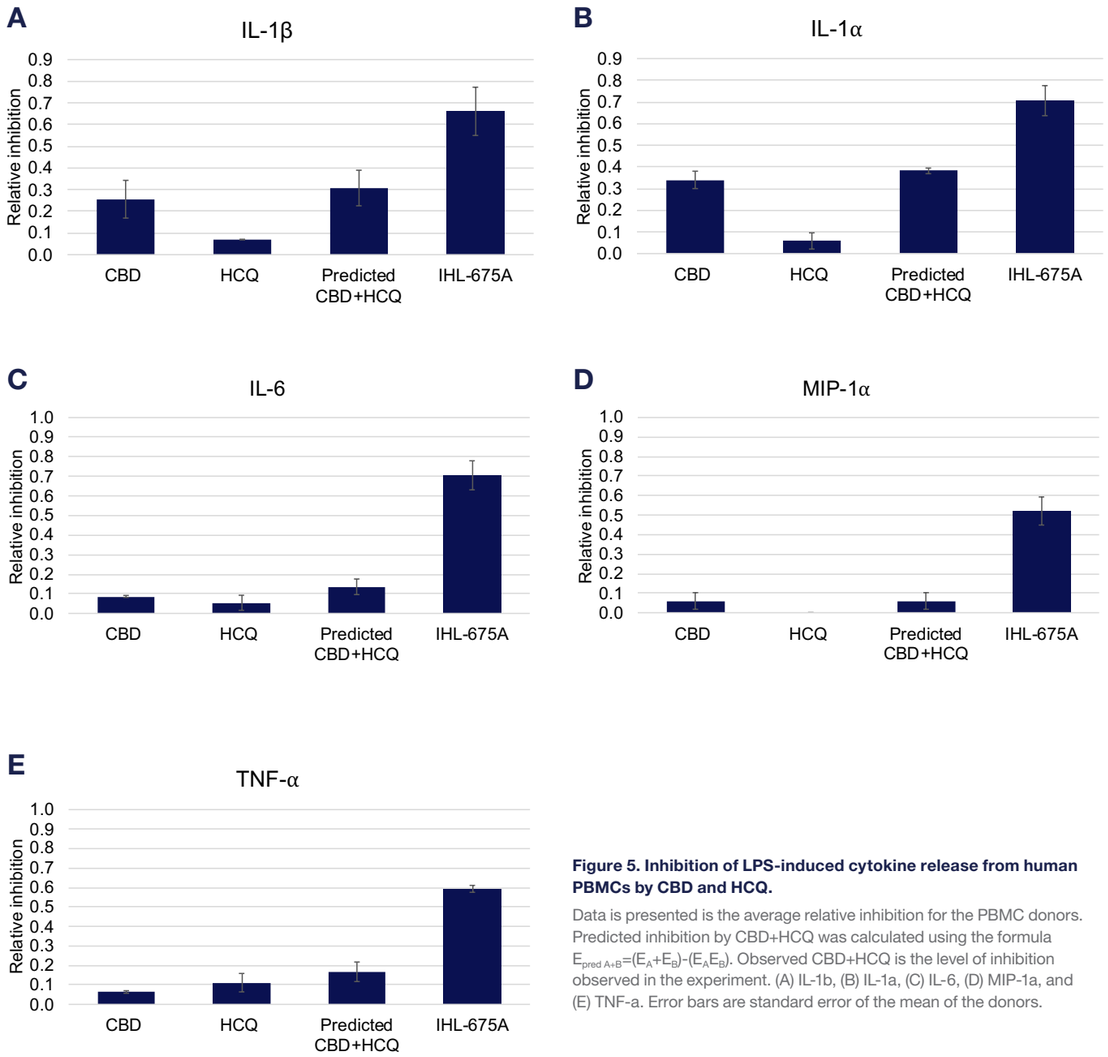

Figure 5. Inhibition of LPS-induced cytokine release from human PBMCs by CBD and HCQ.

Data is presented is the average relative inhibition for the PBMC donors. Predicted inhibition by CBD+HCQ was calculated using the formula $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$. Observed CBD+HCQ is the level of inhibition observed in the experiment. (A) IL-1b, (B) IL-1a, (C) IL-6, (D) MIP-1a, and (E) TNF-a. Error bars are standard error of the mean of the donors.

Preclinical in vivo study of IHL-675A against inflammation

In November of 2020, we announced the results of an in vivo study assessing IHL-675A in a mouse model of sepsis. To determine whether CBD and HCQ synergize in vivo, mice from 11 groups of 10 mice, weighing 18-20g were injected with CBD and HCQ both alone and in combination. After one hour, the mice were injected with LPS to induce an inflammatory response. Each mouse in every cohort was assessed for each of the 5 inflammatory cytokines. Two hours after LPS injection, blood was collected from the mice by cardiac puncture. Sera were processed and analyzed for cytokine levels using a Luminex based assay. For synergy analysis, data was baseline subtracted using sham treated (no LPS injection) cytokine levels and then the values for each cytokine were normalized relative to maximum values across the groups. The normalized values were used to calculate the relative inhibition where a value of 1 is complete inhibition and a value of 0 is no inhibition. Synergy was calculated using the EOB method, or the difference between the observed and predicted inhibition between the combination of drug concentrations where the predicted inhibition is determined using the equation $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$. An EOB score of greater than 0 is indicative of synergy.

The results of the in vivo study are presented in Figure 6, showing the optimal fixed dose IHL-675A combination assessed for each cytokine in 11 groups of 10 mice. The bars noted as 'Predicted CBD + HCQ' represent IHL's expectation based on the activity of each drug alone. The observed results from the study significantly exceeded the predicted results across the inflammatory cytokines analyzed. CBD and HCQ synergize to inhibit the production of inflammatory cytokines IL-1β, IL-6, TNF-α, IL12(p70), and IFN-γ in a mouse model of LPS induced sepsis. The average EOB scores ranged from 0.15-0.30. Levels of the five inflammatory cytokines were reduced compared to animals treated with vehicle to a greater extent in animals treated with IHL-675A than in those treated with CBD alone. Reduction in cytokine levels compared to vehicle treated group in the group treated with IHL-675A was 26% to 81% greater relative to the predicted effect of the CBD HCQ combination across the five analyzed cytokines after 2 hours.

Preclinical in vivo study of IHL-675A against Pulmonary Inflammation (ARDS, COPD, Asthma and Bronchitis)

In February 2021, we announced the results of an in vivo study assessing IHL-675A anti-inflammatory capabilities regarding chronic obstructive pulmonary disease, asthma, bronchitis, and other inflammatory respiratory conditions. We also assessed the anti-inflammatory effect of our proprietary IHL-675A formulation on Pulmonary Neutrophilia, which is a primary underlying cause of COPD, asthma, bronchitis, and other inflammatory respiratory conditions. We reported encouraging results, as discussed below, which facilitate a substantial expansion of the potential uses for IHL-675A and represent new patient treatment opportunities.

A rodent model of pulmonary inflammation was used to assess the anti-inflammatory efficacy of IHL-675A in lungs. In this study, ten groups of six mice each were pre-treated with either CBD, HCQ or IHL-675A prior to intratracheal administration of bacterial lipopolysaccharide ("LPS"), which was then inhaled and acts as an inflammatory stimulus in the lungs. A sham group where LPS was not administered to the mice was also included as a control. The lungs were flushed with a saline solution 24 hours after LPS administration and bronchoalveolar lavage fluid ('BALF') was analyzed for cytokine levels using a Luminex based assay. Cytokines are proteins that mediate the inflammatory response and a reduction in cytokine levels is indicative of reduced inflammation. A white blood cell ('WBC') count was also performed on the BALF. When inflammation occurs in the lungs, WBCs are recruited as part of the inflammatory response. A reduction in WBC count is also indicative of reduced inflammation.

Cytokine levels were normalized to those detected in vehicle treated mice and then the relative inhibition was calculated. IHL-675A reduced levels of all assessed inflammatory cytokines IL-1β, IL-6, TNF-α, CXCL1 and MCP-1 to a greater extent than either CBD or HCQ alone. WBC counts were normalized using the same method used for cytokines and IHL-675A reduced WBC counts to a greater extent than CBD or HCQ alone. These results indicate that IHL-675A has superior anti-inflammatory activity compared to CBD and HCQ in a mouse pulmonary inflammation model. Based on these results IHL-675A will be assessed for efficacy in the treatment of pulmonary inflammation in humans. These results have not been analysed for statistical significance.

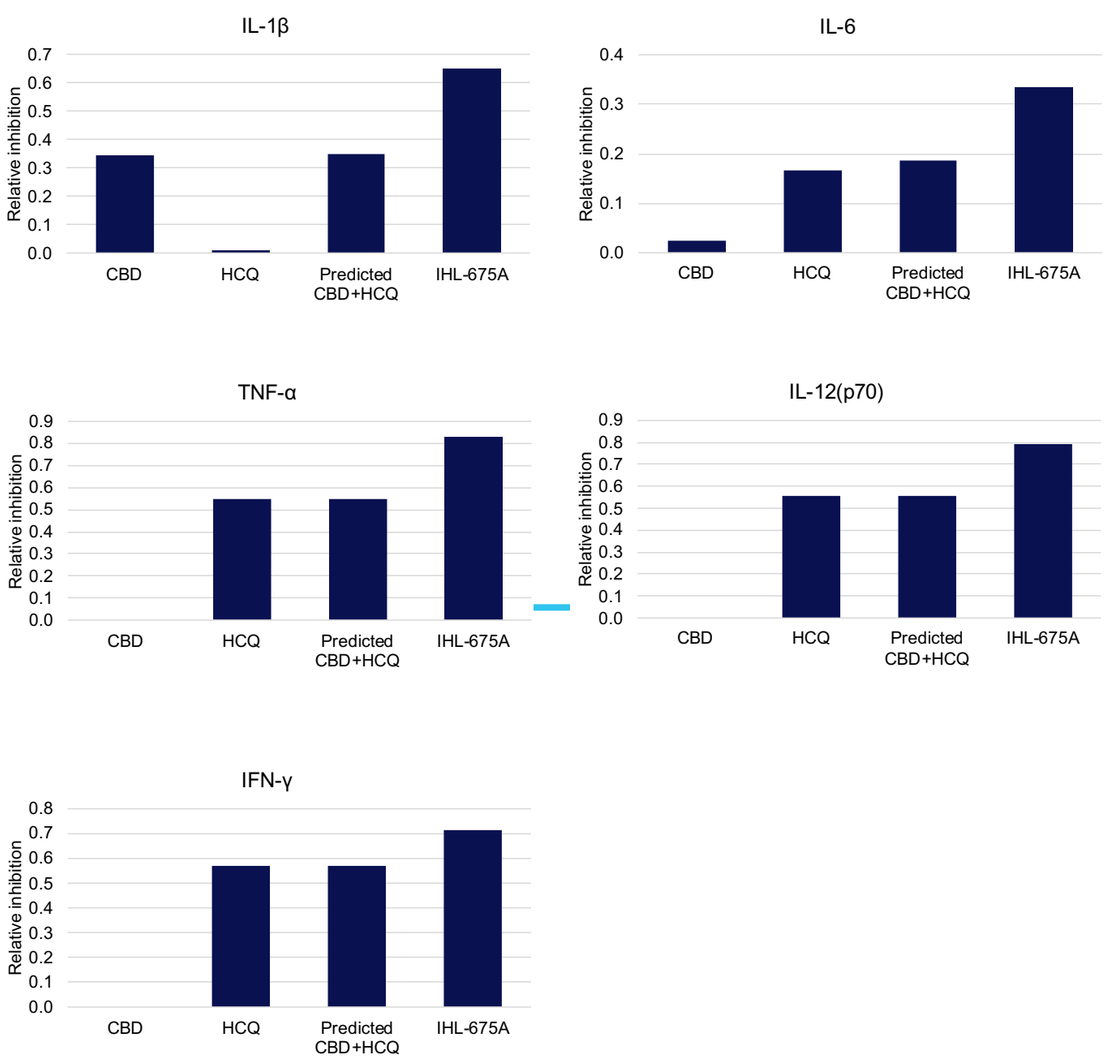

Figure 6. Synergistic anti-inflammatory activity of CBD and HCQ in a mouse sepsis model.

The anti-inflammatory activity of the combination of CBD and HCQ was greater than that predicted using the Excess over Bliss method. The CBD+HCQ combination was synergistic at inhibiting release of IL-1β, IL-6, TNF-α, IL12(p70), and IFN-γ.

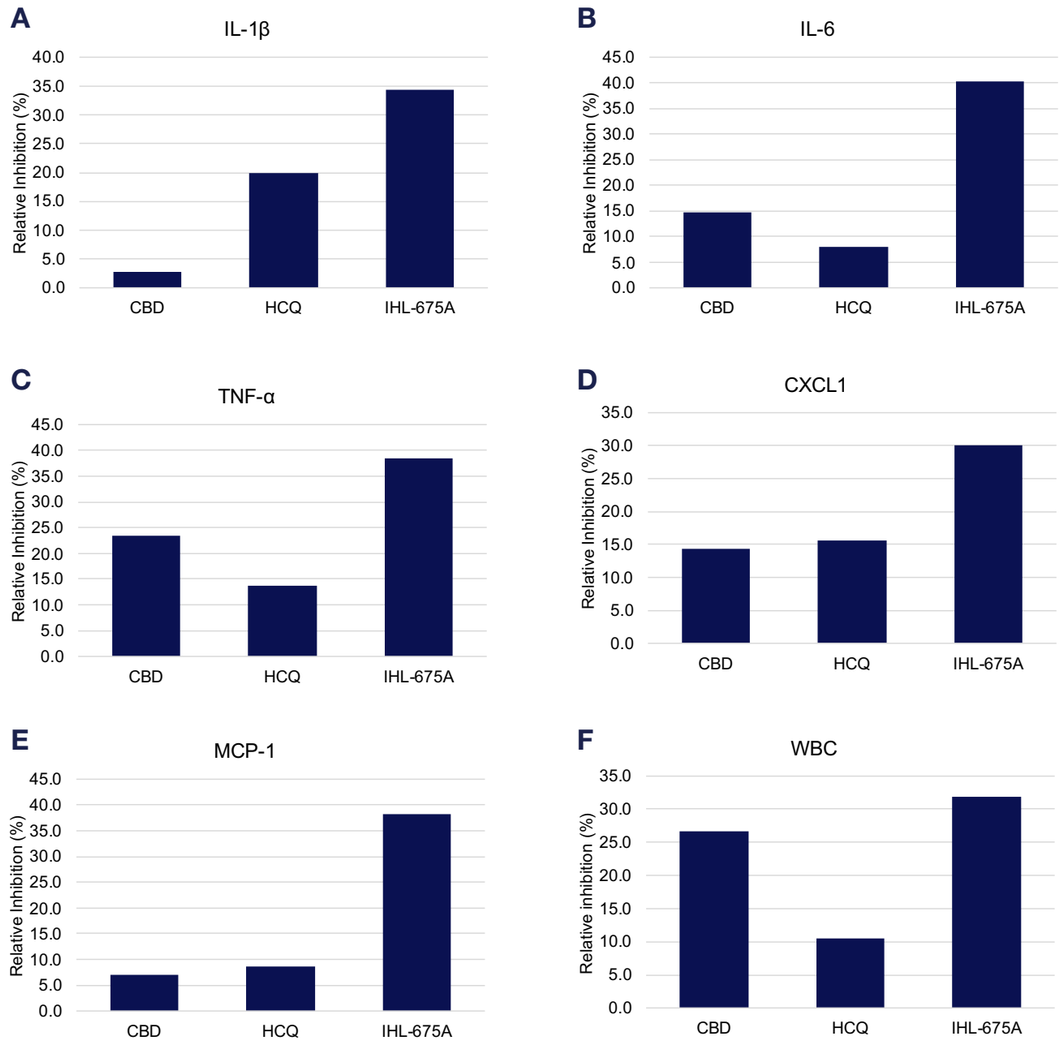

Figure 7. Reduction in cytokine levels and white blood cell count in BALF resulting from treatment with by IHL-675A, CBD or HCQ in a mouse model of pulmonary inflammation.

Mice were treated with CBD, HCQ or a combination of CBD and HCQ (IHL-675A) and then LPS was administered intratracheally. Twenty-four hours after LPS administration bronchioalveolar lavage fluid (BALF) was analyzed for cytokine levels and white blood cell count. The reduction in cytokine levels by IHL-675A was greater than that for either drug alone. Drug concentrations were 1 mg/kg CBD and 25 mg/kg HCQ for (A) IL-1β, (B) IL-6, (C) MCP1 and (E) TNF-α, 10 mg/kg CBD and 2.5 mg/kg HCQ for CXCL-1 and WBC (white blood cell count).

Preclinical study of IHL-675A in a model of Rheumatoid Arthritis

In March 2021, we announced the results of an in vivo study assessing IHL-675A's anti-inflammatory capabilities in a rheumatoid arthritis model. Results indicate that a low dose of IHL-675A was 1.06 to 3.52 times more effective at reducing disease severity scores across multiple assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels compared to a standard dose of HCQ only. HCQ is approved and widely used for the treatment of rheumatoid arthritis in the form of hydroxychloroquine sulfate, which is marketed as Plaquenil.

In this model of rheumatoid arthritis, female Lewis rats were challenged with porcine type-II collagen with Freund's adjuvant on Day 1 (0.2 mg/0.2 mL/rat) by subcutaneous injection at the base of the tail to induce arthritis. A booster injection at 0.1 mg/0.1 mL/rat was injected on day 7. On day 16, rats were allocated into groups of six. There were ten groups of modelled rats and one sham injected group. CBD, HCQ or IHL-675A were injected intraperitoneally once per day from day 17 to 30 (total of 14 days). Drug doses were 1 and 10 mg/kg CBD and 2.5 and 25 mg/kg HCQ. The 10 mg/kg CBD and 25 mg/kg HCQ doses were selected as they are representative of standard doses in humans based on the FDA body surface area dose equivalence estimation for rats to humans of 6/37. For a 60 kg person, the 10 mg/kg CBD dose in rats is equivalent to 97 mg and the 25 mg/kg HCQ dose in rats is equivalent to 243 mg. The maintenance dose range recommended for rheumatoid arthritis in the Plaquenil prescribing information is 200-400 mg daily.

Disease severity was assessed by measuring hind paw volume with a plethysmometer and using a qualitative severity score system on days 1, 7 ,10, 14, 16, 18, 20, 22, 24, 26, 28 and 30. Post termination on day 30, blood was collected from all rats and analyzed for levels of the inflammatory cytokines IL-1β and IL-6 using commercially available ELISA kits. These two cytokines were selected as they are known to be involved in the pathophysiology of rheumatoid arthritis. Both hind paws were harvested, weighed and formalin-fixed for histopathology. Histopathological evaluation consisted of an evaluation of cartilage and bone destruction by pannus formation (an abnormal layer of fibrovascular or granulated tissue) and mononuclear cell infiltration in synovial joint tissues. A total histology score, which is a sum of the pannus formation and mononuclear cell infiltration scores, was also calculated. For all assessments, the score was sham subtracted and then the reduction relative to the vehicle group was calculated.

In the rat model of arthritis, IHL-675A treated animals had a greater reduction (relative to vehicle treated animals) in clinical score and paw volume at days 24 and 30, pannus formation, total histology score, IL-1β and IL-6 than animals treated with HCQ alone or CBD alone (at equivalent doses). The reduction in disease assessments by IHL-675A was 1.07-8.72 times that observed for HCQ alone at an equivalent dose, which indicates that IHL-675A has a benefit in a rat model of arthritis greater than that of HCQ alone and demonstrates that IHL-675A has potential as a treatment for rheumatoid arthritis in humans.

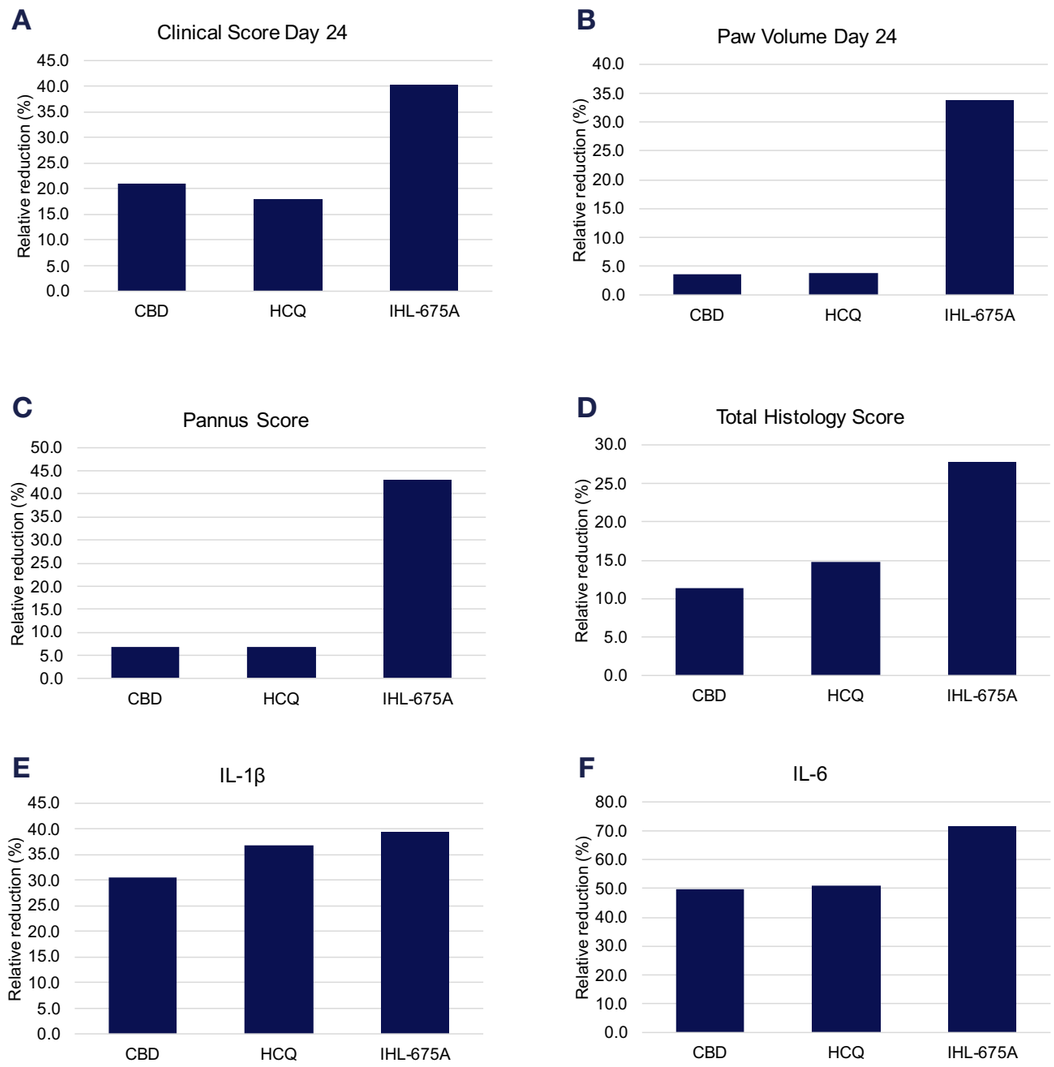

Figure 8. Comparison of IHL-675A to its component drugs CBD and HCQ in reduction of disease assessments in a rat model of rheumatoid arthritis.

Groups of rats that had undergone collagen-induced arthritis modelling were treated with IHL-675A, CBD or HCQ at equivalent doses (1 mg/kg CBD, 2.5 mg/kg HCQ). The reduction in arthritis disease severity in IHL-675A treated rats was greater than for either CBD or HCQ treated rats with respect to (A) clinical score at day 24, (B) paw volume at day 24, (C) pannus formation, (D) total histology score, (E) serum IL-1b levels and (F) serum IL-6 levels.

Preclinical studies of IHL-675A in models of inflammatory bowel disease

In February 2021, we announced the results of an in vivo study assessing IHL-675A's anti-inflammatory capabilities regarding inflammatory bowel disease. IHL-675A demonstrated a reduction in the Colitis index of 46%, while CBD only and HCQ only treatment achieved a reduction of 25% and 27% respectively, demonstrating that IHL-675A has superior anti-inflammatory activity compared to CBD only and HCQ only, which indicates that IHL-675A has the potential to be a treatment for inflammatory bowel disease in humans.

This study used eleven groups of six mice. Mice were treated with IHL-675A, CBD or HCQ for four consecutive days after administration of TNBS/ethanol to induce ulcerative colitis. A vehicle treated group and sham group were included in the study. Stool consistency was monitored over the course of the experiment. On Day 5 mice were sacrificed, blood collected for cytokine analysis and the colon removed for analysis.

Endpoint measurements include stool consistency score (an ordinal scale that measures stool consistency with a higher number indicative of looser stools) , colon weight, colon macroscopic damage score (an ordinal scale that combines adhesions, strictures, ulcers/inflammations and instances of wall thickening), colitis index (a composite scale from the histological examination of colon sections) and myeloperoxidase (an enzyme abundantly expressed in neutrophil granulocytes that contributes to inflammatory damage in IBD) levels in the colon tissue at day 5. The results from each of these endpoints were sham subtracted and the relative reduction was calculated. The data was not analysed for statistical significance.

Animals treated with IHL-675A displayed a greater reduction (relative to vehicle treated animals) in colitis index, macroscopic damage score, stool consistency score, colon to body weight ratio and myeloperoxidase (MPO) levels than animals treated with either CBD or HCQ alone. These results indicate that IHL-675A has a benefit in a mouse model of ulcerative colitis greater than that of CBD or HCQ alone, which indicates that IHL-675A is a potential treatment for inflammatory bowel disease in humans.

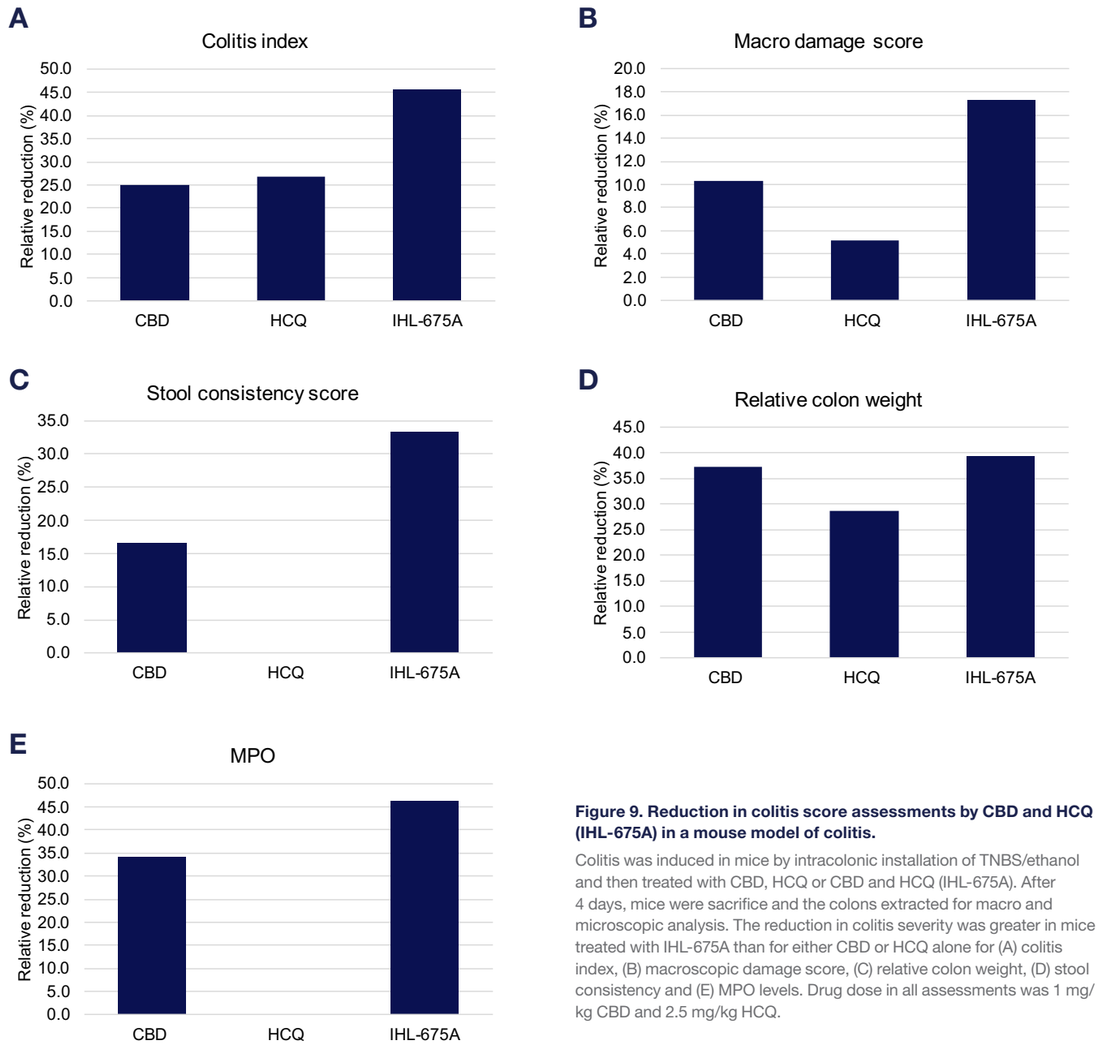

Figure 9. Reduction in colitis score assessments by CBD and HCQ (IHL-675A) in a mouse model of colitis.

Colitis was induced in mice by intracolonic installation of TNBS/ethanol and then treated with CBD, HCQ or CBD and HCQ (IHL-675A). After 4 days, mice were sacrifice and the colons extracted for macro and microscopic analysis. The reduction in colitis severity was greater in mice treated with IHL-675A than for either CBD or HCQ alone for (A) colitis index, (B) macroscopic damage score, (C) relative colon weight, (D) stool consistency and (E) MPO levels. Drug dose in all assessments was 1 mg/kg CBD and 2.5 mg/kg HCQ.

Planned phase 1 clinical trial for IHL-675A

We have designed a Phase 1 clinical trial in Australia to assess the safety and pharmacokinetics of IHL-675A in healthy volunteers, the results of which will form part of our FDA IND submissions across the indications of lung inflammation, rheumatoid arthritis and inflammatory bowel disease. The aims of this study are to demonstrate that there are no, or minimal, additional risks/side effects associated with the combination of CBD and HCQ compared to each drug alone and that the uptake and metabolism (pharmacokinetics) of the two drugs do not interfere with one another. A total of 36 subjects will participate in the trial, evenly divided across three arms. The three arms of 12 subjects each will receive one of IHL-675A, Epidiolex (CBD), or Plaquenil (HCQ). The safety and pharmacokinetic assessments will be identical across the three arms.

CBD and HCQ both have both been used historically as treatments for our targeted indications when used independently. However, as with any pharmaceuticals there are risks involved. Part of the strategy in the design of IHL-675A is that the combination of CBD with HCQ permits a reduction in HCQ, which reduces the known risks associated with cumulative HCQ dose, without sacrificing efficacy. Results from the preclinical studies we have conducted to-date have led to the hypothesis that a lower cumulative dose of HCQ, when combined with CBD, will also reduce disease severity scores in IHL-675A's target indications in humans. Nonetheless, there is always potential for two drugs to interact and exacerbate minor concerns that exist when used alone or lead to new safety concerns. Demonstrating that a combination drug containing CBD and HCQ has a similar safety profile to the component drugs is an important step in the development program and is a requirement set out by regulatory agencies. This clinical trial will be performed in a Phase 1 unit with around the clock monitoring in the event that an adverse event needs to be managed. Safety assessments will include cardiac monitoring via ECG and blood biomarkers, serum liver enzyme levels, blood cell counts and biochemistry, monitoring of vital signs and mental health questionnaires. Due to the substantial evidence of synergy between HCQ and CBD required to produce a superior outcome on inflammatory markers, dosages of HCQ and CBD may be significantly lower than for treatment with the individual drugs and this will be further evaluated in clinical trials.

The other component of this study is monitoring the pharmacokinetics of the two active pharmaceutical ingredients ("API") of IHL-675A, CBD and HCQ, and comparing them to their respective reference listed drugs Epidiolex and Plaquenil. Study participants will be dosed with either IHL-675A, Epidiolex or Plaquenil with equivalent amounts of the respective API. Blood samples will be drawn at predetermined intervals over a 72-hour period and analyzed for levels of CBD and HCQ as well as their major metabolites. For each molecule the maximum concentration ("Cmax"), time to maximum concentration ("Tmax ") and total exposure ("AUC") will be determined. The pharmacokinetic parameters for IHL-675A, Epidolex and Plaquenil will be compared to determine whether the APIs in IHL-675A are bioequivalent to the reference listed drugs. Bioequivalence is an important component of the FDA 505(b)2 approval pathway that IHL is targeting with IHL-675A.

Results from this study, which has received clearance from the Bellberry human research ethics committee to proceed, will form a component of future regulatory applications for IHL-675A and will also inform the design of Phase 2 efficacy and safety studies across indications.

Psilocybin-assisted Psychotherapy for General Anxiety Disorder (Psi-GAD)

Generalized Anxiety Disorder

Generalized Anxiety Disorder ('GAD') is characterized by diffuse, excessive, uncontrollable anxiety that frequently occurs and is not restricted to any particular environmental circumstances. Symptoms are variable, including feelings of persistent and excessive worry, nervousness, restlessness, difficulty in concentrating fatigue, irregular sleeping patterns, muscle tension, irritability, and nausea.

Generalized anxiety disorder is a relatively common and serious psychiatric condition affecting around 4-6% of the population during their lifetime. GAD can severely affect quality of life and professional career prospects. An estimated 8 million people in Australia and the United States have moderate to severe GAD at any point in time, of which, 1 million people reside in Australia and 7 million people reside in the United States.

Existing treatments

International guidelines for GAD treatment recommend selective serotonin reuptake inhibitors ("SSRIs"), serotonin and noradrenaline reuptake inhibitors ("SNRIs"), and pregabalin as first-line options, with benzodiazepines such as diazepam as second-line options. GAD is also treated with psychotherapy alone or in combination with pharmacotherapies. However, these treatments show limited efficacy, with less than half of patients achieving remission following these treatments and substantial treatment side-effects and cost. In particular, the side effects associated with long term use of these pharmacotherapies include emotional numbness, reduced positivity, weight gain, sexual disfunctions, and suicidal thoughts. Due to the limitations of existing treatments, we believe there is significant unmet need for new therapies to improve quality of life outcomes for patient diagnosed with GAD.

Psilocybin as a treatment for generalized anxiety disorder

Psychedelic-assisted psychotherapy may provide rapid, significant, and lasting benefit in treating unipolar depression, depression and anxiety symptoms associated with a terminal illness, and substance misuse. Psilocybin is a psychoactive molecule that occurs naturally in several genera of mushrooms, which primarily acts on the serotonin receptor system, and can modulate states of consciousness, cognition, perception, and mood.

When combined with specialized forms of psychotherapeutic support, psilocybin does not lead to clinically significant adverse events and can reduce scores on mental health severity assessments. Through the 1950s and 1960s, tens of thousands of individuals participated in psychedelic research. While methodologically limited by modern standards, the findings from many of these studies showed substantial improvements in anxiety, depression and addiction levels, and quality of life.

Following decades of socio-political obstruction to psychedelic treatments, an increasing number of clinical psychedelic trials are now being conducted at highly esteemed institutions around the world, including Imperial College London, John Hopkins University, University of California, and now Monash University, Melbourne, in partnership with us.

Over the past decade, the therapeutic potential of psilocybin in anxiety, depression and addiction has been demonstrated in various academic-sponsored studies. In these studies, psilocybin-assisted psychotherapy, provided a rapid reduction in anxiety and depression symptoms on the day of administration with generally maintained treatment effects at follow-up assessments many months later. These studies have shown psilocybin to be generally well-tolerated, with low toxicity and no serious adverse events reported.

We believe that the following four studies detailed below support psilocybin-assisted therapy for treating anxiety using treatment dosages up to 30mg/70kg:

- New York University, Ross et al 2016 (n=29): **Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial.** Psilocybin produced immediate, substantial, and sustained improvements in anxiety and depression, as well as decreases in cancer-related demoralization and hopelessness, improved spiritual wellbeing, and increased quality of life.
- Imperial College London, Carhart-Harris et al 2018 (n=20): **Psilocybin with psychological support for treatment-resistant depression: six-month follow-up.** Good tolerability, effect sizes large and symptom improvements appeared rapidly after just two psilocybin treatment sessions and remained significant six months post-treatment in a treatment-resistant cohort.
- University of California, Los Angeles, Grob et al 2011 (n=12): **Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer.** The State-Trait Anxiety Inventory trait anxiety subscale demonstrated a significant reduction in anxiety at one and three months after treatment. There were no clinically significant adverse events with psilocybin.
- John Hopkins University, Griffiths et al 2017 (n=51): **Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: a randomized double-blind trial.** Large and significant decreases in clinician-rated and self-rated measures of depression, anxiety or mood disturbance, and increase measures of quality of life, life meaning, death acceptance, and optimism.

Two psilocybin research programs for depression have received breakthrough designation from the FDA. A small number of other psilocybin treatment development programs are underway globally. Should the results from any of these research programs be positive, approval of psilocybin-assisted psychotherapy as a prescription treatment could occur within the next five years.

Our investigational psilocybin therapy for Generalized Anxiety Disorder

Our psilocybin therapy combines psilocybin with psychological therapy that has been specifically designed for patients diagnosed with generalized anxiety disorder by a multidisciplinary team of experts lead by Principal Investigator Dr Paul Liknaitzky, along with Co-Investigators Professor Suresh Sundram and Professor Murat Yucel. The wider research team includes experts in psychedelic-assisted therapies, psychometric evaluation, qualitative research, therapist training, and risk management. We are in the process of coordinating two clinical trials as part of our clinical development program. On October 28, 2021, we conducted a pre-IND meeting with the FDA on the psilocybin-assisted psychotherapy for GAD program, which was ultimately aimed at FDA approval of our psilocybin therapy administered to patients with GAD.

Phase 2 exploratory clinical trial

Our Phase 2 Australian exploratory clinical trial was approved by the human research ethics committee ('HREC') in late 2021 and this approval from an independent board of examiners permitted us to recruit trial participants in Australia. Participant screening and recruitment commenced in February 2022 and the first participants to the trial commenced treatment in March 2022.

The study is a Phase 2 randomized triple-blind active-placebo-controlled trial to assess the safety and efficacy of psilocybin-assisted psychotherapy for GAD. Participants experience two psilocybin or active-placebo dosing sessions and up to 11 non-drug, specialist psychotherapy sessions over a period of 10 weeks. Primary outcomes are safety, efficacy and tolerability, and secondary outcomes are quality of life, functional impairment, and comorbidities. Safety is assessed by monitoring adverse events including but not limited to liver function tests and scores on the Ultra Brief Checklist of Suicidality. Efficacy is assessed by comparing the change in Hamilton Anxiety Rating Scale from baseline between the placebo and treatment group. Tolerability is assessed by comparing the proportion of participants who complete both dosing sessions in the placebo and treatment groups. Secondary endpoints will be assessed by monitoring disability, comorbidity, productivity and quality of life using patient reported outcome measures.

A preliminary analysis of patient data will be conducted by an independent data safety monitoring board after 30 patients have completed primary endpoint assessment. All 30 participants are anticipated to have been enrolled and commenced their treatment programs within Q3, 2022. The preliminary analysis will allow the trial investigators to inform the second part of the trial (n=42) and, or decide to initiate activities to commence a pivotal phase 2b clinical trial that Incannex is actively planning.

FDA development plan and pre-IND meeting

In October 2021, we conducted a pre-IND meeting with the FDA on the psilocybin-assisted psychotherapy for GAD program. The pre-IND meeting package was prepared with the assistance of Camargo Pharmaceuticals LLC, who also attended the meeting with us. The FDA confirmed, in both writing and teleconference, that the therapeutic strategy for a psilocybin-assisted therapy for GAD is appropriate and conveyed interest in its development. FDA also provided guidance on Incannex's proposed long-term development strategy with regards to what will be required for a successful NDA (FDA approval) and marketing authorization. Specific feedback from the FDA on our proposed clinical trial designs will shape a pivotal Phase 2b clinical trial, which will be the IND opening study following either interim or full results from the Phase 2 exploratory trial.

Intellectual Property Strategy

We strategically protect our innovations with a harmonized IP strategy, combining patent protection with regulatory and market exclusivity. We are pursuing patent protection for aspects of our psilocybin therapy program. The patent position that will be available to us is unlikely to cover psilocybin alone as a clinical entity. However, we are pursuing a patent position in relation methods of treatment using psilocybin including combination therapies (e.g., formulations, actives plus psychotherapeutic modalities) and other therapeutic methods (e.g., specific dosage regimens).

Psilocybin therapy protocol

Our psilocybin therapy comprises administration of medication with psychotherapy by mental health professionals that have undergone our specialised therapist training program. Therapy is designed to optimize patient safety and therapeutic outcomes in GAD with specific support before, during and after psilocybin dosing sessions.

Each participant receives two therapeutic doses of our investigational product, which will be composed of a specified dosage of psilocybin, with psychotherapy before, during and after each dose session. The psychotherapy comprises four distinct phases:

- Preliminary psychotherapy: conducted during the screening stage with key focus on clinical formulation, therapeutic alliance, psychedelic treatment psychoeducation and practical preparation for dosing.
- Preparation psychotherapy: conducted following full enrollment and prior to the first dosing session with a key focus on extending preliminary psychotherapy work, and covering more targeted and GAD-specific psychological and practical preparation for dosing.
- After dosing support: conducted within a week following the preparation session with key focus on trust, suitable mindset, conducive physical setting, and participant-led support. Dosing support is the psychotherapy session.
- Integration psychotherapy: conducted following the dosing sessions, including the day directly following each dosing session, with key focus on sustaining benefits through specific mindful, emotion and somatic-focused therapy, meaning-centered support, and facilitating contextual changes that support outcomes.

Monash University

In December 2020, we entered into a partnership agreement with Monash University (“Monash”) in Australia to conduct a psilocybin-assisted psychotherapy trial to treat GAD. Monash sponsors our initial Phase 2 exploratory clinical trial, ensuring rigorous scientific independence and the highest standards in ethical and safe research. We are funding and supporting this investigator-initiated trial, and retain all intellectual property created by the trial. We are also investigating the commencement of other psychedelic medicine research projects that would offer an opportunity to address what we believe is an unmet need in patients diagnosed with other mental illnesses.

Monash is one of Australia’s leading universities and consistently ranks among the world’s top 100. Psychedelic treatment for our exploratory trials are delivered within BrainPark, a state-of-the-art research platform at Monash’s Turner Institute for Brain and Mental Health and Biomedical Imaging Facility, that provides a highly conducive environment for psychedelic treatments in a research context. Both the School of Psychological Sciences within the Turner Institute for Brain and Mental Health, and the Department of Psychiatry within the School of Clinical Sciences, have combined forces to conduct psychedelic research and the team comprises leading researchers and clinicians in relevant fields of psychiatry, psychotherapy, and mental health treatment development.

Virtual Reality (‘VR’) Exposure Response Therapy (‘ERP’) and psychede lics

In March 2022, we entered into a license agreement with Monash to develop a novel treatment that combines Virtual Reality and psychedelics. The license agreement provides an exclusive and perpetual license over an immersive therapeutic Virtual Reality environment developed by BrainPark. The license allows Incannex to investigate the use of the Virtual Reality therapy tool in combination with a psychedelic drug to develop a new treatment for severe forms of one of more anxiety disorders.

The associated research and development will be led by Dr Paul Liknaitzky at Monash, a highly reputable, globally recognized, and innovative university that ranked #40 in the world in the US News and World Report 2022. Incannex and Monash are in advanced stages of discussion in relation to a research agreement for the clinical trials required to develop the new treatment form. The initial clinical trial will assess efficacy, safety, tolerability, and optimal dose of the treatment method.

Clinical trial investigators

The Principal Investigator is Dr Paul Liknaitzky, with Co-Investigators Professor Murat Yucel and Professor Suresh Sundram.

Dr. Liknaitzky is Head of the Clinical Psychedelic Research Lab within the Turner Institute and the Dept of Psychiatry, Monash. He is a Chief Principal Investigator and Research Fellow at Monash University, and has Adjunct or Honorary appointments at St Vincent’s Hospital, Macquarie University, Deakin University, and the University of Melbourne. He earned an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne. His work examines mechanisms of mental illness and treatment development primarily within mood, anxiety and addiction research. Liknaitzky is an Investigator across a number of Australia’s first clinical psychedelic trials. He has been invited to deliver numerous academic, professional, and public talks on psychedelic-assisted psychotherapy, and has been interviewed on the topic for print media, radio, and podcasts. Liknaitzky leads Australia’s first clinical psychedelic lab, coordinates Australia’s first applied psychedelic therapist training program, and is establishing Australia’s largest psychedelic trial (Psi-GAD). His work is focused on developing a rigorous program of research in psychedelic medicine at Monash University that seeks to evaluate therapeutic effects, innovate on treatment design, mitigate known risks, explore potential drawbacks, and understand therapeutic mechanisms.

Professor Murat Yucel gained a PhD combined with specialist clinical training in Clinical Neuropsychology in 2001 at La Trobe University. He then worked across as numerous mental health research centres at the University of Melbourne and was promoted to professor in 2012. He now works within the Monash School of Psychological Sciences, where he heads the mental health and addiction research programs. He is a director of BrainPark — a world-first neuroscience research clinic designed to bring the latest neuroscience with diagnostic or therapeutic benefit to the community in an accessible way.

Professor Suresh Sundram is the Head, Department of Psychiatry, School of Clinical Sciences, Monash University and Director of Research, Mental Health Program, Monash Health. He has been investigating the molecular pathology of schizophrenia and related psychotic disorders using pharmacological, neurochemical and neuropathological approaches. These inter-related methods have been applied to parse components of the disorder such as treatment resistance and suicide to better understand their neurobiological substrates. He undertook his doctoral and post-doctoral studies at the Mental Health Research Institute in Melbourne before establishing his laboratory there and subsequently at the Florey Institute and concurrently establishing a clinical research laboratory undertaking clinical trial and biomarker research in psychotic disorders. He then transferred to and integrated his research program at Monash University and Monash Medical Centre.

Acquisition of APIRx Pharmaceuticals

In May 2022, Incannex announced that it completed a binding share sale and purchase agreement to acquire 100% of the issued share capital in APIRx Pharmaceuticals USA, LLC ('APIRx'). The stakeholders in APIRx ('Sellers') have been issued a total of 218,169,506 new shares at a notional value of A$0.573 per share to satisfy the purchase of APIRx, which represents the price agreed at the signing of the binding terms sheet announced on March 24, 2022. IHL share purchase consideration is equivalent to approximately 8,726,780 IXHL American Depositary Shares (ADS). Approval to issue the shares to the APIRX sellers in consideration for the acquisition of APIRx was sought and approved at a meeting of shareholders on June 9, 2022. 99.27% of voting shareholders approved the issue of shares to the sellers. The Company completed the acquisition on APIRx Pharmaceuticals on the 5th of August, via the issuance of 218,169,497 IHL ordinary shares to the stakeholders of APIRx. Legal transfer of the APIRx group of companies to Incannex has been finalised so that the group of companies sit within a wholly owned subsidiary of Incannex.

The acquisition of APIRx presents Incannex with both long and short-term opportunities for significant value growth. APIRx has twenty-two (22) active clinical and pre-clinical research and development projects underpinned by an intellectual property portfolio that includes 19 granted patents and 23 pending patents. It holds a diverse portfolio of promising therapeutic candidates targeted at treating an extensive range of conditions including pain disorders, addiction disorders, mental illnesses, gastrointestinal diseases, gum disease, skin conditions and ophthalmic conditions. The indications being pursued represented an aggregate addressable market of US$400B per annum.

Founders of APIRx, Dr George Anastassov and Mr Lekhram Changoer (M.Science) have joined the Incannex team as non-executive director and chief technology officer respectively. Dr. Anastassov is responsible for APIRx commercial operations, strategic decision- making, and oversight of all clinical development assets. He 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, which achieved an all-time-high market capitalization of approximately US$1.2B. Mr. Changoer is responsible for the Company's R&D, clinical & product development, commercial operations, quality assurance and Sales & Marketing of technical, consumer healthcare and pharmaceutical products. He has co-developed several patents in the cannabinoid field. Previously, he was CTO and Co-founder of AXIM Biotechnologies.

The initial priority APIRx drug candidates for Incannex are:

MedChew Dronabinol for chemotherapy induced nausea and vomiting

According to the WHO, cancer is one of the leading causes for death and chemotherapy is utilized by approximately ten (10) million cancer patients annually and this statistic is expected to grow by 53% by 2040. Nausea and vomiting are two of the most dreaded cancer treatment-related side effects. Dronabinol, which is synthetic Tetrahydrocannabinol ('THC') is an approved treatment of chemotherapy associated nausea and vomiting as well as anorexia associated with HIV/AIDS. Oral dronabinol is taken up slowly, however, taking 1-2.5 hours to reach peak plasma concentration, and is also subject to first pass metabolism, which means that only 10-20% of the dose reaches the circulation.

MedChew Dronabinol is a chewable variant of Dronabinol that has been developed and patented by APIRx to bypass first pass metabolism. In a phase 1a study of MedChew Dronabinol, THC appears in circulation within 10 minutes and a sustained release profile of 4 to 8 hours was observed in most study subjects so that the product is more useful in the time in which it is required. There is an open IND with the FDA for MedChew Dronabinol and the next developmental step for the product is to conduct a bioavailability/ bioequivalence clinical study to support application for approval by bridging to publicly available data on Marinol, the marketing name of generic dronabinol. The economic size of the global drug market for chemotherapy induced Nausea and Vomiting is anticipated to be US$3.1B per annum by 2024.

MedChew Rx for pain and spasticity in multiple sclerosis ('MS')

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. MedChew™ Rx is absorbed through the oral mucosal membrane and bypasses the liver, and first pass metabolism. MedChewTM Rx contains the same constituent formulation of CBD and THC as the product Sativex, which has received EMA drug approval. MedChew Rx, however, facilitates extended dosing and reduces the need to readminister, which for Sativex is up to 12 times per day. It does not contain alcohol, which Sativex does, and will not exacerbate the dry mouth that is often associated with MS pharmacotherapy. MedChew Rx has underlying

patent protection via granted patents related to chewing gums comprising cannabinoids. APIRx staff have completed pre-IND meetings with Swiss-Medic (Switzerland) and CBG-MEG (Netherlands). There is potential to fast track to EMA drug approval with bioequivalent phase 1 bridging study to bridge to Sativex CBD/THC oral spray safety and efficacy data.

Cannabinoid Chewing Gums and chewable tablets

Medicated chewing gum and chewable tablets ('MCGT') is a drug delivery system growing in favour in the medical community due to its application as an extended-release dosage form that supports continuous, ongoing release of the medicine contained. MCGTs are fast acting as they deliver the active ingredients into the oral mucosa, reducing the potential for gastric intolerance amongst patients. These qualities make MCGTs an excellent delivery system for medicinal combinations designed to treat sustaining pain and addiction disorders. MCGTs are also well tolerated by patients as there are no capsules to swallow or messy liquids to administer. The benefits of mastication, otherwise known as chewing, are well documented and include improved cerebral circulation, an anti-anxiety effect, memory improvement, neuroprotection, and an analgesic effect. These qualities make MCGTs an excellent delivery system for medicinal combinations designed to treat sustaining pain and addiction disorders.

We have data for CheWell as a high bioavailability product. A 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. 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 therapeutic effect in IBS. International regulatory analysis is being undertaken to identify what is required for commercial launch in different jurisdictions. 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 could 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.

Medicated Chewing Gum 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.

CheWell for Cannabis Dependence

CheWell is a CBD chewable tablet with high bioavailability that can be used in the treatment of people with marijuana addiction. Cannabis dependence is predicted to be the fastest growing segment of drug dependence market and preliminary data observed by APIRx suggest a possible beneficial impact of CBD on mitigating the craving effect of cannabis. A case report has shown positive outcomes for one patient treated with CBD during the withdrawal and relapse phase of cannabis dependence. A pre-IND for the use of CheWell in patients with cannabis dependence is with FDA is currently pending.

CanQuit for Smoking Cessation

CanQuit is a medicated chewing gum that combines cannabinoids and nicotine to reduce cravings for cigarettes or tobacco vaping utensils. CanQuit is designed to better assist addicted smokers to quit smoking and we intend to trial our product for effectiveness against existing nicotine chewing gums. A more effective and cost effective cannabinoid/nicotine combination medicated gum may have the potential to disrupt the incumbent global nicotine gum market, which had observed sales of US$ 5.2B in 2020.

CanQuit O for Opioid Addiction

CanQuit O is a medicated chewing gum that combines cannabinoids with opioid agonists and/or antagonists, which is designed to suppress opioid-based drug cravings in people addicted to opioids. We intend CanQuit O to be a prescription product to help combat the ongoing opioid addiction crisis in the United States and elsewhere. We believe CanQuit O has the potential to be a simple solution to a complex addiction disorder and nationwide problem with far reaching consequences. Opioid use disorder has an annual addressable market size estimated to be US$64B by 2028 and with many people being addicted but untreated.

CanChew Rx and SuppoCan for Inflammatory Bowel Disease

68 million people suffer from Inflammatory Bowel Disease (IBD) globally. Signs and symptoms of IBD, which encompass both Crohn's disease and ulcerative colitis, include diarrhea, fatigue, abdominal pain and cramping, reduced appetite, and unintended weight loss. Heretofore, the main medications for IBD are anti-inflammatory medications and analgesics. Anti-inflammatories include courses of corticosteroids which are used to induce remission but are immunosuppressing. APIRx has developed a CBD-containing controlled-release functional chewing gum called CanChew Rx and Suppocan to be used in conjunction with one another. SuppoCan is a CBD-containing suppository to facilitate local delivery of cannabinoids. In experiments, CBD has shown efficacy in treating IBD in animals and we intend to undertake a phase 1 clinical trial to assess CanChew Rx and Suppocan.

OraxiMax for Periodontal Disease and Gingivitis

Up to 50% of adults suffer from moderate to severe periodontitis and/or gingivitis. Heretofore, periodontal disease treatment has been limited to professional dental cleaning and the use of systemic antibiotics. OraxiMax Toothpaste and Mouthwash contain CBD and Cannabigerol (CBG) and are backed by fully granted IP protection. There products provide for disruption of dental plaque formation, therefore preventing gingivitis and periodontitis. Due to their proprietary formulations, the local availability of APIs are increased while systemic absorption is kept to minimum.

Benefits of CBD in dental protection include:

- Reduction in inflammation that can lead to gum diseases
- Attacks on bacteria associated with tooth decay, reducing the risk of cavities.
- Fights bad breath.
- Relieves dental and gum sensitivity
- Encourages tooth remineralization, and
- Restores pH balance.

We have observed encouraging bioavailability data for Oraximax products and intend to undertake a phase 2 study to, subject to clinical success, achieve results that demonstrate appropriate safety and efficacy to register the products as a medical device under the FDA 510(k) approval process in the United States.

Topical cannabinoid development

APIRx developed and patented a combination of CBD and CBG, a minor cannabinoid that also has potent anti-inflammatory properties, in a topical formulation. the topical solutions combine anti-inflammatory activity with antimicrobial activity of CBD/CBG to treat skin diseases. APIRx completed in-human proof of concept studies in three different skin diseases with dosing occurring for 6 weeks. Our drug product was well tolerated and displayed a 10% improvement in patients with Vitiligo, up to a 33% improvement in patients with Psoriasis and up to a 22% improvement in patients with atopic dermatitis. Patents are pending for compositions and methods of use for treatment of each of the three indications and we intend to call a pre-IND meeting with the FDA to discuss our best development pathways for the topical cannabinoid solutions.

Cannabinoids for Ophthalmic Conditions

Via the acquisition of APIRx, we have two granted patents for ophthalmic formulations of cannabinoids. Anecdotal evidence supports therapeutic benefit for cannabis and cannabinoids in the treatment of ophthalmic conditions including: glaucoma, conjunctivitis, age related macular degeneration, and dry eye syndrome. We proposed that a therapeutic effect in these eye conditions is derived from the neuroprotective, anti-inflammatory, and anti-microbial activities of cannabinoids. We intend to undertake a phase 1 safety and proof of concept clinical trial to advance the development of cannabinoids for ophthalmic conditions.

Director's interests in the Company

As at the date of this report, the interests of the directors in the shares and options of the Company were:

Director	Number of fully paid ordinary shares	Number of options over ordinary shares	No. of performance rights/shares
Mr Troy Valentine	36,651,198	2,800,000	–
Mr Peter Widdows	16,573,685	–	–
Mr Joel Latham	23,748,413	10,100,000	–
Dr George Anastassov	66,972,077	–	–
Mr Robert Clark	–	–	

Dividends

No dividends have been paid or declared since the start of the financial year and the directors do not recommend the payment of a dividend in respect of the financial year.

After Balance Date Events

On 17 August 2022, the company appointed Robert Bruce Clark to the board as a non-executive Director.

On 5 August 2022, the Company completed the acquisition on APIRx Pharmaceuticals. The acquisition was completed by an all-scrip transaction by issuing 218,169,497 IHL ordinary shares to the stakeholders of APIRx.

On 5 August 2022, the Company issued shares and options to Ryba LLC post year end pursuant to the mandate executed between the companies in November 2021. As the transaction between the Company and APIRx was deemed complete on 05 August 2022 the shares and options were issued.

No further significant events have occurred since the end of the financial year.

Share Options

The Company has the following options on issue as at the date of the Directors' Report.

Expiry Date	Exercise Price	Listed/ Unlisted	Number
30/06/2025	$0.05	Unlisted	750,000
30/06/2026	$0.05	Unlisted	750,000
30/06/2027	$0.05	Unlisted	750,000
30/06/2025	$0.05	Unlisted	750,000
30/06/2026	$0.05	Unlisted	750,000
30/06/2027	$0.05	Unlisted	750,000
20/11/2023	$0.15	Unlisted	8,200,000
20/11/2023	$0.25	Unlisted	20,000,000
20/11/2023	$0.20	Unlisted	6,650,000
01/07/2025	$0.26	Unlisted	533,333
01/07/2026	$0.31	Unlisted	533,333
01/07/2027	$0.35	Unlisted	533,334
28/04/2023	$1.00	Unlisted	33,644,386
28/04/2023	$1.00	Unlisted	928
01/07/2025	$0.26	Unlisted	1,399,999
01/07/2026	$0.31	Unlisted	1,399,999
01/07/2027	$0.35	Unlisted	1,400,002
01/07/2025	$0.26	Unlisted	1,399,999
01/07/2026	$0.31	Unlisted	1,399,999
01/07/2027	$0.36	Unlisted	1,400,002
04/08/2025	$0.612	Unlisted	3,000,000
04/08/2025	$0.69	Unlisted	3,000,000
04/08/2025	$0.765	Unlisted	3,000,000

Unissued Shares under Option

As at the date of this report, there were 91,995,314 unissued ordinary shares under options (2021: 338,378,176).

Option holders do not have any right, by virtue of the options, to participate in any share issue of the Company or any related body corporate.

Shares issued as a result of the exercise of options

During the financial year there were 207,650,638 ordinary shares issued as a result of the exercise of options (2021: 286,500,523).

Indemnification and Insurance of Directors and Officers

Indemnification

The Company has agreed to indemnify the directors of the Company, against all liabilities to another person (other than the Company or a related body corporate) that may arise from their position as directors of the Company, except where the liability arises out of conduct involving a lack of good faith. The agreement stipulates that the Company will meet the full amount of any such liabilities, including costs and expenses.

Insurance premiums

The Company has arranged directors' and officers' liability insurance, for past, present or future directors, secretaries, and executive officers. The insurance cover relates to:

- costs and expenses incurred by the relevant officers in defending proceedings, whether civil or criminal and whatever their outcome; and
- other liabilities that may arise from their position, with the exception of conduct involving a wilful breach of duty or improper use of information or position to gain a personal advantage.

The insurance policies outlined above do not contain details of the premiums paid in respect of individual directors or officers of the Company.

Environmental Regulations

The Group is not subject to any significant environmental regulation.

Remuneration Report (Audited)

This report, which forms part of the Directors' Report, outlines the remuneration arrangements in place for the key management personnel of Incannex Healthcare Limited (the "Company") for the financial year ended 30 June 2022.

The key management personnel of the Company are the Directors of the Company including the Managing Director/ Chief Executive Officer.

Remuneration philosophy

The performance of the Company depends upon the quality of the directors and executives. The philosophy of the Company in determining remuneration levels is to:

- set competitive remuneration packages to attract and retain high calibre employees;
- link executive rewards to shareholder value creation; and
- establish appropriate, demanding performance hurdles for variable executive remuneration.

Remuneration Structure

In accordance with best practice Corporate Governance, the structure of non–executive director and executive remuneration is separate and distinct.

Non–executive director remuneration

The Board seeks to set aggregate remuneration at a level that provides the Company with the ability to attract and retain directors of the highest calibre, whilst incurring a cost that is acceptable to shareholders. The amount of aggregate remuneration apportioned amongst directors is reviewed annually. The Board considers the fees paid to non–executive directors of comparable companies when undertaking the annual review process. Independent advice is obtained when considered necessary to confirm that remuneration is in line with market practice.

Each director receives a fee for being a director of the Company. Non–executive directors may receive performance rights (subject to shareholder approval) as it is considered an appropriate method of providing sufficient reward whilst maintaining cash reserves.

Executive director remuneration

Remuneration consists of fixed remuneration and variable remuneration (comprising short–term and long–term incentive schemes).

Fixed remuneration

Fixed remuneration is reviewed annually by the Board. The process consists of a review of relevant comparative remuneration in the market and internally and, where appropriate, external advice on policies and practices. The Board has access to external, independent advice where necessary.

The fixed remuneration component of key management personnel is detailed in Tables 1 and 2.

Variable remuneration

The objective of the short–term incentive program is to link the achievement of the Group's operational targets with the remuneration received by the KMP charged with meeting those targets. The total potential short–term incentive available is set at a level so as to provide sufficient incentive to the KMP to achieve the operational targets and such that the cost to the Group is reasonable in the circumstances.

Actual payments granted to each KMP depend on the extent to which specific operating targets set at the beginning of the financial year are met. A short–term incentive remuneration of $245,000 is payable for the financial year ended 30 June 2022 to Joel Latham.

The Company also makes long term incentive payments to reward senior executives in a manner that aligns this element of remuneration with the creation of shareholder wealth. The long–term incentive is provided in the form of performance rights and options over ordinary shares in the Company.

Employee Share Option Plan (ESOP)

The Incannex Healthcare Limited ESOP provides for the directors to set aside shares in order to reward and incentivise employees. Directors will not set aside more than 5% of the total number of issued shares in the Company at the time of the proposed issue. Officers and employees both full and part–time are eligible to participate in the plan.

1,600,000 shares and 1,600,000 options have been issued under the ESOP during the year (2021: nil).

Performance Rights Plan (PRP)

Shareholders approved the Company's PRP at the Annual General Meeting held on 23 November 2011. The PRP is designed to provide a framework for competitive and appropriate remuneration so as to retain and motivate skilled and qualified personnel whose personal rewards are aligned with the achievement of the Company's growth and strategic objectives.

No performance rights have been issued under the PRP during the year (2021: nil).

Executive Employment Contracts

For the year ended 30 June 2022, Mr Joel Latham, was appointed as Chief Executive Officer under an employment agreement. The material terms of the agreement are set out as follows:

- Commencement date: 1 July 2018
- Term: No fixed term
- Fixed remuneration: $484,000 per annum, plus $30,000 Board fees, plus superannuation
- Variable remuneration up to 50% of base salary subject to achieving certain performance hurdles
- Grant of 2,800,000 ordinary shares and 2,800,000 options which vest upon continuing tenure. 933,333 ordinary shares and 933,333 options vested on 30 June 2022. All shares and options granted have received shareholder approval.
- Termination for cause: no notice period
- Termination without cause: three–month notice period

Table 1: Remuneration of key management personnel (KMP) for the year ended 30 June 2022

	Short–term (cash–based payments)			Long–term (share based payments)	Post–employment		
Key Management Personnel name	Salary & fees $	Bonus $	Other $	Performance Rights, Shares and Options $	Super-annuation $	Total $	Performance Related %
Mr Troy Valentine[1]	92,750	–	240,000	312,538	9,275	654,563	47.8
Mr Peter Widdows[2]	84,742	–	–	–	8,474	93,216	–
Mr Joel Latham[3]	533,500	245,000	–	716,096	24,998	1,519,594	63.3
Dr Sud Agarwal[4]	48,000	–	90,000	–	4,800	142,800	–
Dr George Anastassov[5]	–	–	–	–	–	–	–
Total	**758,992**	**245,000**	**330,000**	**1,028,634**	**47,547**	**2,410,173**	

1. Remuneration owed to Mr Valentine at 30 June 2022 is $38,750 included in accrued expenses. Mr Valentine was paid $240,000 for consulting fees invoiced to the Company, outside of Director fees.
2. Remuneration owed to Mr Widdows at 30 June 2022 is $42,076 included in accrued expenses.
3. Remuneration owed to Mr Latham at 30 June 2022 is $245,000 included in accrued expenses.
4. Remuneration owed to Dr Agarwal at 30 June 2022 is $25,300 is included in accounts payable. Dr Agarwal received $90,000 in fees billed through Medical Life Publishing Pty Ltd, for services provided as Chief Medical Officer. Dr Agarwal resigned on the 28th of June 2022.
5. Dr Anastassov was appointed on the 28th of June 2022.

Table 2: Remuneration of key management personnel (KMP) for the year ended 30 June 2021

	Short–term (cash–based payments)			Long–term (share based payments)	Post–employment		
Key Management Personnel name	Salary & fees $	Bonus $	Other $	Performance Rights, Shares and Options $	Super-annuation $	Total $	Performance Related %
Mr Troy Valentine[1]	54,000	–	127,500	–	5,130	186,630	–
Mr Peter Widdows[2]	48,000	–	–	–	4,560	52,560	–
Mr Joel Latham[3]	278,731	115,000	–	217,712[5]	24,627	636,070	34.2
Dr Sud Agarwal[4]	48,000	–	90,000	454,987[6]	4,560	597,547	76.1
Total	**428,731**	**115,000**	**217,500**	**672,699**	**38,877**	**1,472,807**	

1. Remuneration owed to Mr Valentine at 30 June 2021 is $73,739 included in accounts payable. Mr Valentine was paid $127,500 for consulting fees invoiced to the Company, outside of Director fees.
2. Remuneration owed to Mr Widdows at 30 June 2021 is $12,000 included in accounts payable.
3. Remuneration owed to Mr Latham at 30 June 2021 is $239,596 included in accrued expenses and leave entitlements.
4. Remuneration owed to Dr Agarwal at 30 June 2021 is $15,717 is included in accounts payable and accrued expenses. Dr Agarwal received $90,000 in fees billed through Medical Life Publishing Pty Ltd, for services provided as Chief Medical Officer.
5. This represents amounts expensed during FY21 for securities granted during FY20.
6. This represents amounts expensed during FY21 for securities granted during FY20.

Performance rights

Each performance right is convertible into one ordinary share upon achievement of the performance hurdles. No performance right will vest if the conditions are not satisfied, hence the minimum value of the performance rights yet to vest is nil.

The assessed fair value at grant date of performance rights granted is expensed according to the performance or market–based conditions attached to the performance hurdle. Performance based hurdles are expensed to each reporting period evenly over the period from grant date to vesting date. Market based hurdles are expensed on the grant date unless there is an explicit or implicit service condition. The relevant amount is included in the remuneration table (Table 1) above.

Fair values at grant date are independently determined using a trinomial pricing model that takes into account the exercise price, term, the share price at grant date and expected price volatility of the underlying share, barrier price / performance hurdles, the expected dividend yield and the risk–free interest rate. For details on the valuation of performance rights, including assumptions used, refer to note 14 of these financial statements.

Performance rights activity for KMP for the year ended 30 June 2022

Performance rights activity for KMP for the year ended 30 June 2022 are set out in the table below.

The number of performance rights held by Key Management Personnel of the Group during the financial year is as follows:

30 June 2022 – Performance Rights

Name	Balance at 1 July 2021	Granted/(Expired) by the Company	Converted to Ordinary shares	Balance at 30 June 2022
Mr Troy Valentine[1]	–	–	–	–
Mr Peter Widdows[1]	–	–	–	–
Mr Joel Latham[1]	–	–	–	–
Dr Sud Agarwal[2]	–	–	–	–
Dr George Anastassov	–	–	–	–

30 June 2021 – Performance Rights

Name	Balance at 1 July 2020	Granted/(Expired) by the Company	Converted to Ordinary shares	Balance at 30 June 2021
Mr Troy Valentine[1]	1,500,000	(1,500,000)	–	–
Mr Peter Widdows[1]	1,500,000	(1,500,000)	–	–
Mr Joel Latham[1]	5,000,000	(5,000,000)	–	–
Dr Sud Agarwal[2]	32,303,593	(2,000,000)	(30,303,593)	–

1. Performance rights expired during the period as performance hurdle not attained. The performance rights lapsed were granted in FY2019, with a value of $13,527.
2. Dr Agarwal's held performance rights at the start of the year, with the initial 2,000,000 expiring upon failure of the performance hurdle. All other performance rights achieved the performance hurdles during the year and converted to ordinary shares accordingly. The performance rights that expired during the year were granted in FY 2020. The value of lapsed performance rights in total was $64,000. $1,341 was expensed in FY2020 and was reversed in the current year. The performance rights converted to shares were granted in FY2020 and were valued initially at $469,324. $281,124 was expensed in FY2021.

Options

Key Management Personnel – Option Holdings

The number of options held by Key Management Personnel of the Group during the financial year is as follows:

30 June 2022 – Options

Name	Balance at 1 July 2021	Other changes during the period	Balance at 30 June 2022 (or on cessation)	Exercisable
Mr Troy Valentine[1]	7,116,950	(4,316,950)	2,800,000	466,666
Mr Peter Widdows[1]	657,895	(657,895)	–	–
Mr Joel Latham[2]	4,700,000	5,400,000	10,100,000	4,683,333
Dr Sud Agarwal[3]	200,000,000	(200,000,000)	–	–
Dr George Anastassov	–	–	–	–

1. Other changes refer to conversion of options held to ordinary shares and share options issued to Troy Valentine approved by shareholders in 2022.
2. 5,400,000 share options were issued to Joel Latham approved by shareholders in 2022.
3. Dr Agarwal's change relates to share options that lapsed during the year and conversion of options held.

30 June 2021 – Options

Name	Balance at 1 July 2020	Other changes during the period	Balance at 30 June 2021 (or on cessation)	Exercisable
Mr Troy Valentine[1]	48,355,557	(41,238,607)	7,116,950	7,116,950
Mr Peter Widdows[1]	3,957,895	(3,300,000)	657,895	657,895
Mr Joel Latham[2]	6,687,500	(1,987,500)	4,700,000	1,700,000
Dr Sud Agarwal[3]	288,000,000	(88,000,000)	200,000,000	200,000,000

1. Other changes refer to conversion of 6,500,000 "IHLOB" options held to ordinary shares and the disposal of 34,738,607 options at $0.007.
2. 2,250,000 share options were issued to Joel Latham, that were granted in 2020 and approved by shareholders in 2021. 2,000,000 options were converted during the year. These options were held on appointment. 2,237,500 were disposed of during the year. These options were held on appointment.
3. Dr Agarwal's change relates to share options that lapsed during the year as the vesting condition was not met. The value of the lapsed options, previously issued to settle outstanding invoices, was $72,656.

Shares

30 June 2022 – Shares

Name	Balance held at 1 July 2021 (or on appointment)	Purchases / Other Acquisitions	Sales / Other Disposals	Balance held at 30 June 2022 (or on cessation)
Mr Troy Valentine[1]	26,734,248	9,916,950	–	36,651,198
Mr Peter Widdows[1]	15,915,790	657,895	–	16,573,685
Mr Joel Latham[2]	17,948,414	5,800,000	–	23,748,413
Dr Sud Agarwal[3]	66,303,593	8,999,500	–	75,303,093
Dr George Anastassov	–	–	–	–

1. The change relates to ordinary shares acquired upon conversion of options.
2. Mr Latham's changes arise from the conversion of 200,000 share options, and new ordinary shares issued as part of his remuneration packages.
3. Mr Agarwal's changes relates to ordinary shares acquired upon conversion of options.

30 June 2021 – Shares

Name	Balance held at 1 July 2020 (or on appointment)	Purchases / Other Acquisitions	Sales / Other Disposals	Balance held at 30 June 2021 (or on cessation)
Mr Troy Valentine[1]	20,234,248	6,500,000	–	26,734,248
Mr Peter Widdows[1]	12,615,790	3,300,000	–	15,915,790
Mr Joel Latham[2]	11,829,129	6,119,285	–	17,948,414
Dr Sud Agarwal[3]	36,000,000	30,303,593	–	66,303,593

1. The change relates to ordinary shares acquired upon conversion of options.
2. Mr Latham's changes arise from the conversion of 2,000,000 share options, and the removal from voluntary escrow of 4,119,285 ordinary shares.
3. Mr Agarwal's changes arise from the conversion of performance rights upon achievement of performance hurdles.

End of Remuneration Report

Non–Audit Services

The Company has not engaged the auditor to perform any non–audit services during the year ended 30 June 2022 (2021: $Nil).

Auditor Independence and Non–Audit Services

Section 307C of the Corporations Act 2001 requires our auditors, PKF Brisbane Audit, to provide the directors of the Company with an Independence Declaration in relation to the audit of the annual report. This Independence Declaration is set out on page 20 and forms part of this directors' report for the year ended 30 June 2022.

Signed in accordance with a resolution of the directors.

Troy Valentine
Chairman

Melbourne, Victoria
19/09/2022

Auditor's Independence Declaration

PKF Brisbane Audit

PKF

AUDITOR'S INDEPENDENCE DECLARATION
UNDER SECTION 307C OF THE CORPORATIONS ACT 2001
TO THE DIRECTORS OF INCANNEX HEALTHCARE LTD

I declare that, to the best of my knowledge and belief, during the year ended 30 June 2022, there have been no contraventions of:

(a) the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and

(b) any applicable code of professional conduct in relation to the audit.

This declaration is in respect of Incannex Healthcare Ltd and the entities it controlled during the year.

PKF

PKF BRISBANE AUDIT

LIAM MURPHY
PARTNER

BRISBANE
19 SEPTEMBER 2022

PKF Brisbane Audit ABN 33 873 151 348
Level 6, 10 Eagle Street, Brisbane, QLD 4000 | GPO Box 1568, Brisbane, QLD 4001 | T: +61 7 3839 9733
Brisbane | Rockhampton www.pkf.com.au

Financial Statements

Consolidated Statement of Comprehensive Income

For the year ended 30 June 2022

	Notes	Consolidated 30 June 2022 $	Consolidated 30 June 2021[1] (restated) $
Revenue	3(a)	–	1,897,596
Other income	3(b)	788,654	75,748
Total revenue and other income		**788,654**	**1,973,344**
Product costs		(6,338)	(911,969)
Administration expense		(280,969)	(99,094)
Advertising and investor relations		(2,746,226)	(4,345,874)
Bad debt expense		(134,626)	–
Research and development costs		(5,371,821)	(4,749,514)
Compliance, legal and regulatory		(3,559,511)	(1,227,244)
Share based payments	14	(1,464,550)	(600,043)
Occupancy expenses		(112,341)	(115,836)
Salaries and employee benefit expense		(2,016,181)	(1,296,569)
Total expenses		**(15,692,563)**	**(13,346,143)**
Loss before tax		**(14,903,909)**	**(11,372,799)**
Income tax benefit	5	–	–
Loss after tax		**(14,903,909)**	**(11,372,799)**
Other comprehensive income		–	–
Total comprehensive loss for the year		**(14,903,909)**	**(11,372,799)**
Earnings per share	6		
Basic loss per share (cents per share)		(1.25)	(1.16)
Diluted loss per share (cents per share)		(1.25)	(1.16)

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The accompanying notes form part of these financial statements

Consolidated Statement of Financial Position

As at 30 June 2022

	Notes	Consolidated 30 June 2022 $	Consolidated 30 June 2021[1] (restated) $
Assets			
Current assets			
Cash and cash equivalents	8	37,500,931	9,123,617
Trade and other receivables	9	294,717	169,088
Other assets	10	83,960	36,090
Total current assets		**37,879,608**	**9,328,795**
Total assets		**37,879,608**	**9,328,795**
Liabilities			
Current liabilities			
Trade and other payables	11	2,010,533	755,049
Total current liabilities		**2,010,533**	**755,049**
Total liabilities		**2,010,533**	**755,049**
Net assets		**35,869,075**	**8,573,746**
Equity			
Issued capital	12	86,586,794	45,852,107
Reserves	13	8,077,191	6,612,641
Accumulated losses		(58,794,910)	(43,891,002)
Net equity		**35,869,075**	**8,573,746**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The accompanying notes form part of these financial statements

Consolidated Statement of Changes in Equity

For the year ended 30 June 2022

Consolidated	Issued Capital $	Equity Reserve $	Accumulated Losses $	Total $
Balance at 30 June 2020	**34,192,043**	**1,490,588**	**(32,518,203)**	**3,164,428**
Options exercised	12,498,706	–	–	12,498,706
Options issued to advisors	–	3,781,344	–	3,781,344
Share based payments	–	600,043	–	600,043
Shares issue costs	(838,642)	740,666	–	(97,976)
Comprehensive loss for the year	–	–	(11,372,799)	(11,372,799)
Balance at 30 June 2021[1] (restated)	**45,852,107**	**6,612,641**	**(43,891,002)**	**8,573,746**
Options exercised	40,274,242	–	–	40,274,242
Options issued to advisors	–	–	–	–
Share based payments	–	1,464,550	–	1,464,550
Share placements	400,000	–	–	400,000
Shares issued to advisors	450,000	–	–	450,000
Shares issue costs	(389,555)	–	–	(389,555)
Comprehensive loss for the year	–	–	(14,903,909)	(14,903,909)
Balance at 30 June 2022	**86,586,794**	**8,077,191**	**(58,794,910)**	**35,869,075**

1 Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The accompanying notes form part of these financial statements

Consolidated Statement of Cash Flows

For the year ended 30 June 2022

	Notes	Consolidated 2022 $	Consolidated 2021[1] (restated) $
Cash flows from operating activities			
Receipts from customers		–	1,974,010
Receipts from other income		782,383	82,807
Payments to suppliers and employees		(13,596,027)	(8,969,276)
Interest received and other income		6,271	2,679
Net cash (used in) operating activities	8	**(12,807,373)**	**(6,909,780)**
Cash flows from investing activities			
Proceeds from disposal of subsidiary		–	29,277
Net cash from investing activities		**–**	**29,277**
Cash flows from financing activities			
Proceeds from shares issued (net of costs)		41,184,687	12,400,730
Net cash from financing activities		**41,184,687**	**12,400,730**
Net increase in cash and cash equivalents		28,377,314	5,520,227
Cash and cash equivalents at beginning of the year		9,123,617	3,603,390
Effect of exchange rate fluctuations on cash held		–	–
Cash and cash equivalents at end of the year	8	**37,500,931**	**9,123,617**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The accompanying notes form part of these financial statements

Notes to the Financial Statements

For the year ended 30 June 2022

1. Significant accounting policies

The principal accounting policies adopted in the preparation of the consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

Nature of Operations

Incannex Healthcare Limited (the "Company") and its consolidated subsidiaries (collectively, the "Group") is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies. The Company's common shares trade on the Australian Securities Exchange ("ASX"). The Company's registered office is at Suite 15, Level 12, 401 Docklands Drive, Docklands 3008, Victoria, Australia.

For the fiscal year ended 30 June 2022, the Group incurred a total comprehensive loss after income tax of $14.9 million and had net cash outflows from operations of $12.8 million. The Group held total cash of $37.5 million as of 30 June 2022.

New or amended Accounting Standards and Interpretations adopted

The Group has adopted all of the new or amended Accounting Standards and Interpretations issued by the International Accounting Standards Board ('IASB') that are mandatory for the current reporting periods.

Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

Historical cost convention

The consolidated financial statements have been prepared under the historical cost convention, except for, where applicable, the revaluation of financial assets and liabilities at fair value through profit or loss, financial assets at fair value through other comprehensive income and derivative financial instruments.

Critical accounting estimates

The preparation of the consolidated financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 2.

Comparatives

Where necessary, comparative information has been reclassified and repositioned for consistency with current year disclosures.

Statement of compliance

These consolidated financial statements were authorised for issue by the Board of Directors in September 2022.

The consolidated financial statements comply with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB).

Parent entity information

In accordance with IFRS 10 *Consolidated Financial Statements*, these consolidated financial statements present the results of the Group only. Supplementary information about the parent entity is disclosed in note 21.

Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of the Company as at 30 June 2022 and 2021 and the results of all subsidiaries for the years then ended. Incannex Healthcare Limited and its subsidiaries together are referred to in these consolidated financial statements as the 'Group'. Details of all controlled entities are set out in Note 19.

Subsidiaries are all those entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Intercompany transactions between entities in the Group are eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Where the Group loses control over a subsidiary, it derecognizes the assets including goodwill, liabilities and non–controlling interest in the subsidiary together with any cumulative translation differences recognized in equity. The Group recognizes the fair value of the consideration received and the fair value of any investment retained together with any gain or loss in profit or loss.

Operating segments

Operating segments are presented at note 4 using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Executive Officer. The Chief Executive Officer is responsible for the allocation of resources to operating segments and assessing their performance.

Foreign currency translation

The consolidated financial statements are presented in Australian dollars, which is the Company's functional and presentation currency.

Foreign currency transactions

Foreign currency transactions are translated into Australian dollars using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at financial year–end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in profit or loss.

Revenue recognition

The Company recognizes revenue to depict the transfer of goods and services to clients in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services by applying the following steps:

- Identify the contract with a client;
- Identify the performance obligations in the contract;
- Determine the transaction price;
- Allocate the transaction price to the performance obligations; and
- Recognize revenue when, or as, the Company satisfies a performance obligation.

Revenue may be earned over time as the performance obligations are satisfied or at a point in time which is when the entity has earned a right to payment, the customer has possession of the asset and the related significant risks and rewards of ownership, and the customer has accepted the asset.

The Company's arrangements with clients can include multiple performance obligations. When contracts involve various performance obligations, the Company evaluates whether each performance obligation is distinct and should be accounted for as a separate unit of accounting under AASB 15, Revenue from Contracts with Customers.

The Company determines the standalone selling price by considering its overall pricing objectives and market conditions. Significant pricing practices taken into consideration include discounting practices, the size and volume of our transactions, our marketing strategy, historical sales, and contract prices. The determination of standalone selling prices is made through consultation with and approval by management, taking into consideration our go–to–market strategy. As the Company's go–to–market strategies evolve, the Company may modify its pricing practices in the future, which could result in changes in relative standalone selling prices.

The Company disaggregates revenue from contracts with customers based on the categories that most closely depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. During the years ended 30 June 2022 and 2021, the Company recognized revenue from only one such category, being cannabinoid oils sales.

The Company receives payment from its clients after invoicing within the normal 28–day commercial terms. If a client is specifically identified as a credit risk, recognition of revenue is stopped except to the extent of fees that have already been collected.

Other income

Other income is recognized when it is received or when the right to receive it is established. Other income primarily consists of grant income and interest income.

Interest income

Interest revenue is recognized as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

Income tax

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognized for prior reporting years, where applicable.

Deferred tax assets and liabilities are recognized for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled, and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognized for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognized and unrecognized deferred tax assets are reviewed at each reporting date. Deferred tax assets recognized are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognized deferred tax assets are recognized to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

Government grants

Income from government grants is recognized only when the Company has reasonable assurance that the grants will be received, and the conditions of the grants will be complied with. Income from Government grants is recognized on a systematic basis over the periods in which the Company recognizes as expenses the related costs for which the grants are intended to compensate. Government grants relate to Australian Federal Government's COVID–19 support package of a "Cash Flow Boost" for eligible organisations, supporting small and medium sized organisations.

Current and non–current classification

Assets and liabilities are presented in the statement of financial position based on current and non–current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non–current.

Deferred tax assets and liabilities are classified as non–current.

Cash

Cash and deposits held at call with financial institutions, other short–term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Trade and other receivables

Trade receivables are initially recognized at fair value and subsequently measured at amortised cost using the effective interest method, less any allowance for expected credit losses. Trade receivables are due for settlement within 30 days.

The Group has applied the simplified approach to measuring expected credit losses, which uses a lifetime expected loss allowance. To measure the expected credit losses, trade receivables have been grouped based on days overdue.

Other receivables are recognized at amortised cost, less any allowance for expected credit losses.

Other financial assets

Other financial assets are initially measured at fair value. Transaction costs are included as part of the initial measurement, except for financial assets at fair value through profit or loss. Such assets are subsequently measured at either amortised cost or fair value depending on their classification. Classification is determined based on both the business model within which such assets are held and the contractual cash flow characteristics of the financial asset unless an accounting mismatch is being avoided.

Financial assets are derecognized when the rights to receive cash flows have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership. When there is no reasonable expectation of recovering part or all a financial asset, its carrying value is written off.

Intangibles

Research and development

Research costs are expensed in the period in which they are incurred. Development costs are capitalised when it is probable that the project will be a success considering its commercial and technical feasibility; the Group is able to use or sell the asset; the Group has sufficient resources and intent to complete the development; and its costs can be measured reliably. Capitalised development costs are amortised on a straight–line basis over the period of their expected benefit, being their finite life of 10 years. The Company has not capitalised any development costs for the years ended June 30, 2022 and 2021.

Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial years and which are unpaid. Due to their short–term nature, they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

Provisions

Provisions are recognized when the Group has a present (legal or constructive) obligation as a result of a past event, it is probable the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the reporting date, taking into account the risks and uncertainties surrounding the obligation. If the time value of money is material, provisions are discounted using a current pre–tax rate specific to the liability. The increase in the provision resulting from the passage of time is recognized as a finance cost.

Employee benefits

Short–term employee benefits

Liabilities for wages and salaries, including non–monetary benefits, annual leave and long service leave expected to be settled wholly within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

Other long–term employee benefits

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are measured at the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on corporate bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

Retirement benefit obligations

All employees of the Group are entitled to superannuation contributions in accordance with Australian law. Contributions to employees' nominated superannuation plans are expensed in the period in which they are incurred.

Share–based payments

Equity–settled compensation benefits are provided to employees.

Equity–settled transactions are awards of shares, performance rights or options over shares, that are provided to employees in exchange for the rendering of services.

The cost of equity–settled transactions are measured at fair value on grant date. Fair value is independently determined using either a trinomial pricing or Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option, together with non–vesting conditions that do not determine whether the Group receives the services that entitle the employees to receive payment. Inputs into the Black–Scholes option pricing models used to calculate fair value are classified as level three inputs under the fair value hierarchy of IFRS 13. No account is taken of any other vesting conditions.

The cost of equity–settled transactions are recognized as an expense with a corresponding increase in equity over the vesting period. The cumulative charge to profit or loss is calculated based on the grant date fair value of the award, the best estimate of the number of awards that are likely to vest and the expired portion of the vesting period. The amount recognized in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognized in previous periods.

Market conditions are taken into consideration in determining fair value. Therefore, any awards subject to market conditions are considered to vest irrespective of whether or not that market condition has been met, provided all other conditions are satisfied.

If equity–settled awards are modified, as a minimum an expense is recognized as if the modification has not been made. An additional expense is recognized, over the remaining vesting period, for any modification that increases the total fair value of the share–based compensation benefit as at the date of modification.

If the non–vesting condition is within the control of the Group or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the Group or employee and is not satisfied during the vesting period, any remaining expense for the award is recognized over the remaining vesting period, unless the award is forfeited.

If equity–settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognized immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new award is treated as if they were a modification.

Fair value measurement

When an asset, liability or equity instrument, financial or non–financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or an equity instrument or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset, liability or equity instrument, assuming they act in their economic best interests. For non–financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Assets, liabilities and equity instruments measured at fair value are classified into three levels, using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. For assets and liabilities measured at fair value after initial recognition, classifications are reviewed at each reporting date and transfers between levels are determined based on a reassessment of the lowest level of input that is significant to the fair value measurement. The three levels of the fair value hierarchy are described as follows:

- Level 1 — quoted (unadjusted) market prices in active markets for identical assets or liabilities;
- Level 2 — valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and
- Level 3 — valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For recurring and non–recurring fair value measurements, external valuers may be used when internal expertise is either not available or when the valuation is deemed to be significant. External valuers are selected based on market knowledge and reputation. Where there is a significant change in fair value of an asset or liability from one period to another, an analysis is undertaken, which includes a verification of the major inputs applied in the latest valuation and a comparison, where applicable, with external sources of data.

Issued capital

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Dividends

Dividends are recognized when declared during the financial years.

Loss per share

Basic loss per share

Basic loss per share is calculated by dividing the profit attributable to the owners of Incannex Healthcare Limited, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial years, adjusted for bonus elements in ordinary shares issued during the financial years. These values are set out in Note 6.

Diluted loss per share

Diluted loss per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares. These values are set out in Note 6.

Goods and Services Tax ('GST') and other similar taxes

Revenues, expenses and assets are recognized net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognized as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from the tax authority is included in other receivables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flow.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the tax authority.

New Accounting Standards not yet adopted

International Financial Reporting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the Group for the annual reporting periods ended 30 June 2022 and 2021.

2. Critical accounting judgements, estimates and assumptions

The preparation of the consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the consolidated financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

Coronavirus (COVID–19) pandemic

Judgement has been exercised in considering the impacts that the Coronavirus (COVID–19) pandemic has had, or may have, on the Group based on known information. This consideration extends to the nature of the products and services offered, customers, supply chain, staffing and geographic regions in which the Group operates. There does not currently appear to be either any significant impact upon the consolidated financial statements or any significant uncertainties with respect to events or conditions which may impact the Group unfavourably as at the reporting date or subsequently as a result of the Coronavirus (COVID–19) pandemic.

Share–based payment transactions

The Group measures the cost of equity–settled transactions with employees and third parties by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using either the trinomial or Black–Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity–settled share–based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

3. Revenue

	Consolidated	
	2022 $	2021 $
(a) Revenue (point in time)		
Cannabinoid oils sales	–	1,897,596
	–	**1,897,596**
(b) Other income		
Income from other arrangements	–	35,568
Government grants	–	37,500
Interest	6,271	2,679
Refundable R&D tax offset	782,383	–
	788,654	**75,747**

4. Segment Information

Identification of reportable operating segments

AASB 8 (IFRS 8) Operating Segments requires operating segments to be identified on the basis of internal reports about components of the Group that are regularly reviewed by the Chief Executive Officer in order to allocate resources to the segment and to assess its performance.

The Group's operating segments have been determined with reference to the monthly management accounts used by the Chief Executive Officer to make decisions regarding the Group's operations and allocation of working capital. Due to the size and nature of the Group, the Board as a whole has been determined as the Chief Executive Officer.

Based on the quantitative thresholds included in AASB 8 (IFRS 8), for the fiscal year ended 30 June 2022, the Group was organised into three operating segments:

1. Research and develop the use of psychedelic medicine and therapies for the treatment of mental health disorders. This activity commenced during the year. During the current year the operations consisted entirely of research and development activities, including clinical trials.
2. Research and develop the use of medicinal cannabinoid products. During the year the Group continued to research and develop its products and the range of its products, including further clinical trials.
3. Corporate operations, consisting of management of the organisation, capital management and management of resources. Revenues consist of finance income and other income.

The Group has only one geographical segment, namely Australia.

The revenues and results of these segments of the Group as a whole are set out in the condensed statement of comprehensive income and the assets and liabilities of the Group as a whole are set out in the condensed statement of financial position. A summary of revenue and expenses for the period and assets and liabilities at the end of the fiscal year for each segment is shown below.[1]

1. Revenue earned in 2021 was from the sale of the cannabinoid oil products through Cannvalate Pty Ltd under a distribution agreement, this agreement was terminated in June 2021.

	Psychedelic products $	Cannabinoid products $	Corporate $	Consolidated $
30 June 2022				
Revenue from external customers	–	–	–	–
Interest revenue	–	96	6,175	6,271
Other revenue	–	782,383	–	782,383
Other expenses	(883,708)	(4,642,796)	(10,166,059)	(15,692,563)
Segment loss after income tax	**(883,708)**	**(3,860,317)**	**(10,159,884)**	**(14,903,909)**
Segment assets	**56,058**	**263,731**	**37,559,819**	**37,879,608**
Segment liabilities	**(354,310)**	**(577,819)**	**(1,078,404)**	**(2,010,533)**
30 June 2021[1] (restated)				
Revenue from external customers	–	1,897,596[2]	–	1,897,596
Interest revenue	–	6	2,673	2,679
Other revenue	–	–	73,068	73,068
Other expenses	(768,316)	(5,202,370)	(7,375,456)	(13,346,143)
Segment loss after income tax	**(768,316)**	**(3,304,768)**	**(7,299,714)**	**(11,372,799)**
Segment assets	**2,000**	**104,267**	**9,222,528**	**9,328,795**
Segment liabilities	**–**	**(86,522)**	**(668,527)**	**(755,049)**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation
2. Of the total revenue from pharmaceuticals in each year, 100% was through Cannvalate Pty Ltd's distribution network.

5. Income tax

The prima facie income tax benefit on pre–tax accounting loss from operations reconciles to the income tax benefit in the financial statements as follows:

	Consolidated	
	2022 $	**2021[1] (restated) $**
Accounting loss before tax	(14,903,909)	(11,372,799)
Income tax benefit at the applicable tax rate of 25% (2021: 26%)	3,725,977	2,956,928
Non–deductible expenses	(564,872)	(1,192,112)
Non–assessable income	195,596	–
Deferred tax assets not recognized	(3,356,701)	(1,764,816)
Income tax benefit	**–**	**–**
Unrecognized Deferred Tax Asset		
Deferred tax asset not recognized in the financial statements:		
Unused tax losses	24,845,264	20,867,835
Net unrecognized tax benefit at 25% (2021: 26%)	**6,211,316**	**5,425,637**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The potential deferred tax benefit has not been recognized as an asset in the financial statements because recovery of the asset is not considered probable in the context of AASB 112 Income Taxes (IAS 12).

The benefit will only be realised if:

a) the Company derives future assessable income of a nature and of an amount sufficient to enable the benefit to be realised.

b) the Company complies with the conditions for deductibility imposed by the law; and

c) no changes in tax legislation adversely affect the Company in realising the benefit.

6. Earnings per share

	Consolidated	
	2022 $	**2021[1] (restated) $**
Basic loss per share – cents per share	(1.25)	(1.16)
Basic loss per share		
The loss and weighted average number of ordinary shares used in the calculation of basic loss per share is as follows:		
Total comprehensive loss for the year	(14,903,909)	(11,372,799)
– Weighted average number of ordinary shares (number)	1,191,154,011	976,931,338

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation

The company notes that the diluted loss per share is the same as basic loss per share.

7. Dividends

The Company has not declared a dividend for the year ended 30 June 2022 (2021: $nil).

8. Cash and cash equivalents

	Consolidated	
	2022 $	2021 $
Cash at bank and on hand	37,500,931	9,123,617
	37,500,931	**9,123,617**

Cash at bank earns interest at floating rates based on daily bank deposit rates.

Reconciliation of loss for the year to net cash flows from operating activities:

	Consolidated	
	2022 $	2021 $
Loss after income tax	(14,903,909)	(11,372,799)
Non–cash based expenses:		
Share–based payments	1,464,550	600,043
Depreciation and amortisation	–	–
Non–cash expense for investor relation services	–	3,781,344
Release of Gameday reserve of sales refund	–	(15,484)
Other non–cash expenses	(594,394)	91,354
Changes in net assets and liabilities:		
(Increase)/Decrease in receivables	(92,320)	214,903
(Increase)/Decrease in inventory	–	183,159
Decrease in other current assets	53,447	172
Increase/(Decrease) in trade payables and accrued expenses	1,111,080	(291,311)
Increase/(Decrease) in other liabilities	154,173	(101,161)
Cash flows used in operations	**(12,807,373)**	**(6,909,780)**

9. Trade and other receivables (Current)

	Consolidated	
	2022 $	2021 $
Current		
Other receivables	–	53,447
GST recoverable	294,717	115,641
	294,717	**169,088**

Expected credit losses

The Group applies the AASB 9 (IFRS 9) simplified model of recognizing lifetime expected credit losses for all trade receivables as these items do not have a significant financing component. In measuring the expected credit losses, the trade receivables have been assessed on a collective basis as they possess shared credit risk characteristics. They have been grouped based on the days past due and also according to the geographical location of customers.

10. Other assets (current)

	Consolidated	
	2022 $	2021 $
Prepayments	45,911	29,784
Office rental bond	24,124	–
Prepayment clinical trial insurance	13,925	6,306
	83,960	**36,090**

11. Trade and other payables (current)

	Consolidated	
	2022 $	2021 $
Trade payables	1,300,696	233,117
Accrued expenses	415,449	381,717
Employee leave entitlements	294,388	140,215
	2,010,533	**755,049**

12. Issued capital

	Consolidated	
	2022 $	2021 (restated) $
Ordinary shares	**86,586,794**	**45,852,107**

	Consolidated	
	2022 $	2022 No. of shares
(a) Ordinary shares - movements during year		
At start of year	45,852,107	1,068,411,224
Issues of new shares – placements	400,000	5,000,000
Issues of new shares – share based payments[2]	–	10,000,000
Exercise of options	40,274,243	207,650,638
Shares in lieu of advisor fees	450,000	1,272,166
Share issue costs	(389,555)	–
At end of year	**86,586,794**	**1,292,334,028**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation
2. The fair value of shares issued to employees and Directors expensed during the period has been recorded through the share base payment equity reserve refer to note 13 for further details.

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of shares held. On a show of hands, every shareholder present at a meeting is entitled to one vote and upon a poll each share is entitled to one vote. Ordinary shares have no par value, and the Company does not have a limited amount of authorised capital.

13. Reserves

	Consolidated	
	2022 $	2021[1] (restated) $
Equity based premium reserve		
Balance at 1 July 2021	6,612,641	1,490,588
Options issued to advisors[2]	–	4,522,010
Equity instruments issued to management and directors	1,464,550	600,043
At 30 June 2022	**8,077,191**	**6,612,641**

1. Reclassified and remeasured amounts due to restatement from error in prior year – see note 22 for explanation
2 During the year ended 30 June 2021, 40,000,000 options exercisable at $0.15, $0.20, and $.25 were issued to consultants for investor relation services. In addition, 30,164,690 options exercisable at $0.08 were issued as consideration for broker support of the exercise of the 262m listed IHLOB options series. During the year ended 30 June 2020, 33,000,000 options exercisable at $0.08 and expiring on 30 September 2021, were issued to brokers who supported the July 2019 capital raisings. These options have been valued using a Black–Scholes option model with inputs being grant date share price of $0.04 risk–free rate of 0.24% and volatility of 92%.

The equity based premium reserve is used to record the value of equity issued to raise capital, and for share–based payments.

14. Share based payments

From time to time, the Company may issue equity securities (i.e., shares, options or performance rights) to its employees, directors or advisors to more closely align rewards for performance with the achievement of the Company's growth and strategic objectives. Where the recipient is a director of the Company, shareholder approval must be sought under the ASX Listing Rules prior to the issue of any equity securities to any director.

Fair value of shares issued

The fair value of shares issued to employees is determined using the closing price of shares on the grant date and expensed over the vesting period. The total fair value of shares issued to employees and directors during the year was $3,588,000, as of 30 June 2022 there was $2,743,854 of total unrecognized compensation cost related to unvested shares.

Options

The exercise price of options outstanding as of 30 June 2022 and 2021 ranged between $0.08 and $0.35.

As of 30 June 2022, there was $1,853,263 of total unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted–average period of approximately 1.39 years.

The fair values at grant date are independently determined using either a trinomial pricing or Black–Scholes option model that take into account any price to exercise, the term of the options or rights, the share price at grant date, the price volatility of the underlying share and the risk–free interest rate for the term of the options or rights. The expensed fair value in the tables below represents the proportion of the total fair value that has been allocated to the current period with the balance to be expensed in future periods.

The following share options were issued to employees and consultants as share based payments during the year ended 30 June 2022:

Options	Number	Grant Date[2]	Expiry Date	Exercise Price	Total fair value
Options granted to Directors					
Unlisted Options	1,399,999	09–Jun–22	01–Jul–25	$0.26	$298,200
Unlisted Options	1,399,999	09–Jun–22	01–Jul–26	$0.31	$309,400
Unlisted Options	1,400,002	09–Jun–22	01–Jul–27	$0.35	$324,800
Unlisted Options	1,399,999	09–Jun–22	01–Jul–26	$0.26	$326,200
Unlisted Options	1,399,999	09–Jun–22	01–Jul–27	$0.31	$334,600
Unlisted Options	1,400,002	09–Jun–22	01–Jul–28	$0.35	$347,200
Options granted to employees					
Unlisted Options	533,333	29–Apr–22	01–Jul–25	$0.26	$139,200
Unlisted Options	533,333	29–Apr–22	01–Jul–26	$0.31	$143,467
Unlisted Options	533,334	29–Apr–22	01–Jul–27	$0.35	$148,800
Total options	**10,000,000**				**$2,371,867**

The following share options were issued to employees and consultants as share based payments during the year ended 30 June 2021:

Options	Number	Grant Date[2]	Expiry Date	Exercise Price	Total fair value
Options granted to third parties					
Unlisted Options	10,000,000	20–Nov–20	20–Nov–23	$0.15	$647,348
Unlisted Options	10,000,000	20–Nov–20	20–Nov–23	$0.25	$527,766
Unlisted Options	10,000,000	25–Feb–21	20–Nov–23	$0.20	$1,352,588
Unlisted Options	10,000,000	25–Feb–21	20–Nov–23	$0.25	$1,253,140
Unlisted Options	30,164,690	2–Oct–20	30–Sep–21	$0.08	$740,665
Total options	**70,164,690**				**$4,521,507**

The fair values at grant date are independently determined using either a trinomial pricing or Black–Scholes option model that take into account any price to exercise, the term of the options or rights, the share price at grant date, the price volatility of the underlying share and the risk–free interest rate for the term of the options or rights. Inputs into the trinomial and Black–Scholes option pricing models used to calculate fair value are classified as level three inputs under the fair value hierarchy of AASB 13 (IFRS 13).

The fair value of the equity–settled share options granted is estimated as at the grant date using a Black–Scholes option model taking into account the terms and conditions upon which the options were granted, as follows for the year ended 30 June 2022:

	$0.26 Options	$0.31 Options	$0.35 Options	$0.26 Options	$0.31 Options	$0.35 Options	$0.26 Options	$0.31 Options	$0.35 Options
	01 Jul 25	01 Jul 26	01 Jul 27	01 Jul 26	01 Jul 27	01 Jul 28	01 Jul 25	01 Jul 26	01 Jul 27
Number	1,399,999	1,399,999	1,400,002	1,399,999	1,399,999	1,400,002	533,333	533,333	533,334
Expected volatility (%)	80%	80%	80%	80%	80%	80%	80%	80%	80%
Risk–free interest rate (%)	3.12%	3.33%	3.33%	3.33%	3.33%	3.33%	2.71%	2.90%	2.90%
Expected life of option (years)	3.06	4.06	5.06	4.06	5.06	6.07	3.18	4.18	5.18
Exercise price (cents)	26	31	35	26	31	35	26	31	35
Grant date share price (cents)	35	35	35	35	35	35	41	41	41
Vesting date	30 Jun 22	30 Jun 23	30 Jun 24	30 Jun 23	30 Jun 24	30 Jun 25	01 Jul 22	01 Jul 23	01 Jul 24

The fair value of the equity–settled share options granted is estimated as at the grant date using a Black–Scholes option model taking into account the terms and conditions upon which the options were granted, as follows for the year ended 30 June 2021:

	$0.08 Options	$0.15 Options	$0.25 Options	$0.20 Options	$0.25 Options
	30–Sep–21	20–Nov–23	20–Nov–23	20–Nov–23	20–Nov–23
Number	30,164,690	10,000,000	10,000,000	10,000,000	10,000,000
Expected volatility (%)	100%	100%	100%	101%	101%
Risk–free interest rate (%)	0.17%	0.11%	0.11%	0.12%	0.12%
Expected life of option (years)	1	3	3	2.7	2.7
Exercise price (cents)	8	15	25	20	25
Grant date share price (cents)	7.7	11.5	11.5	22	22
Vesting date	2–Oct–20	20–Nov–20	20–Nov–20	25–Feb–21	25–Feb–21

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

Performance Rights

Movement in number of Performance Shares and Performance Rights for the years ended:

Security Description	$0.08 Options	Balance at start of year	Granted by the Company	Converted or expired	Balance at end of year
30 June 2022	30–Sep–21	–	–	–	–
30 June 2021	30–Sep–21	41,553,593	–	(41,553,593)	–

1. 30,303,593 performance rights converted into ordinary shares upon achievement of designated performance hurdles and 11,250,000 performance rights expired.

15. Remuneration of auditors

	Consolidated	
	2022 $	2021 $
Audit or review of the financial reports of the company		
Amounts received & receivable by the auditor:		
Audit services – PKF Brisbane Audit	85,000	
Audit services – HLB Mann Judd	23,138	43,000
Audit services – Withum Smith & Brown (US auditor)	357,208	–
Other services – Withum Smith & Brown (US auditor)	–	287,975
	465,346	330,975

Withum Smith & Brown, PC were appointed auditors in the US in preparation for listing the Company's securities in the US. During the year the work carried out involved the PCAOB compliant audit of the financial statements, along with advisory work in relation to the listing of securities.

16. Financial Instruments

The Group's principal financial instruments comprise cash and short–term deposits.

The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial liabilities such as trade payables, which arise directly from its operations. It is, and has been throughout the year under review, the Group's policy that no trading in financial instruments shall be undertaken. The main risks arising from the Group's financial instruments are cash flow interest rate risk, liquidity risk, and credit risk. The Board reviews and agrees policies for managing each of these risks and they are summarised below.

(a) Interest rate risk

The Group's exposure to the risk of changes in market interest rates relates primarily to the Group's short–term deposits with a floating interest rate.

The Group's exposure to interest rate on financial assets and financial liabilities is detailed in the sensitivity analysis section of this note.

(b) Sensitivity analysis

During 2022, if interest rates had been 50 basis points higher or lower than the prevailing rates realised, with all other variables held constant, there would have been an immaterial change in post–tax result for the year. The impact on equity would have been the same.

(c) Net fair values

The net fair value of cash and cash equivalents and non–interest bearing monetary financial assets and liabilities approximates their carrying value.

(d) Commodity price risk

The Group's exposure to price risk is minimal.

(e) Credit risk

There are no significant concentrations of credit risk within the Group.

With respect to credit risk arising from the other financial assets of the Group, which comprise cash and cash equivalents, available–for–sale financial assets and certain derivative instruments, the Group's exposure to credit risk arises from default of the counter party, with a maximum exposure equal to the carrying amount of these instruments.

Since the Group trades only with recognized third parties, there is no requirement for collateral.

(f) Liquidity risk

The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of share issues and convertible notes.

The Group's contractual liabilities at 30 June 2022 were as follows:

Description	Less than 1 month $	1 to 3 months $	3 months to 1 year $	1 to 5 years $	Total $
Consolidated					
Payables & accruals	1,828,527	–	–	–	1,828,527
	1,828,527	–	–	–	1,828,527

The Group's contractual liabilities at 30 June 2021 were as follows:

Description	Less than 1 month $	1 to 3 months $	3 months to 1 year $	1 to 5 years $	Total $
Consolidated					
Payables & accruals	614,834	–	–	–	614,834
	614,834	–	–	–	614,834

(g) Capital Management

The Group's objectives when managing capital are to safeguard its ability to continue as a going concern, so that it may continue to provide returns for shareholders and benefits for other stakeholders. Due to the nature of the Group's activities, it does not have ready access to credit facilities and therefore is not subject to any externally imposed capital requirements, with the primary source of Group funding being equity raisings. Accordingly, the objective of the Group's capital risk management is to balance the current working capital position against the requirements to meet research and development programmes and corporate overheads. This is achieved by maintaining appropriate liquidity to meet anticipated operating requirements, with a view to initiating fund raisings as required.

17. Commitments and contingencies

Lease commitments

The Group holds three commercial leases for its office premises in Melbourne, Sydney and Perth, Australia. All of these leases had terms of 12 months from the commencement date of the lease. The lease payment are therefore recognized on a straight line basis over the lease term.

Other commitments

The Group entered into an arrangement with Monash University ("Monash") on 23 November 2020, whereby Monash will provide Research Trials in relation to Psi–GAD–1 over a 3–year period. The agreement sets out the scope of the Trials to be conducted, and the cost to the Group, of which 50% was paid on commencement of the agreement

18. Key Management Personnel compensation and related party disclosure

The Key Management Personnel of Incannex Healthcare Limited during the year were:

- Troy Valentine
- Peter Widdows
- Joel Latham
- Sud Agarwal (resigned 28 June 2022)
- George Anastassov (appointed 28 June 2022)

Key management personnel compensation

	2022 $	2021 $
Short–term employee benefits	1,333,992	761,231
Post–employment benefits	47,547	38,877
Share based payments	1,028,634	672,699
Total KMP compensation	2,410,173	1,472,807

Transactions with related entities

Transactions between related parties are on commercial terms and conditions, no more favourable than those available to other parties unless otherwise stated.

During the year, $407,824 (2021: $97,976) in fees were paid to Alignment Capital Pty Ltd ("Alignment"), an entity in which Mr Valentine is a director. Alignment was engaged by the Company to manage the exercise of IHLOB options program.

19. Details of the controlled entities

The consolidated financial statements include the financial statements of Incannex Healthcare Limited ('IHL') and its wholly owned subsidiaries Incannex Pty Ltd ('IXPL') and Psychennex Pty Ltd ('PXPL'). IXPL is incorporated in Australia and IHL owns 100% of the issued ordinary shares in IXPL (2021: 100%). PXPL is incorporated in Australia and IHL owns 100% of the issued ordinary shares in PXPL (2021: 100%).

20. Events Subsequent to Reporting Date

On 17 August 2022, the company appointed Robert Bruce Clark to the board as a non–executive Director.

On 5 August 2022, the Company completed the acquisition on APIRx Pharmaceuticals via the issuance of 218,169,497 IHL ordinary shares to the stakeholders of APIRx in an all–scrip transaction. As substantially all of the fair value of the assets acquired in the transaction relates to intangible assets (e.g., patents, trademarks, active clinical and pre-clinical research and development projects), the transaction has been determined to be an asset acquisition and not a business combination.

On 5 August 2022, the Company issued shares and options to Ryba LLC post year end pursuant to the mandate executed between the companies in November 2021. As the transaction between the Company and APIRx was deemed complete on 4 August 2022 the shares and options were issued.

No further significant events have occurred since the end of the financial year.

21. Parent entity disclosures

The individual financial statements for the parent entity show the following aggregate amounts.

Statement of financial position	2022 $	2021 $
Financial Position		
Current assets	37,559,819	9,222,528
Non–current assets	–	–
Total assets	**37,559,819**	**9,222,528**
Current liabilities	(1,078,404)	(668,527)
Non–current liabilities	–	–
Total liabilities	**(1,078,404)**	**(668,527)**
Net assets	**36,481,415**	**8,554,001**
Issued capital	86,586,794	45,852,107
Reserves	8,077,191	6,612,641
Accumulated losses	(58,182,570)	(43,910,747)
Shareholders' equity	**36,481,415**	**8,554,001**

Contingencies of the Parent Entity

There are no contingent liabilities involving the parent entity (2021: Nil).

Guarantees of the Parent Entity

There are no guarantees involving the parent entity (2021: Nil)

22. Restatement of financial statements

It was identified in the current period that the accounting for share options issued to consultants and advisors as share-based payments during the year 30 June 2021 were recorded using the incorrect vesting dates. As such, this was an error in the financial report for the year ended 30 June 2021. Details of the restated accounts appear below:

Statement of Financial Position	Reported at 30 June 2021 $	Effect of error $	Restated 30 June 2021 $
Assets			
Total assets	9,328,795	–	9,328,795
Liabilities			
Total liabilities	755,049	–	755,049
Net Assets	**8,573,746**	**–**	**8,573,746**
Equity			
Issued capital	45,938,576	(86,469)	45,852,107
Reserves	3,316,963	3,295,678	6,612,641
Accumulated losses	(40,681,793)	(3,209,209)	(43,891,002)
Total Equity	**8,573,746**	**–**	**8,573,746**

Statement of Comprehensive Income	Reported at 30 June 2021 $	Effect of error $	Restated 30 June 2021 $
Advertising and promotion	(1,136,666)	(3,209,208)	(4,345,874)
Loss before tax	(8,163,590)	(3,209,208)	(11,372,799)
Net loss for the period	(8,163,590)	(3,209,208)	(11,372,799)
Total comprehensive loss for the period	**(8,163,590)**	(3,209,208)	**(11,372,799)**
Earnings per share			
Basic loss per share (cents per share)	(0.83)	(0.33)	(1.16)
Diluted loss per share (cents per share)	(0.83)	(0.33)	(1.16)

Directors' Declaration

1. In the opinion of the Directors:
   a. the accompanying financial statements, notes and additional disclosures are in accordance with the *Corporations Act 2001* including:
      i. giving a true and fair view of the Group's financial position as at 30 June 2022 and of its performance for the year then ended; and
      ii. complying with Accounting Standards and Corporations Regulations 2001; and
   b. there are reasonable grounds to believe the Company will be able to pay its debts as and when they become due and payable.
   c. the financial statements and notes thereto are in accordance with International Financial Reporting Standards issued by the International Accounting Standards Board.
2. This declaration has been made after receiving the declarations required to be made to the Directors in accordance with Section 295A of the *Corporations Act 2001* for the financial year ended 30 June 2022.

This declaration is signed in accordance with a resolution of the Board of Directors.

Troy Valentine
Chairman

Melbourne, Victoria
19/09/2022

Auditor's Independence Report

PKF Brisbane Audit

PKF

INDEPENDENT AUDITOR'S REPORT

TO THE MEMBERS OF INCANNEX HEALTHCARE LTD

Report on the Financial Report

Opinion

We have audited the accompanying financial report of Incannex Healthcare Ltd (the company), which comprises the consolidated statement of financial position as at 30 June 2022, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the company and the consolidated entity comprising the company and the entities it controlled at the year's end or from time to time during the financial year.

In our opinion the financial report of Incannex Healthcare Ltd is in accordance with the *Corporations Act 2001*, including:

a) Giving a true and fair view of the consolidated entity's financial position as at 30 June 2022 and of its performance for the year ended on that date; and

b) Complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Report section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We are independent of the consolidated entity in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Key Audit Matters

Key audit matter is the matter that, in our professional judgement, was of most significance in our audit of the financial report of the current period. This matter was addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on this matter. For each matter below, our description of how our audit addressed the matter is provided in that context.

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1. Valuation of share-based payments

Why significant

During the year ended 30 June 2022, the company issued options and shares ("securities") to employees including key management personnel, which were accounted for as share-based payments under AASB 2: *Share-based Payment*.

Equity Instrument	No. Issued	Fair Value $	Expensed during FY22 $
Options	10,000,000	2,371,867	529,386
Shares	10,000,000	3,588,000	844,146
	20,000,000	**5,959,867**	**1,373,532**

In addition, a further $4,614,910 exists representing the balance of the fair value of securities issued as share based payments that are unrecognised as at 30 June 2022. The value of these securities has not yet been recognised as the balance represents the unamortised value of securities issued that are being recognised over the vesting period.

Total share-based payment expense for the year, including expense recognised in relation to securities issued as share-based payments in prior years, totalled $1,464,550.

This is a key audit matter because

1. the company valued the options using the Black Scholes model, where inputs such as volatility and risk-free rate require judgement.
2. The significance of the share-based payment expense to the company's financial performance.
3. the level of unamortised value of securities issued that will be expensed over future reporting periods.

Refer to Notes 1, 2, 13 and 14 to the financial report for a description of the accounting policy, significant estimates and judgements applied, and other details in relation to share-based payments.

How our audit addressed the key audit matter

Our audit procedures included but were not limited to:

- Obtaining an understanding of the key terms and conditions of the options and shares by inspecting relevant supporting documentation.
- Assessing the competence and qualifications of management's expert.
- Assessed the reasonableness of key inputs into the valuation model used by the expert engaged by management.
- Recalculating the estimated fair value of the options using the Black Scholes option valuation methodology.
- Testing the accuracy of the amortisation of share-based payments over the vesting period and the recording of an expense in the statement of profit or loss and an increment to the share-based payment reserve (options) or issued capital (shares).
- Reviewing the adequacy of the company's disclosures in respect of the accounting treatment of share-based payments in the financial statements, including the significant judgments involved, and the accounting policy adopted.

Other Information

The Directors are responsible for the other information. The other information comprises the information included in the consolidated entity's Annual Report, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report, or our knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Directors' Responsibilities for the Financial Report

The Directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the consolidated entity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the consolidated entity or to cease operations, or have no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report. As part of an audit in accordance with Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the consolidated entity's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Directors.

- Conclude on the appropriateness of the Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the consolidated entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our

conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the consolidated entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.

- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the consolidated entity to express an opinion on the group financial report. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

From the matters communicated with the Directors, we determine those matters that were of most significance in the audit of the financial report of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on the Remuneration Report

We have audited the Remuneration Report included in the directors' report for the year ended 30 June 2022. The Directors of the company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

Opinion

In our opinion, the Remuneration Report of Incannex Healthcare Ltd for the year ended 30 June 2022 complies with section 300A of the *Corporations Act 2001*.

PKF

PKF BRISBANE AUDIT

LIAM MURPHY
PARTNER

BRISBANE
19 September 2022

Corporate Governance Statement

Incannex Healthcare's governance practices guide the Company and its controlled entities' activities and decision-making to ensure the Company meets stakeholder expectations of sound corporate governance and continuous improvement in company performance.

This Corporate Governance statement reviews the Company's corporate governance practices against the ASX Corporate Governance Principles and Recommendations – 4th Edition (Corporate Governance Principles). All these practices, unless otherwise stated, were in place as at 24 January 2022.

The Corporate Governance Principles are as follows:

Principle 1:	Lay solid foundations for management and oversight
Principle 2:	Structure the board to be effective and add value
Principle 3:	Instil a culture of acting lawfully, ethically and responsibly
Principle 4:	Safeguard the integrity of corporate reports
Principle 5:	Make timely and balanced disclosure
Principle 6:	Respect the rights of security holders
Principle 7:	Recognize and manage risk
Principle 8:	Remunerate fairly and responsibly

Given the differences in size, complexity, history and culture of listed companies, the Corporate Governance Principles adopt an "if not, why not" approach to compliance and disclosure, requiring companies to explain the reasons for any departure from the Corporate Governance Principles recommendations. These explanations are included in section 9 of this statement.

Specific corporate governance policies of the Group are detailed on the Company's investor website under the 'Investor Centre' tab, at https://www.incannex.com.au/investors/. In this statement Incannex Healthcare and its controlled entities together are referred to as the "Group" or "Company".

Principle 1: Lay Solid Foundations for Management And Oversight

1.1 Board Charter and roles and responsibilities

The Board has adopted a Board Charter establishing corporate governance roles and responsibilities within the Group.

Under its Charter, the Board is ultimately responsible to the Company's shareholders for all matters related to the running of the Company. The Board's role is to govern the Company rather than to manage it, with the role of Senior Executives and Management to manage the company in accordance with the direction and delegations of the Board.

In general, the Board is responsible for overseeing all policies, practices, management, and operations of the Company, including corporate reporting systems, risk management, remuneration frameworks, governance issues, succession planning, and stakeholder communications. The Board also takes decisions regarding matters of fundamental importance to the Group.

The Board's focus is to enhance the interests of shareholders and other key stakeholders and to ensure the Group is properly managed. Management is directly accountable to the Board to deliver timely, accurate, and relevant information to enable the Board to perform its responsibilities. Management is also responsible for operating within the relevant directives and the risk appetite established by the Board whilst supporting the Managing Director in executing day-to- day operations.

The respective roles and responsibilities of the Board include:

- providing strategic guidance to the Group, including contributing to the development of and approving the corporate strategy reviewing and approving business plans, the budget, financial plans, and major capital expenditure initiatives
- overseeing and monitoring:
  a) organisational performance and the achievement of the Group's strategic goals and objectives
  b) progress of major capital expenditures and other significant corporate projects including any acquisitions or divestments or clinical trials
  c) financial performance including approval of the annual and half-year financial reports and liaison with the Group's auditors; and
  d) effectiveness of the Group's governance policies and procedures
- appointment, performance assessment and, if necessary, removal of the Managing Director
- ratifying the appointment and/or removal and contributing to the performance assessment of members of the Senior Executive team including the CFO, Chief Operating Officer and Company Secretary
- ensuring there are effective management processes in place and approving major corporate initiatives enhancing and protecting the reputation of the Group
- overseeing the operation of the Group's system for compliance and risk management reporting to shareholders
- ensuring appropriate resources are available to the Senior Executive

Incannex Healthcare Limited ABN 93 096 635 246 is committed to:

(a) complying with its disclosure obligations under the Corporations Act and ASX Listing Rules;

(b) the promotion or investor confidence by ensuring that all investors have equal and timely access to material information concerning the Company, including material information about its financial position, performance, ownership and governance; and

(c) providing announcements that are accurate, balanced and expressed in a clear and objective manner.

The purpose of this policy is to:

(a) raise awareness of the Company's obligations under the continuous disclosure regime;

(b) establish a process to ensure that information about the Company which may be market sensitive, and which may require disclosure is brought to the attention of the relevant person in a timely manner and is kept confidential; and

(c) sets outs obligations of Directors, officers, employees and contractors of the Company to ensure that the Company complies with its continuous disclosure obligations.

Compliance with this policy does not obviate the need for the Company to comply with 'Annual Report Disclosure'.

1. Responsibilities

1.1 Executive Management

(a) Understand the continuous disclosure regulations; and Report potentially material information immediately to either the Company Secretary, the Managing Director or the Chair.

1.2 Company Secretary

(a) Liaise with the Managing Director and/or Chair on information supplied to determine if it needs to be disclosed under continuous disclosure regulations; and

(b) Report the material information to the market.

2. Policy

(a) Executive Management will make themselves aware of the continuous disclosure regulations in the ASX Listing Rules.

(b) In the event that any member of management becomes aware of any fact or circumstance which may give rise to a requirement to disclose such information under the ASX Listing Rules, they will immediately inform either the Company Secretary, the Managing Director or the Chair.

(c) Prior to disclosure, the Company Secretary, in conjunction with the Managing Director and/or the Chair, will review the information to enable a judgement as to the appropriate disclosure to be made.

(d) If there is uncertainty over the requirement to comply with the continual disclosure requirements, then the Company will seek external legal advice.

(e) The Company, through the Company Secretary, will notify the market of any information it is determined is required to be disclosed.

(f) In accordance with ASX Listing Rules, the Company will immediately notify the market of information:

  (i) concerning the Company that a reasonable person would expect to have a material effect on the price or value of the Company's securities;

  (ii) that would, or would be likely to, influence persons who commonly invest in securities in deciding whether to acquire or dispose of the Company's securities; and

  (iii) The only exception to this is where the ASX Listing Rules do not require such information to be disclosed.

(g) The Board must receive a copy of all material ASX announcements promptly after they have been made.

2.2 Internal notification and decision-making concerning the disclosure obligation

The Board has designated the Company Secretary as the person responsible for overseeing and coordinating disclosure of information to the market as well as communicating with the relevant authorities. The Company Secretary will be responsible for ensuring that Company announcements are made in a timely manner and will establish a vetting procedure to ensure that the announcements are factual and do not omit any material information.

The Company Secretary will also ensure that Company announcements are expressed in a clear and objective manner that allows investors to assess the impact of the information when making investment decisions.

To assist the Company Secretary, fulfil the Company's disclosure requirements, executive staff are responsible for immediately communicating to the Company Secretary any possible continuous disclosure matter concerning the operations of the Company. Executive staff are responsible for ensuring that the information is provided to the Company Secretary as soon as they become aware of it and that it is factual and does not omit any material information. Executive staff will promptly respond to requests from the Company Secretary for further information concerning the possible continuous disclosure matter.

The Company Secretary, after consultation with the Chair and Managing Director, determines whether information should be disclosed to the market.

Before an announcement is released to ASX, the Company must ensure:

(a) the Company Secretary has completed its review process; and

(b) the announcement has been circulated to the Board for review; and

(c) the Board has authorised the release of the announcement in writing.

2.3 Promoting and monitoring compliance

The Company has a Continuous Disclosure Committee, comprising the following:

(a) Company Secretary;

(b) General Counsel;

(c) Managing Director; and

(d) The Chair and Non-Executive Directors will form part of the Committee for major announcements

The purpose of the Continuous Disclosure Committee is to promote and monitor compliance with the Company's continuous disclosure obligations and to ensure that all employees are aware of this policy. In addition, the Continuous Disclosure Committee is responsible for ensuring that all staff are aware of the type of information that needs to be communicated and their obligation to communicate to the Company Secretary any possible continuous disclosure matter.

A meeting of the Committee may be convened from time to time to consider particular continuous disclosure issues.

On a daily basis, the Company Secretary is charged with monitoring compliance with this policy. As part of that monitoring, all major announcements to the market will be reviewed for compliance with this policy. All public announcements will also be audited for compliance. These compliance reviews will be reported to the Continuous Disclosure Committee as part of their regular review of compliance. Any possible non-compliance will be reported to the Board at its next meeting. The Company Secretary must notify both the Chair and the Managing Director at the earliest opportunity if they believe that a false market in the Company's securities either exists or has the possibility to exist.

2.4 Measures for seeking to avoid the emergence of a false market in the Company's securities

The Company recognizes that a false market in the Company's securities may result if the Company provides incomplete information to the market or if the Company fails to respond to market and media speculation that may, or may be likely to, have an impact on the price of the Company's securities.

While the Company does not, in general, respond to market speculation or rumours unless required to do so by law or other relevant bodies, the Company is committed to disclosing as much information as possible, without harming the Company, to a wide audience of investors through media releases of important milestones, including information that may not strictly be required under continuous disclosure requirements. Information given to the market will also be provided to investors through media releases.

Where appropriate, the Company will request a trading halt to prevent trading in the Company's securities by an inefficient and uninformed market until the Company can make an announcement to the market.

2.5 Safeguarding confidentiality of corporate information to avoid premature disclosure

All employees are advised of the confidentiality of Company information. In addition, the Company imposes communication blackout periods for financial information between the end of financial reporting periods and the announcement of results to the market. To protect against inadvertent disclosure of price sensitive information, the Company does not hold meetings or briefings to discuss financial information with individual investors, institutional investors, analysts or media representatives during the communication blackout periods, unless such meetings or briefings are the subject of a specific announcement to the market.

2.6 Media contact and comment

The Board has designated the Managing Director or the Chair (where appropriate) to speak to the press on matters associated with the Company. In speaking to the press, the Managing Director or the Chair will not comment on price sensitive information that has not already been disclosed to the market, however, they may clarify previously released information. To assist in safeguarding against the inadvertent disclosure of price sensitive information, the Managing Director or the Chair will be informed of what the Company has previously disclosed to the market on any issue prior to briefing anyone outside the Company.

Subject to the policies of the Board and any committee that the Board may appoint from time to time, the Chair is authorised to comment on:

(a) annual and half yearly results at the time of the release of the annual or half yearly report;

(b) resolutions to be put to General Meetings of the Company;

(c) changes in Directors, any matter related to the composition of the Board or Board processes;

(d) any speculation concerning Board meetings or the outcomes of Board meetings; and

(e) other matters specifically related to shareholders.

Subject to the policies of the Board and any committee that the Board may appoint from time to time, the Managing Director is authorised to comment on:

(a) the Company's future outlook;

(b) any operational matter;

(c) media queries concerning operational issues which reflect either positively or negatively on the Company;

(d) proposed or actual legal actions; and

(e) queries and general discussion concerning the Company's industry.

There will be times when Directors and employees will be approached by the media for public comment. On such occasions, the Director(s) or employee(s) should comply with the following:

(a) refer the person to the Managing Director or the Chair of the Board as appropriate for comment;

(b) refrain from disclosing any information, documents or other forms of data to the person without the prior consent of the Managing Director or the Chair of the Board; and

(c) report the person who contacted the Director/employee, the reason (explicit or inferred) for the contact and a summary of any other relevant information as soon as possible to the Managing Director or the Chair.

2.7 External communications including analyst briefings and responses to shareholder questions

The Company discloses its financial and operational results to the market each year/half year/quarter as well as informing the market of other events throughout the year as they occur. Quarterly financial reports, media releases and AGM speeches are all lodged with the relevant authority. As all financial information is disclosed, the Company will only comment on factual errors in information and underlying assumptions when commenting on market analysts' financial projections, rather than commenting on the projections themselves.

In addition to the above disclosures, the Company does conduct briefings and discussions with analysts and institutional investors. However, price sensitive information will not be discussed unless that particular information has been formally disclosed to the market via an announcement. Slides and investor presentations used in briefings will also be released immediately prior to the briefing to the market.

After the conclusion of each briefing or discussion, it will be reviewed to determine whether any price sensitive information has been inadvertently disclosed. If any price sensitive information was disclosed, it will be announced immediately to the market.

Similarly, when answering shareholder questions, price sensitive information will not be discussed unless that particular information has been formally disclosed to the market via an announcement.

Where a question can only be answered by disclosing price sensitive information, the Company will decline to answer it or take it on notice and announce the information to the market prior to responding.

If any new price sensitive information is to be used in briefing media, institutional investors and analysts or in answering shareholder queries, written materials containing such information will be lodged with the relevant authority prior to the briefing commencing. These briefing materials may also include information that may not strictly be required under continuous disclosure requirements.

This policy will form a component of the induction process for all new employees.

The Company is committed to the full and accurate reporting of its financial results. Consequently, when complying with its periodic disclosure requirements, the Company will provide commentary on its financial results. The purpose of the commentary will be to clarify and balance the information in the financial results.

This commentary will be delivered in a manner that is neutral, free from any bias and easy to understand. This may involve the provision of both positive and negative information about the Company that the Company believes is necessary to keep investors fully informed.

The Company respects the rights of its shareholders and to facilitate the effective exercise of those rights the Company is committed to:

(a) communicating effectively with shareholders;

(b) giving shareholders ready access to balanced and understandable information about the Company and corporate proposals; and

(c) making it easy for shareholders to participate in general meetings of the Company.

2.8 Provision of information

The Company will communicate with shareholders in three main ways:

(a) through ASX releases to the market;

(b) through information provided directly to shareholders at general meetings of the Company; and

(c) other market releases.

It is the Company's policy to comply with its continuous and periodic disclosure obligations. In accordance with the Company's continuous disclosure policy, unless exempted by the ASX Listing Rules, the Company will immediately notify the market of information:

(a) concerning the Company that a reasonable person would expect to have a material effect on the price or value of the Company's securities; and

(b) that would, or would be likely to, influence persons who commonly invest in securities in deciding whether to acquire or dispose of the Company's securities.

Where practicable the Company will also make available the opportunity for shareholders to participate in new and substantive investor presentations by dial-in or live-stream or by uploading a transcript or recording of the presentation to ASX subsequently. The Company is not required to make available presentations that do not contain new market sensitive information.

"Substantive" presentations include results presentations and the types of presentations given at annual general meetings, investor days or broker conferences.

2.9 Provision of Information to the Board

The Company Secretary is to ensure that a copy of all material market announcements is to be circulated to the Board as soon as is practicable after its release.

2.10 Company website

The Company provides general information about the Company and its operations, details of the Company's corporate governance policies and procedures and information specifically targeted at keeping the Company's shareholders informed about the Company on its website.

In particular, where appropriate, after confirmation of receipt by the relevant authority, the following will be posted to the website:

(a) relevant announcements made to the market;

(b) media releases;

(c) information provided to analysts or the media during briefings;

(d) the full text of notices of meeting and explanatory material;

(e) information related to general meetings, including the Chair's address, speeches and voting results;

(f) copies of press releases and announcements for the preceding year; and

(g) copies of annual and half-yearly reports including financial statements for the preceding year.

Where possible, the website will also be used for web-casting or teleconferencing analyst and media briefings as well as general meetings of the Company. Where the Company does webcast the preceding events, and even where it is not possible to do so, a transcript or summary of the information discussed will be posted to the website.

2.11 Direct communications with shareholders

Throughout the year it may be appropriate for the Company to directly communicate with shareholders. For example, to give shareholders notice of general meetings or to update shareholders by way of a Chair's letter.

In relation to information that is directly communicated to shareholders, all shareholders have the right to elect to receive all such information by post, facsimile or electronic mail.

2.12 Meetings of the Company

In preparing for general meetings of the Company, the Company will draft the notice of meeting and related explanatory information so that they provide all of the information that is relevant to shareholders in making decisions on matters to be voted on by them at the meeting. This information will be presented clearly and concisely so that it is easy to understand and not ambiguous.

The Company will use general meetings as a tool to effectively communicate with shareholders and allow shareholders a reasonable opportunity to ask questions of the Board of Directors and to otherwise participate in the meeting.

The external auditor of the Company will be asked to attend each annual general meeting and to be available to answer shareholder questions about the conduct of the audit and the preparation and content of the auditor's report.

2.13 Other information

While the Company aims to provide sufficient information to shareholders about the Company and its activities, it understands that shareholders may have specific questions and require additional information. To ensure that shareholders can obtain all relevant information to assist them in exercising their rights as shareholders, the Company will make available a telephone number and email address for shareholders to make their enquiries.

2.14 Investor Presentations

Where a new and substantive investor or analyst presentation is to be given, the Company will release a copy of the presentation materials on the ASX market announcements platform ahead of the presentation.

3. Review

This policy will be reviewed annually be the Board to ensure it is operating effectively and determine whether any amendments are required.

Securities Exchange Information

Additional information required by the ASX Limited Listing Rules, and not disclosed elsewhere in this report.

Shareholdings

No individual shareholder is recorded as being a substantial shareholder (>5% of the Company's ordinary share capital).

Class of Shares and Voting Rights

The voting rights attached to the Fully Paid Ordinary shares of the Company are:

a. at a meeting of members or classes of members each member entitled to vote may vote in person or by proxy or by attorney; and

b. on a show of hands every person present who is a member has one vote, and on a poll every person present in person or by proxy or attorney has one vote for each ordinary share held.

Options do not carry any voting rights.

Twenty Largest Shareholders (as at 22 August 2022)

Position	Holder Name	Holding	% IC
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	76,046,581	4.99%
2	DR SUDHANSHU AGARWAL	75,303,093	4.94%
3	GEORGE ANASTASSOV	66,972,077	4.40%
4	PRASCH BV	63,954,841	4.20%
5	CANNVALATE PTY LTD	32,000,000	2.10%
6	MR RAYMOND LAURENCE CARROLL	30,000,000	1.97%
7	MR JOEL BRADLEY LATHAM	23,748,414	1.56%
8	BROWNARROWS PTY LTD <EJM A/C>	21,615,707	1.42%
9	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	20,699,995	1.36%
10	NATIONAL NOMINEES LIMITED	17,332,787	1.14%
11	MR PETER WIDDOWS	15,973,694	1.05%
12	IMI LLC	14,642,234	0.96%
13	BAGBO PTY LTD	14,516,434	0.95%
14	GEMINI CAPITALL LLC <THE ARS A/C>	13,787,086	0.90%
15	ALIGNMENT CAPITAL PTY LTD	13,194,248	0.87%
16	RYBA LLC	13,090,170	0.86%
17	MR BRIAN PETER BYASS	13,062,500	0.86%
18	MR KAIDE WANG	12,699,699	0.83%
19	ERIC HOCHI KIM	12,216,405	0.80%
20	CIPATER PTY LTD	12,206,477	0.80%
Total		**563,062,442**	**36.96%**

Distribution of Shareholders (as at 22 August 2022)

Holding Ranges	Holders	Total Units	% Issued Share Capital
above 0 up to and including 1,000	648	420,167	0.03%
above 1,000 up to and including 5,000	4,308	11,832,722	0.86%
above 5,000 up to and including 10,000	1,991	15,091,242	1.10%
above 10,000 up to and including 100,000	4,148	136,237,493	9.93%
above 100,000	1,302	1,207,817,874	88.07%
Totals	**12,397**	**1,371,399,498**	**100.00%**

There were 1,492 shareholders holding less than a marketable parcel (less than 1,639 shares at $ 0.305) at 22 August 2022 – a total of 1,523,934 shares.

There is no current on-market buy back taking place.

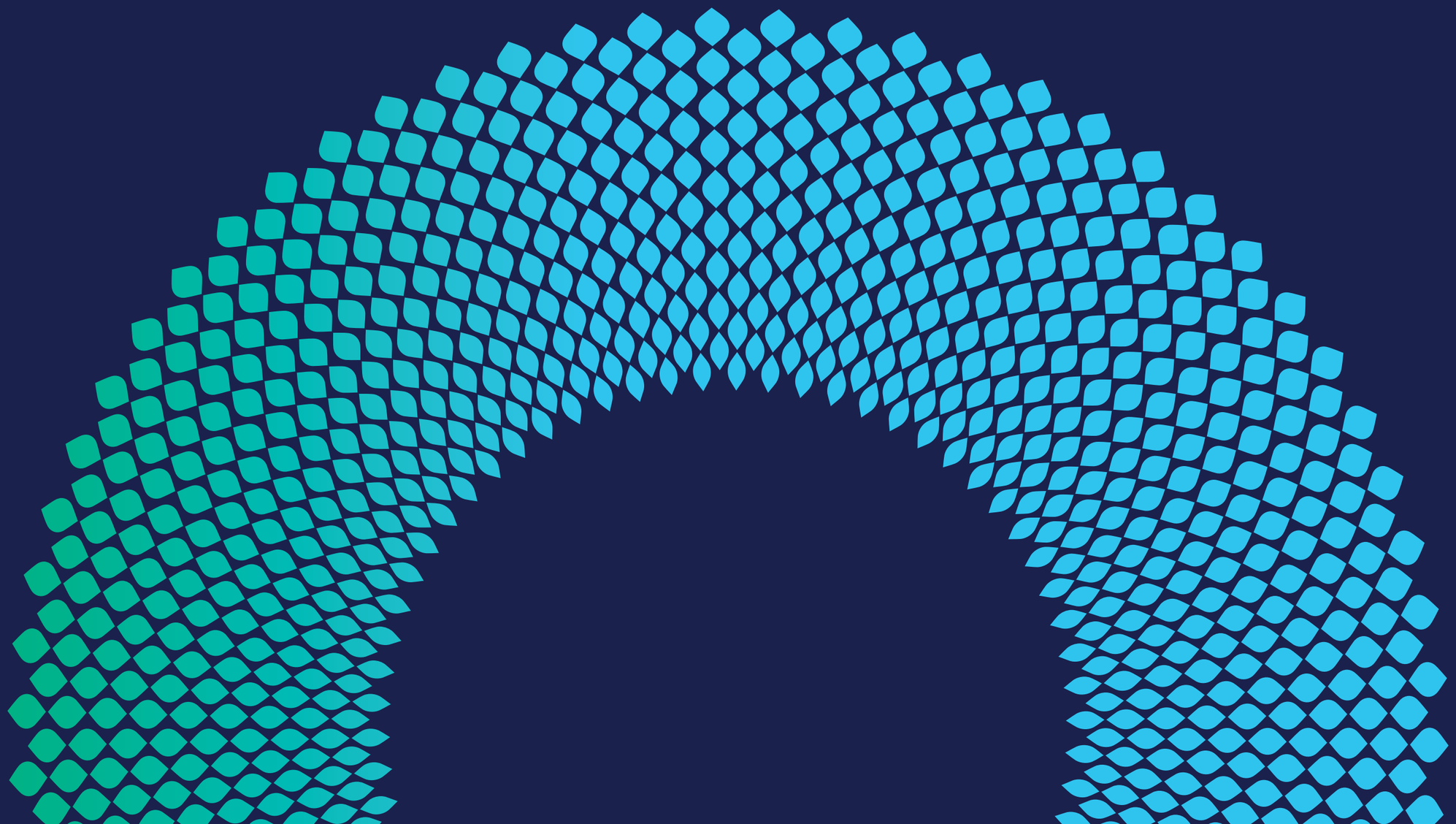
During the reporting year the Company used its cash and assets in a manner consistent with its business objectives.

The Company had the following unlisted equity securities on issue as at 22 August 2022:

Class	Number
All classes of OPTIONS	91,994,386

Incannex

The potential is limitless



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