

Incannex Healthcare Limited ABN 93 096 635 246

# Appendix 4E For the year ended 30 June 2021

Information for ASX under listing rule 4.3A

Reporting Period: Comparative Period: 30 June 2021 30 June 2020

# 2. Results for announcement to the market

				\$
2.1 Revenue				
Revenues from ordinary activities - continuing	up	213.7%	to	1,897,596
Revenues from discontinued operations	down	100%	to	Nil
<b>2.2 Loss for the year</b> Loss from ordinary activities after tax attributable to the owners of Incannex Healthcare Limited	up	73.8%	to	(8,163,590)
<b>2.3 Net loss for the year</b> Net Loss for the year attributable to the owners of Incannex Healthcare Limited	up	82.2%	to	14,526

# 2.4 Dividends

No dividends have been paid, declared or proposed in respect of the year ended 30 June 2021 (2020: Nil).

# 2.6 Results for the year

Refer to the attached financial statements and review of operations in the Directors' Report for an explanation of the results for the year.

# 3 Statement of profit and loss and other comprehensive income

Refer to attached financial statements.

#### 4 Statement of financial position

Refer to attached financial statements.

# 5 Statement of changes in equity

Refer to attached financial statements.

# 6 Statement of cash flows

Refer to attached financial statements.

# 7 Details of dividends and distribution payments

Not applicable.

#### 8 Dividend and distribution reinvestment

Not applicable.

# 9 Net tangible asset per security

30 June 2021	0.80 cents
30 June 2020	0.42 cents

# **10 Controlled entities**

Psychennex Pty Ltd ('PXPL') was incorporated on 30 November 2020 in Australia and IHL owns 100% of the issued ordinary shares in PXPL.

#### 11 Joint ventures and associates

Not applicable.

#### 12 Other information

Not applicable.

# **13 Foreign entities**

Not applicable.

# 14 Commentary on results

Refer to the Review of Operations included in the attached Annual Financial Report.

# 15 Audit

The figures in this report are based on the attached Financial Report which is audited.

# 16 Not applicable

# **17 Audit Opinion**

The independent audit report is not subject to any modified opinion, emphasis of matter or other matter paragraph.

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Troy Valentine Chairman Melbourne, Victoria, 30 August 2021



Incannex Healthcare Limited ABN 93 096 635 246

# **Annual Financial Report**

For the year ended 30 June 2021

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# **CORPORATE INFORMATION**

Incannex Healthcare Limited ABN 93 096 635 246

# Directors

Mr Troy Valentine (Non-Executive Chairman) Mr Peter Widdows (Non-Executive Director) Dr Sud Agarwal (Non-Executive Director) Mr Joel Latham (Managing Director)

# **Company Secretary**

Madhukar Bhalla

# **Registered Office**

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

# **Principal Place of Business**

207/11 Solent Circuit Norwest NSW 2153

# **Share Register**

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

# Auditors

HLB Mann Judd (WA Partnership) Level 4, 130 Stirling Street Perth Western Australia 6000

# Securities Exchange Listing

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

#### 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 2021.

The past year has seen exciting research results and rapid progress within the Company's novel drug development program. Our talented and knowledgeable team has continued to demonstrate their commitment to delivering world-class clinical programs in a determined pursuit to achieve FDA approval.

We have taken further leaps in developing-out our unique cannabinoid-based and now psychedelic medicines in no less than six indications with major unmet patient needs. Those unmet needs represent potential multibillion-dollar markets in sleep apnoea, traumatic brain injury, rheumatoid arthritis, lung inflammation, inflammatory bowel disease and generalised anxiety disorder.

Incannex has focused its expenditures on research and development and has spared no expense to ensure that its research programs are consistent with FDA processes. During the last financial year, we entered regulatory discussions with the FDA regarding drug candidate IHL-675A and I am pleased to report that those meetings have enabled us to establish a regulatory pathway to registration, subject to clinical success. As such, we will commence clinical trials for IHL-675A here in South Australia in the 4th quarter of this year.

We look forward to having further discussions with the FDA regarding our other drug candidates during the current financial year. Particularly, as we finalise phase 2 studies for IHL-42X in patients with obstructive sleep apnoea and commence phase 2 clinical studies for our psilocybin therapy program.

During the year, we expanded our partnerships with scientific experts and world-renowned academic institutions. We are proud to have entered collaborations with The Alfred Hospital, Monash University and the University of Western Australia as these organisations lend scientific exceptionalism to our clinical programs.

Dr Paul Liknaitzky became a member of our scientific advisory board during the year, and I would like to sincerely thank him for his contribution to our psychedelic psychotherapy program. Dr Liknaitzky is Australia's only full-time psychedelic medicine and therapy researcher, and he is world-renowned for his knowledge, commitment, and dedication to developing therapies that have the potential to transform the lives of people with mental-ill health.

From a corporate perspective, we welcomed Canary Capital as Australian corporate advisors to our company. Their keen interest in and continued support for Incannex has been greatly appreciated. We would also like to thank Eddie Sugar and EAS Advisors for their support and work in assisting us with our plans to list on Nasdaq in the United States.

I would sincerely like to thank our Managing Director and CEO Mr Joel Latham for the unwavering commitment and drive that he brings to the Company on a daily basis. His efforts, in conjunction with the work of our core medical team comprising our CMO Dr Sud Argawal, our CSO Dr Mark Bleackley, our CRM Mrs Rosemarie Walsh and our Head of Psychedelic Medicine Dr Paul Liknaitzky, continue to play leading roles in driving Incannex to become a world leader in drug development and healthcare.

I would also like to thank my fellow directors for their efforts over the past twelve months and, finally I would like to extend to all our shareholders the best of health and safety to them and their families during the ongoing Covid-19 crisis. We very much appreciate your support and look forward to continuing to enjoy our exciting journey together over the next twelve months.

Troy Valentine Chairman

# **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 2021. 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.

# Names, qualifications, experience and special responsibilities and other directorships

# 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 Sud Agarwal – Non Executive Director

BSc(Hons), MB ChB, FANZCA

# Appointed 24 July 2019

Dr Sud Agarwal has been our Chief Medical Officer of Incannex since June 2019. He is responsible for the oversight over the Company's cannabinoid clinical program and pipeline of proprietary products. Dr Agarwal is a specialist anaesthesiologist and physician researcher and passed his board exams and was made a Fellow of the Australian and New Zealand College of Anaesthetists in 2009. Dr. Sud Agarwal is a key opinion leader in the clinical use of medicinal cannabis and is regularly invited as a keynote to industry and pharmaceutical events, including the World Cannabis Conference (June 2019), the Australian Medicinal Cannabis Conference (March 2019), Prohibition Partners (September 2020) and the forthcoming International Cannabinoid Derived Pharmaceuticals Summit in Boston (September 2021).

Since 2018, Dr. Agarwal also serves as Chief Executive Officer and Chairman of Cannvalate, an Australian private medicinal cannabis company that owns a 3% beneficial interest in Incannex.

# Mr Joel Latham – Executive Director – Chief Executive Officer

#### Appointed 24 July 2019

Joel Latham has been the Chief Executive Officer and Managing Director of Incannex since July 2018. Mr. Latham is responsible for the Company's commercial operations, strategic decision-making, and oversight of all clinical development assets for Incannex Healthcare. Prior to his appointment as Chief Executive Officer, Mr. Latham had been a key member of our senior leadership team acting as General Manager since 2016. During this time, he was instrumental in the marketing and procurement of multiple revenue-generating opportunities and partnerships, including with Pacific Smiles (ASX:PSQ), 1300 Smiles (ASX: ONT), the National Rugby League, the Australian Football League, ONE Fighting Championship, FIT Technologies and Cannvalate. During his time at the Company, Mr. Latham has been pivotal in the development and execution of Incannex's drug development and regulatory strategy.

Prior to joing Incannex in 2016, Mr. Latham had over 14 years' experience, with major firms such as Mars Foods, Tabcorp and Philip Morris International in management and commercial operational roles.

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.

# COMPANY SECRETARY

#### Madhukar Bhalla

Appointed 7 July 2021

Madhukar "Madhu" is an experienced company secretary who has previously worked with multiple ASXlisted 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.

# **Glenn Fowles**

Appointed 7 December 2017 Resigned 7 July 2021

Glenn has over 30 years' experience working with listed companies having worked for HSBC Asset Management and Contango Asset Management in the funds management industry. He has held positions of Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and Company Secretary within these organisations as well as serving as a Director and Company Secretary of a number of companies listed on ASX. Glenn resigned on 7 July 2021.

# DIRECTORS' 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	
Sud Agarwal	10	10	
Joel Latham	10	10	

# **PRINCIPAL ACTIVITIES**

During the course of the financial year the principal activities of the Company were:

- (1) Research, development and sales of medicinal cannabinoid products.
- (2) On 20 November 2020 the Group established a separate business to research and develop the use of psychedelic medicine and therapies for the treatment of mental health disorders.

# **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 2021 after income tax was \$8,163,590 (2019: Loss of \$4,697,636).

# **Business activities**

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 (EMEA, TGA).

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 ("TBI")/concussion, rheumatoid arthritis, inflammatory bowel disease 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 Dr. Sud Agarwal (our Chief Medical Officer and Director), 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:

• <u>Advance our novel investigational drug candidates towards approval in the United States</u> <u>and elsewhere</u>. 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 Europe Union, Japan, Australia and Israel.

• <u>Take advantage of accelerated commercialization pathway options for our drug</u> <u>candidates</u>. 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.

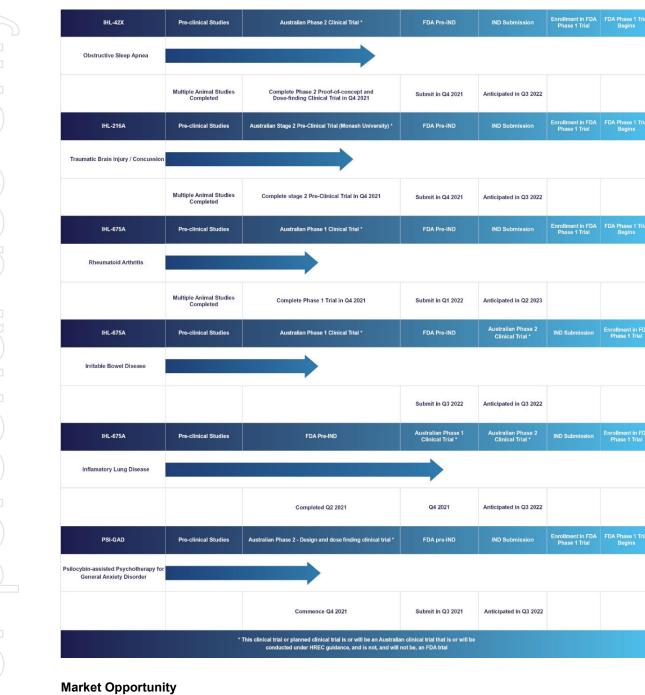
• **Develop future clinical products targeting unmet medical needs.** We intend to only develop clinical products that treat unmet medical conditions. As a result, we may have opportunities to accelerate commercialization of such products.

• <u>Maintain a strong intellectual property portfolio</u>. 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.

Enrollment in FD. Phase 1 Trial

# **Clinical Approach**

We are pursuing FDA approval of all our drug candidates currently being developed. The graphic here below 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.



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**

#### IHL-42X

#### Obstructive Sleep Apnea

Obstructive sleep apnea is characterized by a narrowing or obstruction of the upper airway in 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.

# IHL-42X in Obstructive Sleep Apnea

IHL-42X is a fixed-dose combination of acetazolamide, a registered pharmaceutical, and dronabinol, a synthetic cannabidiol; both agents have been shown to reduce the apnea hypopnea index ("AHI"). We believe that the activity of synthetic 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 can have a therapeutic benefit at doses of each constituent drug that are safe and tolerable.

#### Australian Stage 2 Clinical Trial for IHL-42X for Obstructive Sleep Apnoea ("OSA")

We are currently conducting a proof-of-concept Phase 2 clinical trial in Australia to support our IND application with the FDA and to inform the clinical design of our planned FDA compliant pivotal Phase 2 clinical trial in Australia to assess the safety and efficacy of IHL-42X in patients with Obstructive Sleep Apnea. We received approval from The Alfred Hospital Human Research Ethic's 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 measurement of reduction in the AHI and the secondary endpoints are reduction 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 is currently underway and well-advanced at the Alfred Hospital in Melbourne Australia and the University of Western Australia Centre for Sleep Science in Perth. We have retained Novotech, a global contract research organization, to manage and to monitor the study. In July 2021, an interim analysis of the data from our ongoing phase 2b double blind randomised placebo-controlled clinical trial was performed and these results have been utilized to support a patent application regarding the methods for the treatment of obstructive sleep apnoea.

Incannex has received ethic's approval to commence an open label extension to the phase 2b clinical trial. The open label extension study will recruit people who have experienced a benefit from IHL-42X in the phase 2b trial and will assess the therapeutic benefit and tolerability of IHL-42X in those patients over an extended timeframe.

The open label extension study will consist of 6 months of treatment with IHL-42X. The primary endpoint will be reduction in Apnoea Hypopnea Index ('AHI') compared to the patient's original, pretreatment baseline measurement. AHI will be assessed during three overnight sleep studies at day 28, 64 and 168. The main goal of this study is to determine whether the reduction in AHI that was observed for these subjects in the phase 2b study is maintained over an extended period.

Additionally, we plan to supply IHL-42X for sale in Australia under the Special Access Scheme for unregistered medicinal synthetic cannabidiol products after the completion of the Phase 2 study and prior to drug registration.

# IHL-216A

#### IHL-216A for Concussion/Traumatic Brain Injury and Chronic traumatic encephalopathy

Concussion/Traumatic Brain Injury 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.

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.

#### 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 such as modulating glutamate release and calcium uptake as well as 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). Ablating 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 unique challenges. Because isoflurane is an inhaled volatile anesthetic, it cannot be used in a typical oral drug combination product. We intend to formulate IHL-216A as a combined inhalational product delivered via a nebulizer. Nebulized drug delivery 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. Development of the nebulized CBD formulation will be an iterative process starting with three steps of refinement based on properties of the solution, generated aerosol and dose delivery. 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.

Appointing Vectura to develop the IHL-216A formulation in parallel with the animal study using the NFL model of concussion will ensure that we are readied with the specific formulation and delivery mechanism required for advancement of a pivotal Phase 2 clinical trial once the Stage 2 in vivo study and formulation is finalized.

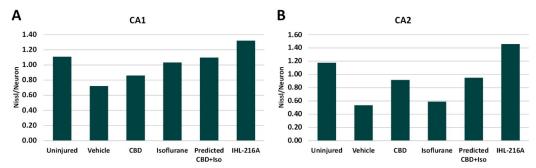
Due to the product's potential therapeutic utility in contact sports, IHL216A is being designed to satisfy the World Anti-doping Authority ("WADA") specifications for use by athletes at risk of TBI and CTE.

#### 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, assessed structural damage to the brain using magnetic resonance imaging and performed micro-scale cellular analysis post-mortem to discern and compare neuronal damage across the cohorts.

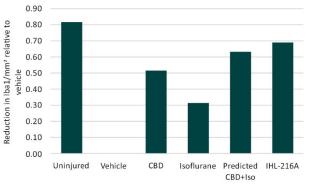
As detailed below, we found that the IHL-216A components, CBD and isoflurane, act synergistically to reduce indicators of neuronal damage, neuroinflammation and behavioral deficits that are consequences of TBI, as IHL-216A outperformed the predicted effect of CBD and isoflurane combined. The predicted 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 on a combined basis; to the extent IHL-216A exceeds the predicted result, we can conclude that the drugs strengthen the effectiveness of one another and synergies exist. The study also found that IHL-216A was significantly more effective than CBD or isoflurane applied on a standalone basis.

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 visual 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. 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, IHL-216A outperformed CBD alone by 53% for CA1 and 60% for CA2, outperformed isoflurane alone by 28% for CA1 and 145% for CA2, and outperformed the predicted effect of CBD and isoflurane combined by 20% for CA1 and 53% for CA2. These results demonstrated less neuronal damage experienced by the rats treated with IHL-216A relative to the predicted value.



**Figure 1.** Synergistic activity of CBD and isoflurane (IHL-216A) in neuronal damage as assessed by NissI 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 NissI staining. NissI staining permits the quantitation of the ratio of NissI bodies to total neurons, a lower ratio being indicative of increased neuronal damage. The NissI/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.

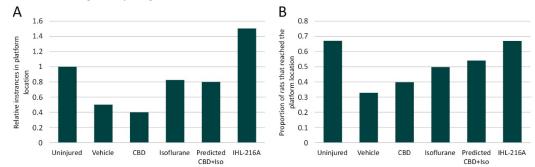
A post-mortem analysis of the rat brains also determined that CBD and isoflurane were synergistic in reducing levels of the neuroinflammation marker Iba1 as detected using immunofluorescence. Iba1 is a protein expressed in microglia, a type of innate immune cell in the brain, that is an established marker 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. IHL-216A reduced the Iba1 neuroinflammation marker by 35% more than CBD alone and 123% more than isoflurane administered alone. IHL-216A also reduced the Iba1 neuroinflammation marker by 10% more than the predicted value of the combined CBD and isoflurane.



**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.

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. IHL-216A outperformed the predicted value of combined CBD and isoflurane when assessing both the number of times rats returned to the location of the platform per group by 87% as

well as the proportion of rats in the group that returned to the location of the platform by 24%, demonstrating the synergistic effect of CBD and isoflurane.



**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. This outperformance by the IHL-216A compared to the predicted performance 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.

# Stage 2 pre-clinical study for IHL-216A

We are currently undertaking 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 is 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 being used in this 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.

# IHL-675A

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 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.

#### 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.

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 value in 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 an animal study, low dose IHL-675A was more effective at reducing arthritis across multiple assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels than the standard dose of HCQ. The reduction in disease assessments by low dose IHL-675A was 1.06-3.52 times that observed for HCQ alone at the standard dose.

This indicates that the combination of CBD and HCQ in IHL-675A has the potential to permit a tenfold 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.

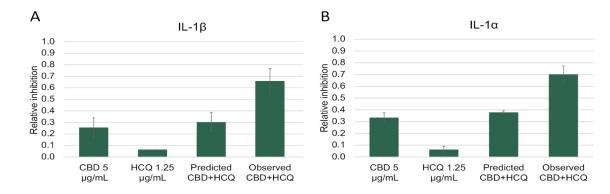
Both ulcerative colitis and Crohn's disease are usually characterized by diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss. IBD can be debilitating and sometimes leads to life-threatening complications.

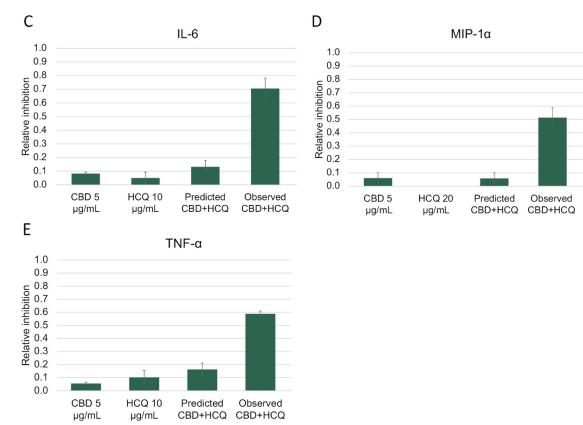
#### Preclinical in vitro study of IHL-675A against lung inflammation

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 peripheral blood 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 Epred A+B=(EA+EB)-(EAEB), is subtracted from the observed inhibition to yield an EOB score. An EOB score of greater than zero indicates that the combination is synergistic.

The study demonstrated that CBD and HCQ act synergistically to inhibit production of the assessed inflammatory cytokines IL-1 $\beta$ , IL-6, TNF- $\alpha$ , IL-1 $\alpha$ , and MIP-1 $\alpha$  by PBMCs from the donors. The average EOB scores ranged from 0.32-0.57. IHL-675A outperformed HCQ alone by 436% to 1320% and CBD alone by 109% to 767% across the five cytokines and outperformed the predicted cytokine inhibition of IHL-675A based on the activity of each drug alone by 87% to 767% across the 5 cytokines. 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 before the study commenced. The observed results from the study exceeded these in each inflammatory cytokine analyzed.





**Figure 4.** 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 Epred A+B=(EA+EB)-(EAEB). An EOB score of greater than 0 is indicative of synergy.

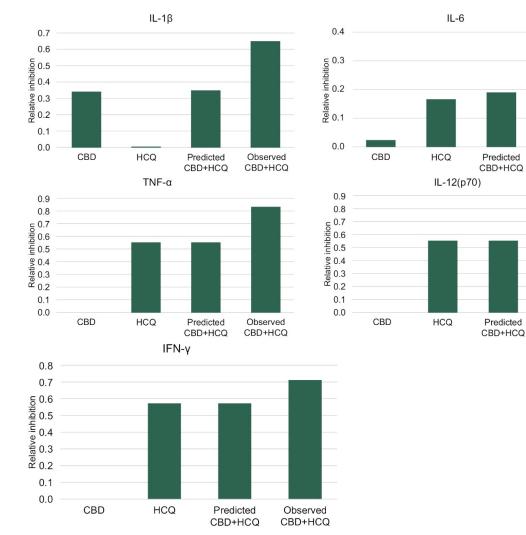
The results of the in vivo study are presented in Figure 5, showing the optimal fixed dose IHL-675A combination assessed for each cytokine in 11 groups of 10 mice. The bars noted as 'Predicted CBD + HCQ' represent IHL's expectation based on the activity of each drug alone. The observed results from the study significantly exceeded the predicted results across the inflammatory cytokines analyzed. CBD and HCQ synergize to inhibit the production of inflammatory cytokines IL-1 $\beta$ , IL-6, TNF-  $\alpha$ , IL12(p70), and IFN-  $\gamma$  in a mouse model of LPS induced sepsis. The average EOB scores ranged from 0.15-0.30. IHL-675A outperformed CBD alone significantly across the five inflammatory cytokines. IHL-675A outperformed the predicted cytokine inhibition based on the activity of each drug alone by 26% to 81% across the five analyzed cytokines after 2 hours.

Observed

CBD+HCQ

Observed

CBD+HCQ



**Figure 5.** 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-1 $\beta$ , IL-6, TNF- $\alpha$ , IL12(p70), and IFN- $\gamma$ .

# 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's 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.

In July 2020, we conducted an animal study using rodents to assess the anti-inflammation efficacy of IHL-675A. 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.

In February 2021, we announced the results from this animal study, where 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-1 $\beta$ , IL-6, TNF- $\alpha$ , 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, and therefore IHL-675A may be effective in the treatment of anti-inflammation in humans.

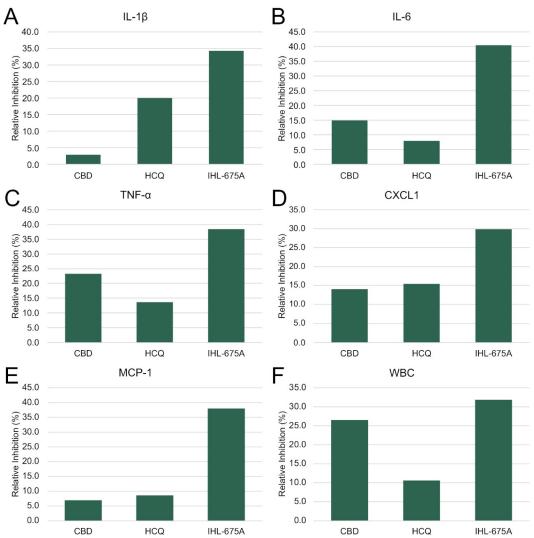


Figure 6. Reduction in cytokine levels and white blood cell count in BALF resulting from treatment with by IHL-675A, CBD or HCQ in a mouse model of pulmonary inflammation. Mice were treated with CBD, HCQ or a combination of CBD and HCQ (IHL-675A) and then LPS was administered intratracheally. Twenty-four 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-1 $\beta$ , (B) IL-6, (C) MCP1 and (E) TNF- $\alpha$ , 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

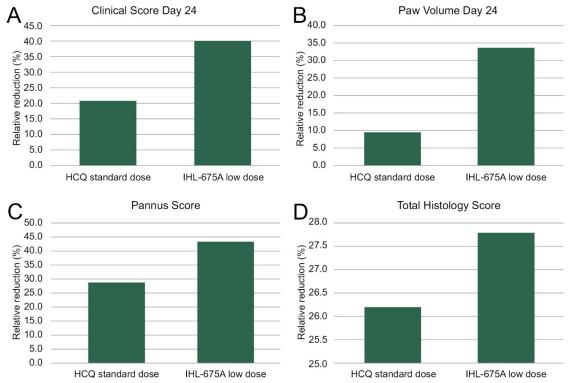
In March 2021, we announced the results of an in vivo study assessing IHL-675A's anti-inflammatory capabilities regarding rheumatoid arthritis. Results indicate that a low dose of IHL-675A was 1.06 to

3.52 times more effective at reducing arthritis 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 sulphate, 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 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 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-1 $\beta$  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.

IHL-675A outperformed HCQ alone in the study (at equivalent doses) at reducing clinical score and paw volume at days 24 and 30, pannus formation, total histology score, IL-1 $\beta$  and IL-6 in the rat model of arthritis. 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 is a potential treatment for arthritis in humans.



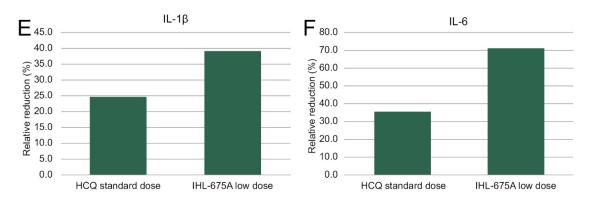


Figure 7. Comparison of low dose IHL-675A and standard dose HCQ in reduction of disease assessments in a rat model of rheumatoid arthritis. Groups of rats that had undergone collageninduced arthritis modelling were treated with low dose IHL-675A (1 mg/kg CBD + 2.5 mg/kg HCQ) or standard dose HCQ (25 mg/kg HCQ). The reduction in arthritis disease severity in low dose IHL-675A treated rats was greater than for standard dose 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-1 $\beta$  levels and (F) serum IL-6 levels.

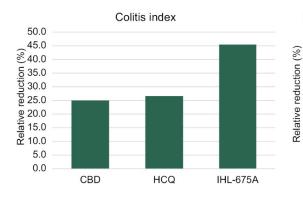
# Preclinical studies of IHL-675A in models of inflammatory bowel disease

In February 2021, we announced the results of an in vivo study assessing IHL-675A's antiinflammatory 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 is a potential treatment for inflammatory bowel disease in humans.

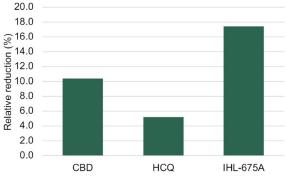
This study used eleven groups of six mice. Mice were treated with IHL-675A, CBD or HCQ for four consecutive days after administration of TNBS/ethanol to induce ulcerative colitis. A vehicle treated group and sham group were included in the study. Stool consistency was monitored over the course of the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

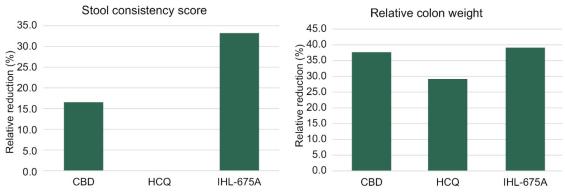
Endpoint measurements include stool consistency score (an ordinal scale that measures stool consistency with a higher number indicative of looser stools), colon weight, colon macroscopic damage score (an ordinal scale that combines adhesions, strictures, ulcers/inflammations and instances of wall thickening), 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.

IHL-675A outperformed both CBD only and HCQ only at reducing the colitis index, macroscopic damage score, stool consistency score, colon to body weight ratio and myeloperoxidase (MPO) levels. 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.



#### Macro damage score





*Figure 8. 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 commenced a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers. The study will be conducted at CMAX Clinical Research (CMAX) in South Australia and managed by Australian CRO Avance Clinical (Avance).

The aims of the study are to demonstrate that there are no, or minimal, additional 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 materially 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, CBD, or HCQ. The safety and pharmacokinetic assessments will be identical across the three arms of the trial.

IHL anticipates that the first participants will be recruited in Q4 2021. Subject to clinical success, the results of this clinical trial will form part of three FDA investigational new drug (IND) applications for each of the three indications the Company is pursuing with IHL-675A. Those indications are lung inflammation, rheumatoid arthritis, and inflammatory bowel disease, representing major markets for IHL to pursue with IHL-675A. Once the IND applications are evaluated and approved, the Company intends to conduct phase 2 and 3 clinical trials partly or wholly in the United States.

On the 16th of July 2021, Incannex announced that it engaged Procaps S.A. ('Procaps') to manufacture soft gel capsules for the Company's clinical trial programs. Procaps manufacturing plant has been inspected and approved for good manufacturing practices (GMP) by multiple regulatory agencies including FDA, TGA, Health Canada and MHRA.

Production of IHL-675A soft gel capsules can quickly ramp up to commercial quantities for sale as either an unregistered or registered product in various markets upon the achievement of successful clinical trial outcomes.

CMAX Clinical Research CMAX Clinical Research is an independent clinical research facility, based in Adelaide, Australia. CMAX has been established as a Phase I-II unit since December 1993, making it the longest-running in Australia which has consistently maintained world class standards with a commitment to providing excellence and quality in all areas of clinical service. CMAX has conducted more than 600 studies since the unit was established and was most recently US FDA audited in 2019 with no findings. CMAX is one of Australia's most modern Phase I-II clinical facilities, adjacent to Adelaide's Biomed City.

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

# Generalized Anxiety Disorder

Generalised Anxiety Disorder (GAD) is characterised by diffuse, excessive, uncontrollable anxiety that is not restricted to any specific environmental circumstances and occurs more days than not for at least 6 months (American Psychiatric Association, 2013). About 3% of the adult population in the USA

and Australia are estimated to have GAD in any 12-month period. This equates to an estimated 9M people in the US (7m moderate to severe) having GAD and approximately 1M people in Australia. Patients experience intense, persistent, and often debilitating anxiety.

First line treatment options for GAD include Cognitive Behavioural Therapy, anti-depressants (SSRIs, SNRIs) and pregabalin, with benzodiazepines (e.g., Diazepam) as a second-line, short-term option. Existing treatments show limited efficacy, with less than 50% of patients achieving remission, alongside high relapse rates. These treatment limitations highlight significant unmet need in this patient group.

GAD tends to be more frequent and severe than within other anxiety disorders (Olatunji et al., 2010), having a chronic, unremitting course. It is associated with a high public burden, and significant distress and impairment in quality of life, relationships, work, or other areas of functioning (Comer et al., 2011; Revicki et al., 2012).

#### 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 can be both a safe and highly effective mental health treatment. 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, which we hope will lead to a Pre-IND submission in Q3 of 2021, and which is ultimately aimed at FDA approval of our psilocybin therapy administered to patients with GAD.

Therapist recruitment in anticipation of the Phase 2 exploratory trial has commenced and therapist training is anticipated to commence in Q3 2021.

# Phase 2a clinical trial

The protocol for our planned Phase 2 Australian exploratory clinical trial has been completed and a research proposal has been submitted to the human research ethics committee (HREC) for approval in Q3 of 2021. HREC approval is required prior to the commencement of patient recruitment in Australia. Dr Paul Liknaitzky has successfully achieved HREC approval for other clinical psilocybin studies in Australia and has successfully acquired regulatory permits and imported psilocybin into Australia.

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. It will include 72 participants that will 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.

A preliminary analysis of patient data will be conducted by an independent data safety monitoring board after 30 patients have completed primary endpoint assessment. The preliminary analysis will allow the trial investigators to inform the second part of the trial, with an opportunity to adjust certain treatment design parameters to optimize patient outcomes, or terminate the trial based on predefined outcomes and adequate conditional power.

#### FDA development plan and pre-IND meeting

In February 2021, we formally engaged Camargo Pharmaceuticals LLC, to advise upon and compile the pre-investigational new drug application information package necessary to formally request a pre-IND meeting with FDA. This meeting request has been submitted to the FDA in Q3 2021 and we anticipate that the meeting will occur in Q4 2021. We believe that FDA guidance will provide us with the regulatory clarity and commercial confidence to submit an IND to the FDA and concurrently conduct a Phase 2b pivotal clinical trial partly or wholly in the United States in 2022.

# 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 will sponsor 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 will be 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.

# 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 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.

# 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).

# DIRECTORS' 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	26,734,248	7,116,950	-
Mr Peter Widdows	15,915,790	657,895	-
Mr Joel Latham	17,948,144	4,700,000	-
Dr Sud Agarwal	66,303,593	200,000,000	-

# 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 21 July 2021, the Company issued 239,103 ordinary shares upon the exercise of unlisted options by option holders with an exercise price of \$0.08 per share, receiving \$19,128 upon conversion.

The Company issued a further 2,739,662 ordinary shares on the exercise of of "IHLAH" share options at an exercise price of \$0.08 per share on 16 August 2021, raising \$219,713.

On 18 August 2021 the Company announced its public filing of Form F-1 with the Securities Exchange Commission ("SEC") in the US, in preparation for the for a proposed listing on the NASDAQ. An extraordinary General Meeting has been called on 17 September 2021 to put a resolution to shareholders to issue up to 180 million ordinary shares in relation to the proposed Initial Public Offering ("IPO") in the US.

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

# LIKELY DEVELOPMENTS AND EXPECTED RESULTS

The Group will continue clinical trials in both its pharmaceutical products and psychotherapy products. The Group has announced a manufacturing agreement for the production of IHL-675A soft-gel capsules for trials in the pharmaceutical sector, as well as open label studies on IHL-42X, a prospective treatment for sleep apnoea. The Group's partnership with Monash University in the development of Psi-GAD, part of the Group's psychotherapy sector, will continue with Phase 2a trials announced subsequent to the year end.

As noted in *After Balance Date Events* the Company has proposed an IPO in the US to list its shares on the NASDAQ. It has filed Form F-1 with the SEC in preparation as well as called an AGM to put a resolution before shareholders to issue up to 180 million ordinary shares in the IPO. The process is ongoing.

# 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
30/09/2021	\$0.08	Unlisted	81,937,328
30/06/2026	\$0.05	Unlisted	750,000
30/06/2027	\$0.05	Unlisted	750,000
30/09/2021	\$0.20	Unlisted	200,000,000
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	10,000,000
20/11/2023	\$0.20	Unlisted	10,000,000
20/11/2023	\$0.25	Unlisted	20,000,000

# **Unissued Shares under Option**

As at the date of this report, there were 326,437,328 unissued ordinary shares under options (2020: 626,095,870).

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 286,500,523 ordinary shares issued as a result of the exercise of options (2020: 34,427,321).

# 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 2021.

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 \$115,000 is payable for the financial year ended 30 June 2021 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.

No shares or options have been issued under the ESOP during the year (2020: 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 (2020: nil).

# Executive Employment Contracts

For the year ended 30 June 2021, 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: \$230,000 per annum, plus \$30,000 Board fees, plus superannuation and vehicle allowance of \$19,500.
- Variable remuneration up to 50% of base salary subject to achieving certain performance hurdles
- Grant of 2,952,619 ordinary shares and 2,250,000 options which vest upon continuing tenure. 984,207 ordinary shares and 750,000 options vested on 30 June 2021. All shares and options granted have received shareholder approval.
- Termination for cause: no notice period
- Termination without cause: three-month notice period

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

Table 1: Remuneration of key management personnel (KMP) for the year ended 30 June 2021

 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.
- This represents amounts expensed during FY21 for securities granted during FY20.
- 6) This represents amounts expensed during FY21 for securities granted during FY20.

$\geq$			Short-term based paymen	ts)	Long-term (share based payments)	Post-employment	Total	Performance
		Salary & fees \$	Bonus \$	Other \$	Performance Rights, Shares and Options \$	Superannuation \$	\$	Related %
	Key Management Personnel name							
	Mr Troy Valentine <sup>1</sup>	105,500	-	-	-	3,610	109,110	-
	Mr Peter Widdows <sup>2</sup>	36,000	-	-	-	3,420	39,420	-
	Mr Joel Latham <sup>3</sup>	226,961	90,000	-	53,710 <sup>6</sup>	19,709	390,380	13.8
	Dr Sud Agarwal⁴	119,067	-	-	511,738 <sup>7</sup>	3,246	634,051	80.7
	Mr Alistair Blake <sup>5</sup>	60,673	-	-	-	-	60,673	-
	Total	548,201	90,000	-	565,448	29,985	1,233,634	

Table 2: Remuneration of key management personnel (KMP) for the year ended 30 June 2020

1) Remuneration owed to Mr Valentine at 30 June 2020 is \$11,110 included in accrued expenses.

2) Remuneration owed to Mr Widdows at 30 June 2020 is \$3,420 included in accrued expenses.

3) Mr Latham was appointed as Managing Director on 24 July 2019. Remuneration owed to Mr Latham at 30 June 2020 is \$128,790 included in accrued expenses and leave entitlements.

4) Dr Agarwal was appointed as a director on 24 July 2019. Remuneration owed to Dr Agarwal at 30 June 2020 is \$17,813 is included in accrued expenses.

5) Fees were paid to Alistair Pty Ltd. Mr Blake ceased as a director on 24 July 2019. Mr Blake ceased all employment on 31 October 2019.

6) This represents \$28,456 from the issue of shares and \$25,254 from the issue of options.

7) This represents \$192,000 from the issue of shares and \$130,667 from the issue of options plus \$189,071 from the issue of performance rights. A total of 2,000,000 milestone and 30,303,593 value-based performance rights were issued to Dr Agarwal. Milestone performance rights will convert to ordinary shares on attainment of clinical milestones being achieved prior to 31 January 2021, 28 February 2021, and 31 March 2021. Value-based performance rights will convert to ordinary shares on attainment of the Company's market capitalisation reaching specified levels. These milestones and market capitalisation levels are set out in the Notice of Extraordinary General Meeting of Shareholders that was sent to shareholders and posted on the ASX announcements platform on 26 May 2020.

# **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 2 of these financial statements.

# Performance rights activity for KMP for the year ended 30 June 2021

Performance rights activity for KMP for the year ended 30 June 2021 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:

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

#### 30 June 2021 – Performance Rights

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.

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.

# 30 June 2020 - Performance Rights

Name	Balance at 1 July 2019	Granted/(Expired) by the Company	Converted to Ordinary shares	Balance at 30 June 2020
Mr Troy Valentine	1,833,334	-	(333,334)	1,500,000
Mr Peter Widdows <sup>1</sup>	1,833,334	-	(333,334)	1,500,000
Mr Joel Latham	6,000,000	-	(1,000,000)	5,000,000
Dr Sud Agarwal	-	32,303,593	-	32,303,593
Mr Alistair Blake 1	3,000,000	(3,000,000)	-	-

<sup>1</sup> Mr Blake resigned 24 July 2019.

Options granted to KMP for the year ended 30 June 2021 No options were granted to KMP during the year.

# 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 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 <sup>1</sup>	48,355,557	(41,238,607)	7,116,950	7,116,950
Mr Peter Widdows <sup>1</sup>	3,957,895	(3,300,000)	657,895	657,895
Mr Joel Latham <sup>2</sup>	6,687,500	(1,987,500)	4,700,000	1,700,000
Dr Sud Agarwal <sup>3</sup>	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.

# 30 June 2020 - Options

Name	Balance at 1 July 2019	Other changes during the period	Balance at 30 June 2020 (or on cessation)	Exercisable at 30 June 2020
Mr Troy Valentine	41,238,607	7,116,950	48,355,557	48,355,557
Mr Peter Widdows	3,300,000	657,895	3,957,895	3,957,895
Mr Joel Latham	4,237,500	2,450,000	6,687,500	6,687,500
Dr Sud Agarwal	-	288,000,000	288,000,000	-
Mr Alistair Blake 1	3,855,184	-	3,855,184	3,855,184

<sup>1</sup>Mr Blake resigned 24 July 2019.

Key Management Personnel – Shareholdings

The number of ordinary shares in Incannex Healthcare Limited held by each KMP of the Group during the financial year is as follows:

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 <sup>1</sup>	20,234,248	6,500,000	-	26,734,248
Mr Peter Widdows <sup>1</sup>	12,615,790	3,300,000	-	15,915,790
Mr Joel Latham <sup>2</sup>	11,829,129	6,119,285	-	17,948,414
Dr Sud Agarwal <sup>3</sup>	36,000,000	30,303,593	-	66,303,593

<sup>1</sup>The change relates to ordinary shares acquired upon conversion of options.

 $^2\,\text{Mr}$  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.

<sup>3</sup> Mr Agarwal's changes arise from the conversion of performance rights upon achievement of performance hurdles.

# 30 June 2020 - Shares

Name	Balance held at 1 July 2019 (or on appointment)	Purchases / Other Acquisitions	Sales / Other Disposals	Balance held at 30 June 2020 (or on cessation)
Mr Troy Valentine	19,900,914	333,334	-	20,234,248
Mr Peter Widdows	10,966,666	1,649,124	-	12,615,790
Mr Joel Latham	9,845,795	1,983,334	-	11,829,129
Dr Sud Agarwal	-	36,000,000	-	36,000,000
Mr Alistair Blake <sup>1</sup>	21,282,518	-	-	21,282,518

<sup>1</sup> Mr Blake resigned 24 July 2019.

# Other Key Management Personnel Transactions

There have been no transactions involving equity instruments other than those described in the above tables. Other transactions with key management personnel during the financial year and not disclosed above are noted below:

For the year ended 30 June 2021, \$97,976 (2020: \$145,200) 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. These fees were in addition to Mr Valentine's remuneration disclosed above.

# 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 2021 (2020: \$Nil).

# AUDITOR INDEPENDENCE AND NON-AUDIT SERVICES

Section 307C of the Corporations Act 2001 requires our auditors, HLB Mann Judd, 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 32 and forms part of this directors' report for the year ended 30 June 2021.

Signed in accordance with a resolution of the directors.

Troy Valentine Chairman Melbourne, Victoria, 30 August 2021



# AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the audit of the consolidated financial report of Incannex Healthcare Limited for the year ended 30 June 2021, I declare that to the best of my knowledge and belief, 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.

Perth, Western Australia 30 August 2021

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L Di Giallonardo Partner

#### hlb.com.au

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HLB Mann Judd (WA Partnership) is a member of HLB International, the global advisory and accounting network.

Consolidated

### STATEMENT OF COMPREHENSIVE INCOME

#### For the year ended 30 June 2021

		2021	2020
	Notes	\$	\$
Revenue	3	1,897,596	604,884
Other revenue	3	75,747	217,170
Product costs		(911,968)	(450,345)
Administration expense		(99,093)	(457,673)
Advertising and promotion		(1,136,666)	(406,225)
Research and development costs	4	(4,749,515)	(2,110,639)
Compliance, legal and regulatory		(1,227,243)	(235,163)
Share based payments	18	(600,043)	(565,448)
Occupancy expenses		(115,836)	(2,084)
Salaries and employee benefit expense		(1,296,569)	(523,760)
Loss before tax from continuing operations		(8,163,590)	(3,929,283)
Income tax benefit	6		-
Loss after tax from continuing operations		(8,163,590)	(3,929,284)
Loss after tax from discontinued operations	7		(768,352)
Net loss for the year		(8,163,590)	(4,697,636)
Other comprehensive income		-	-
Total comprehensive loss for the year		(8,163,590)	(4,697,636)
Basic loss per share from continuing and discontinued operations (cents per share)	8	(0.83)	(0.69)
Basic loss per share from continuing operations (cents per share)	8	(0.83)	(0.60)

#### STATEMENT OF FINANCIAL POSITION

#### As at 30 June 2021

		Conso	lidated
		2021	2020
	Notes	\$	\$
Assets			
Current assets			
Cash and cash equivalents	10	9,123,617	3,603,390
Trade and other receivables	11	169,088	413,268
Other assets	12	36,090	36,262
Inventory	13		183,159
Total current assets		9,328,795	4,236,079
Total assets		9,328,795	4,236,079
Liabilities			
Current liabilities			
Trade and other payables	14	755,049	955,006
Other liabilities	15		116,645
Total current liabilities		755,049	1,071,651
Total liabilities		755,049	1,071,651
Net assets		8,573,746	3,164,428
Equity			
Issued capital	16	45,938,576	34,192,043
Reserves	17	3,316,963	1,490,588
Accumulated losses		(40,681,793)	(32,518,203)
Net equity		8,573,746	3,164,428

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### STATEMENT OF CHANGES IN EQUITY

### For the year ended 30 June 2021

Consolidated	Issued Capital	Equity Reserve	Accumulated Losses	Total
	\$	\$	\$	\$
Balance at 1 July 2019	26,951,744	451,643	(27,820,567)	(417,180)
Comprehensive loss for the year	-	-	(4,697,636)	(4,697,636)
Options exercised	1,077,093	-	-	1,077,093
Options issued to advisors	-	449,093	-	449,093
Share based payments	-	589,852	-	589,852
Shares issued	7,105,354	-	-	7,105,354
Shares issue costs	(942,148)	-	-	(942,148)
Balance at 30 June 2020	34,192,043	1,490,588	(32,518,203)	3,164,428
Comprehensive loss for the year	-	-	(8,163,590)	(8,163,590)
Options exercised	12,498,706	-	-	12,498,706
Options issued to advisors	-	572,136	-	572,136
Share based payments	-	600,043	-	600,043
Shares issue costs	(752,173)	654,196	-	(97,977)
Balance at 30 June 2021	45,938,576	3,316,963	(40,681,793)	8,573,746

### STATEMENT OF CASH FLOWS

For the year ended 30 June 2021

		Conso	idated
		2021	2020
	Notes	\$	\$
Cash flows from operating activities			
Receipts from customers		2,006,325	1,389,254
Payments to suppliers and employees		(9,013,852)	(5,299,667)
Interest received and other income		97,247	3,079
Net cash (used in) operating activities	10	(6,910,280)	(3,907,334)
Cash flows from investing activities			
Proceeds from disposal of subsidiary		29,277	-
Proceeds from disposal of property, plant and equipment		-	13,000
Net cash from investing activities		29,277	13,000
Cash flows from financing activities			
Proceeds from shares issued (net of costs)		12,401,230	7,469,392
Debt repaid		-	(65,000)
Net cash from financing activities		12,401,230	7,404,392
Net increase in cash and cash equivalents		5,520,227	3,510,058
Cash and cash equivalents at beginning of the year		3,603,390	93,332
Cash and cash equivalents at end of the year	10	9,123,617	3,603,390

### NOTES TO THE FINANCIAL STATEMENTS

#### For the year ended 30 June 2021

#### 1. Significant accounting policies

These financial statements are general purpose financial statements that have been prepared in accordance with Australian Accounting Standards, Australian Accounting Interpretations and the *Corporations Act 2001*, as appropriate for-profit oriented entities.

The financial statements cover the Company and the entities it controlled during the year for the year ended 30 June 2021. The Company is a company limited by shares, incorporated and domiciled in Australia.

The principal activities of the Group for the year were:

- (1) Research, development and sales of medicinal cannabinoid products.
- (2) On 20 November 2020 the Group established a separate business to research and develop the use of psychedelic medicine and therapies for the treatment of mental health disorders.

Except for the Statement of Cash Flows, the financial statements have been prepared on the accruals basis.

The financial statements were authorised for issue by the Directors on 30 August 2021.

#### 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 Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period. This has had no material effect on the Group.

#### Historical cost convention

The financial statements have been prepared under the historical cost convention, modified where appropriate by the measurement of fair value of selected non-current assets. All amounts are presented in Australian dollars unless otherwise noted.

#### Critical accounting estimates

The preparation of the 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 financial statements, are disclosed in note 2.

#### Comparatives

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

#### Parent entity information

In accordance with the Corporations Act 2001, these financial statements present the results of the Group only. Supplementary information about the parent entity is disclosed in note 25.

#### **Principles of consolidation**

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Incannex Healthcare Limited ('company' or 'parent entity') as at 30 June 2021 and the results of all subsidiaries for the year then ended. Incannex Healthcare Limited and its subsidiaries together are referred to in these financial statements as the 'Group'.

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, balances and unrealised gains on transactions between entities in the Group are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

The acquisition of subsidiaries is accounted for using the acquisition method of accounting. A change in ownership interest, without the loss of control, is accounted for as an equity transaction, where the difference between the consideration transferred and the book value of the share of the non-controlling interest acquired is recognised directly in equity attributable to the parent.

Non-controlling interest in the results and equity of subsidiaries are shown separately in the statement of profit or loss and other comprehensive income, statement of financial position and statement of changes in equity of the Group. Losses incurred by the Group are attributed to the non-controlling interest in full, even if that results in a deficit balance.

Where the Group loses control over a subsidiary, it derecognises the assets including goodwill, liabilities and noncontrolling interest in the subsidiary together with any cumulative translation differences recognised in equity. The Group recognises 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 using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers ('CODM'). The CODM is responsible for the allocation of resources to operating segments and assessing their performance.

### Foreign currency translation

The financial statements are presented in Australian dollars, which is Incannex Healthcare Limited'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 recognised in profit or loss.

#### **Revenue recognition**

The Group recognises revenue as follows:

### Revenue from contracts with customers

Revenue is recognised at an amount that reflects the consideration to which the Group is expected to be entitled in exchange for transferring goods or services to a customer. For each contract with a customer, the Group: identifies the contract with a customer; identifies the performance obligations in the contract; determines the transaction price which takes into account estimates of variable consideration and the time value of money; allocates the transaction price to the separate performance obligations on the basis of the relative stand-alone selling price of each distinct good or service to be delivered; and recognises revenue when or as each performance obligation is satisfied in a manner that depicts the transfer to the customer of the goods or services promised.

Variable consideration within the transaction price, if any, reflects concessions provided to the customer such as discounts, rebates and refunds, any potential bonuses receivable from the customer and any other contingent events. Such estimates are determined using either the 'expected value' or 'most likely amount' method. The measurement of variable consideration is subject to a constraining principle whereby revenue will only be recognised to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. The measurement constraint continues until the uncertainty associated with the variable consideration is subsequently resolved. Amounts received that are subject to the constraining principle are recognised as a refund liability.

#### Sale of goods

Revenue from the sale of goods is recognised at the point in time when the customer obtains control of the goods, which is generally at the time of delivery.

#### Interest and Other revenue

Interest revenue is recognised when it is received or when the right to receive it is established.

#### 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 recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised 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 liabili
  transaction that is not a business combination and that, at the time of the transaction, affects neither the accounti
  taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, a timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the forese future.

Deferred tax assets are recognised 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 recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised 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 unrecognised deferred tax assets are recognised 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.

### **Discontinued operations**

A discontinued operation is a component of the Group that has been disposed of or is classified as held for sale and that represents a separate major line of business or geographical area of operations, is part of a single co-ordinated plan to dispose of such a line of business or area of operations, or is a subsidiary acquired exclusively with a view to resale. The results of discontinued operations are presented separately on the face of the statement of comprehensive income.

### 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 always classified as non-current.

#### Cash and cash equivalents

Cash and cash equivalents includes cash on hand, 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. For the statement of cash flows presentation purposes, cash and cash equivalents also includes bank overdrafts, which are shown within borrowings in current liabilities on the statement of financial position.

### Trade and other receivables

Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any allowance for expected credit losses. Trade receivables are generally 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 recognised at amortised cost, less any allowance for expected credit losses.

### Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realisable value on a 'first in first out' basis. Cost comprises of direct materials and delivery costs, direct labour, import duties and other taxes, an appropriate proportion of variable and fixed overhead expenditure based on normal operating capacity, and, where applicable, transfers from cash flow hedging reserves in equity. Costs of purchased inventory are determined after deducting rebates and discounts received or receivable.

Stock in transit is stated at the lower of cost and net realisable value. Cost comprises of purchase and delivery costs, net of rebates and discounts received or receivable.

Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

### 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 derecognised 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 of a financial asset, it's carrying value is written off.

### Financial assets at fair value through profit or loss

Financial assets not measured at amortised cost or at fair value through other comprehensive income are classified as financial assets at fair value through profit or loss. Typically, such financial assets will be either: (i) held for trading, where they are acquired for the purpose of selling in the short-term with an intention of making a profit, or a derivative; or (ii) designated as such upon initial recognition where permitted. Fair value movements are recognised in profit or loss.

### Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income include equity investments which the Group intends to hold for the foreseeable future and has irrevocably elected to classify them as such upon initial recognition.

#### Impairment of financial assets

The Group recognises a loss allowance for expected credit losses on financial assets which are either measured at amortised cost or fair value through other comprehensive income. The measurement of the loss allowance depends upon the Group's assessment at the end of each reporting period as to whether the financial instrument's credit risk has increased significantly since initial recognition, based on reasonable and supportable information that is available, without undue cost or effort to obtain.

Where there has not been a significant increase in exposure to credit risk since initial recognition, a 12-month expected credit loss allowance is estimated. This represents a portion of the asset's lifetime expected credit losses that is attributable to a default event that is possible within the next 12 months. Where a financial asset has become credit impaired or where it is determined that credit risk has increased significantly, the loss allowance is based on the asset's lifetime expected credit losses. The amount of expected credit loss recognised is measured on the basis of the probability weighted present value of anticipated cash shortfalls over the life of the instrument discounted at the original effective interest rate.

For financial assets mandatorily measured at fair value through other comprehensive income, the loss allowance is recognised in other comprehensive income with a corresponding expense through profit or loss. In all other cases, the loss allowance reduces the asset's carrying value with a corresponding expense through profit or loss.

#### 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.

### Patents and trademarks

Significant costs associated with patents and trademarks are deferred and amortised on a straight-line basis over the period of their expected benefit, being their finite life of 10 years.

#### Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year 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.

#### Borrowings

Loans and borrowings are initially recognised at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortised cost using the effective interest method.

#### Lease liabilities

A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.

Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

#### **Finance costs**

Finance costs attributable to qualifying assets are capitalised as part of the asset. All other finance costs are expensed in the period in which they are incurred.

#### Provisions

Provisions are recognised 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 recognised 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 recognised 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 the Binomial 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. No account is taken of any other vesting conditions.

The cost of equity-settled transactions are recognised 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 recognised in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognised 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 recognised as if the modification has not been made. An additional expense is recognised, 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 recognised 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 recognised 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 or liability, 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 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 or liability, 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 and liabilities 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. 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.

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 recognised when declared during the financial year and no longer at the discretion of the company.

### Earnings/(loss) per share

#### Basic earnings/(loss) per share

Basic earnings/(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 year, adjusted for bonus elements in ordinary shares issued during the financial year.

### Diluted earnings/(loss) per share

Diluted earnings/(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.

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

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised 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, or payable to, the tax authority is included in other receivables or other payables 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 flows.

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

### New Accounting Standards and Interpretations not yet mandatory or early adopted

Australian Accounting 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 period ended 30 June 2021. The directors are satisfied that these standards will not have a material impact on the Group.

#### 2. Critical accounting judgements, estimates and assumptions

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the 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 (refer to the respective notes) 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. Other than as addressed in specific notes, there does not currently appear to be either any significant impact upon the 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, where the value of services cannot be reliably measured, 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. Refer to note 18 for further information.

### 3. Revenue

	Conso	olidated
(a) Revenue (point in time)	2021 \$	2020 \$
Cannabinoid oils sales	1,897,596	604,884
	1,897,596	604,884
(b) Other income		
Revenue from other contractual arrangements	35,568	123,125
Government grants	37,500	89,500
Interest	2,679	4,545
	75,747	217,170
. Expenses		
Leases		
Short term lease payments	86,703	47,352
Include in Employee expenses:		
Director fees	150,000	108,567
Superannuation (defined contribution scheme)	66,694	72,042
Research costs		
Research costs (Pharmaceutical)	1,790,805	1,746,191
Clinical trials (Pharmaceutical)	2,043,923	174,536
Consulting fees (Pharmaceutical)	4,005	189,912
Research costs (Psychotherapy)	142,712	-
Clinical trials (Psychotherapy)	668,070	-
Consulting fees (Pyschotherapy)	100,000	-
	4,749,515	2,110,639

### 5. Segment Information

### Identification of reportable operating segments

AASB 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 Operating Decision Maker 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 Operating Decision maker 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 Operating Decision Maker.

Based on the quantitative thresholds included in AASB 8, for the financial year ended 30 June 2021, the Group was organised into three operating segment:

 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.

- Research, development and sale of medicinal cannabinoid products. During the year the Group generated revenue from sales of pharmaceutical products, and continued to research and develop its products and the range of its products, including further clinical trials.
- 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 period for each segment is shown below.

30 June 2021	Psychedelic products	Cannabinoid Products	Corporate	Consolidated
	\$	\$	\$	\$
Revenue from external				
customers	-	1,897,596 <sup>1</sup>	-	1,897,596
Interest revenue	-	6	2,673	2,679
Other revenue	-	-	73,068	73,068
Other expenses	(768,316)	(5,202,370)	(4,166,247)	(10,136,933)
Segment loss after income				
tax	(768,316)	(3,304,768)	(4,090,506)	(8,163,590)
Segment assets	2,000	104,267	9,222,528	9,328,795
beginent assets	2,000	104,207	3,222,320	5,520,755
Segment liabilities	-	(86,522)	(668,527)	(755,049)
30 June 2020	Oral and Dental Devices	Pharmaceuti cals	Unallocated	Consolidated
	(discontinued)	•••••		
Revenue from external	(**********			
customers	718,656	604,884 <sup>1</sup>	-	1,446,665
Interest revenue	8	2	4,544	4,555
Other revenue	140,816	212,625	-	230,316
Depreciation	(14,854)	-	-	(14,854)
Amortisation	(21,688)	-	-	(21,688)
Other expenses	(1,591,290)	(2,899,761)	(1,851,578)	(6,342,630)
Segment loss after income				
tax	(768,352)	(2,082,250)	(1,847,034)	(4,697,636)
Segment assets	-	662,414	3,573,665	4,236,079
Segment liabilities	-	(567,423)	(504,228)	(1,071,651)

<sup>1</sup> Of the total revenue from pharmaceuticals in each year, 100% was through Cannvalate Pty Ltd's distribution network.

3,872,022

### 6. 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:

financial statements as follows:	Consc	olidated
	2021 \$	2020 \$
Accounting loss before tax	(8,163,590)	(4,697,636)
Income tax benefit at the applicable tax rate of 27.5%		
(2020: 27.5%)	2,244,987	1,291,850
Non-deductible expenses	(322,211)	(155,498)
Non-assessable income	10,313	
Deferred tax assets not recognised	(1,933,089)	(1,136,352)
Income tax benefit		-
Unrecognised Deferred Tax Asset		
Deferred tax asset not recognised in the financial statements:		
Unused tax losses	21,109,495	14,080,080

Net unrecognised tax benefit at 27.5% (2020: 27.5%)

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

5,805,111

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.

#### . Discontinued operations

#### Description

On 30 June 2020 the Group sold its 100% subsidiary - Gameday International Pty Ltd ("Gameday"), for consideration of \$29,277 which was the carrying value of its assets at that date so no loss on disposal was incurred. Gameday produced and sold the Group's dental devices and had been a loss maker since 2016. As a result of the COVID-19 pandemic it suffered further as a result of the shut-down of community sport which directly affected the sale of its main product being sporting mouthguards. The disposal of Gameday will allow the Group to pursue and focus entirely on its medicinal cannabis activities.

### 8. Loss per share

	Consolidated	
	2021	2020
Basic loss per share – continuing and discontinued operations - cents per share	(0.83)	(0.69)
Basic loss per share – continuing operations - cents per share	(0.83)	(0.60)
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:		
- Loss from continuing and discontinued operations (\$)	(8,163,590)	(4,697,636)
- Loss from continuing operations (\$)	(8,163,590)	(4,075,011)
<ul> <li>Weighted average number of ordinary shares (number)</li> </ul>	978,017,743	684,035,399
9. Dividends		

The Company has not declared a dividend for the year ended 30 June 2021 (2020: \$nil).

### 10. Cash and cash equivalents

	Consolid	Consolidated		
	2021 \$	2020 \$		
Cash at bank and on hand	9,123,617	3,603,390		
	9,123,617	3,603,390		

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:

Loss after income tax	(8,163,590)	(4,697,636)
Non-cash based expenses:		
Share-based payments	1,171,677	565,448
Depreciation and amortisation	-	36,542
Other non-cash expenses	91,355	97,221
Changes in net assets and liabilities:		
(Increase)/Decrease in receivables	214,903	(315,484)
(Increase)/Decrease in inventory	183,159	(30,355)
Decrease in other current assets	172	2,928
(Increase)/Decrease in trade payables and accrued expenses	(291,311)	464,223
Increase/(Decrease) in other liabilities	(116,645)	(30,221)
Cash flows used in operations	(6,910,280)	(3,907,334)

# 11. Trade and other receivables (Current)

Current	Consolidated		
	2021 \$	2020 \$	
Receivables	53,447	276,151	
GST recoverable	115,641	137,117	
	169,088	413,268	

### **Expected credit losses**

The Group applies the AASB 9 simplified model of recognising 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.

12. Other assets (current)		
Prepayments	36,090	11,083
Office rental bond	-	25,179
	36,090	36,262
13. Inventories		
Current		
Medicinal cannabis products in-transit, at cost	-	183,159
Total inventories	-	183,159
14. Trade and other payables (current)		
Trade payables	233,117	590,099
Accrued expenses	381,717	316,046
Employee leave entitlements	140,215	48,861
	755,049	955,006
15. Other current liabilities		
Provision for sales refunds	-	116,645
	-	116,545
Movement in provision:		
Opening balance	116,545	-
Provision made	-	116,545
Repayments made	(101,061)	-
Provision written off	(15,484)	-
	-	116,545

### 16. Issued capital

			Consolidate 2021	ed 2020
			\$	\$
Issued Capital			45,938,576	34,192,043
(a) Ordinary shares - movements d	uring year			
	Year ended 30	June 2021	Year ended 30	) June 2020
	No. of shares	\$	No. of shares	\$
At start of year	748,654,489	34,192,043	581,897,040	26,951,744
Issues of new shares – placements	-	-	114,663,460	7,105,354
lssues of new shares – share based payments	2,952,619	-	5,750,000	-
Conversion of performance rights	30,303,593	-	11,916,668	-
Exercise of options	286,500,523	12,498,706	34,427,321	1,077,093
Cost of issuing shares	-	(752,173)	-	(942148)
At end of year	1,068,411,224	45,938,576	748,654,489	34,192,043

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.

#### (b) Movement in number of options on issue for the year

#### At 30 June 2021

Expiry date	Balance at start	Granted	Exercised /	Balance at end
and exercise price	of year	during	(expired)	of year
		year	during year	
30-Sep-2020 \$0.04 IHLOB	260,533,407	-	(260,533,407)	-
01-Dec-2020 \$0.06 unlisted <sup>1</sup>	14,000,000	-	(14,000,000)	-
01-Dec-2020 \$0.08 unlisted <sup>1</sup>	16,000,000	-	(16,000,000)	-
01-Dec-2020 \$0.10 unlisted <sup>1</sup>	18,000,000	-	(18,000,000)	-
01-Dec-2020 \$0.12 unlisted <sup>1</sup>	20,000,000	-	(20,000,000)	-
01-Dec-2020 \$0.14 unlisted <sup>1</sup>	20,000,000	-	(20,000,000)	-
30-Sep-2021 \$0.08 unlisted <sup>2</sup>	89,919,705	30,164,690	(25,967,116)	94,117,279
30-Sep-2021 \$0.20 unlisted	200,000,000	-	-	200,000,000
30-Jun-2025 \$0.05 unlisted <sup>3</sup>	750,000	750,000	-	1,500,000
30-Jun-2026 \$0.05 unlisted <sup>3</sup>	750,000	750,000	-	1,500,000
30-Jun-2027 \$0.05 unlisted <sup>3</sup>	750,000	750,000	-	1,500,000
20-Nov-2023 \$0.15 unlisted <sup>4</sup>	-	10,000,000	-	10,000,000
20-Nov-2023 \$0.20 unlisted <sup>5</sup>	-	10,000,000	-	10,000,000
20-Nov-2023 \$0.25 unlisted <sup>4,5</sup>	-	20,000,000	-	20,000,000
Total	640,703,112	72,414,690	(374,500,523)	338,617,279
Weighted average price (\$)	\$0.104	\$0.152	\$0.058	\$0.166

<sup>1</sup> Options lapsed were previously issued to settle outstanding invoices. See note 18, page 54.

<sup>2</sup> 30,164,690 options were issued to brokers who supported the exercise of the IHLOB series of listed options and the associated shortfall.

<sup>3</sup> 2,250,000 options were issued to the Company's Chief Executive Officer (Mr Joel Latham), after approval by shareholders on 26 June 2020. The options were granted in FY2020.

<sup>4</sup> 10,000,000 \$0.15 and 10,000,000 \$0.25 options were issued to Canary Capital per the ASX announcement of November 2020.

<sup>5</sup> 10,000,000 \$0.20 and 10,000,000 \$0.25 options were issued to EAS Advisors per the ASX announcement of February 2021.

At 30 June 2020				
Expiry date	Balance at start	Granted	Expired	Balance at end
and exercise price	of year	during year	during year	of year
30-Sep-2020 \$0.04 IHLOB	262,960,728	-	(2,427,321)	260,533,407
01-Jan-2020 \$0.02 unlisted <sup>1</sup>	-	10,000,000	(10,000,000)	-
01-May-2020 \$0.03 unlisted <sup>1</sup>	-	10,000,000	(10,000,000)	-
01-May-2020 \$0.04 unlisted <sup>1</sup>	-	12,000,000	(12,000,000)	-
01-Dec-2020 \$0.06 unlisted <sup>1</sup>	-	14,000,000	-	14,000,000
01-Dec-2020 \$0.08 unlisted <sup>1</sup>	-	16,000,000	-	16,000,000
01-Dec-2020 \$0.10 unlisted <sup>1</sup>	-	18,000,000	-	18,000,000
01-Dec-2020 \$0.12 unlisted <sup>1</sup>	-	20,000,000	-	20,000,000
01-Dec-2020 \$0.14 unlisted <sup>1</sup>	-	20,000,000	-	20,000,000
30-Sep-2021 \$0.08 unlisted <sup>2</sup>	-	89,919,705	-	89,919,705
30-Sep-2021 \$0.20 unlisted <sup>3</sup>	-	200,000,000	-	200,000,000
30-Jun-2025 \$0.05 unlisted <sup>4</sup>	-	750,000	-	750,000
30-Jun-2026 \$0.05 unlisted <sup>4</sup>	-	750,000	-	750,000
30-Jun-2027 \$0.05 unlisted <sup>4</sup>	-	750,000	-	750,000
Total	262,960,728	412,169,705	(34,427,321)	640,703,112
Weighted average price (\$)	\$0.04	\$0.139	\$0.031	\$0.104

<sup>1</sup> A total of 120,000,000 options were issued to Cannvalate Pty Ltd upon approval by shareholders on 9 August 2019.

<sup>2</sup> 22,368,422 options were issued to participants of the July 2019 equity capital raisings attaching to shares subscribed for under those raisings and 33,000,000 options were issued to brokers who supported those equity capital raisings. A further 34,551,283 options were issued to participants of the October 2019 capital raising attaching to shares subscribed for under that raising. <sup>3</sup> 200,000,000 options were issued as remuneration for the Company's Chief Medical Officer (Dr Sud Agarwal), after approval by

shareholders on 26 June 2020.

<sup>4</sup> 2,250,000 options were issued as FY20 remuneration for the Company's Chief Executive Officer (Mr Joel Latham), after approval by shareholders on 26 June 2020.

#### (C) Movement in number of Performance Shares and Performance Rights for the year

#### At 30 June 2021

Security Description	Balance at start of year	Granted by the Company	Converted or Expired	Balance at end of year
Performance Rights <sup>1</sup>	41,553,593	-	(41,553,593)	-

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

#### At 30 June 2020

Security Description	Balance at start of year	Granted by the Company	Converted or Expired	Balance at end of year
Performance Rights	24,166,668	32,303,593	(14,916,668)	41,553,593
Performance Shares	20,000,002	-	(20,000,002)	-

### 17. Reserves

Equity based premium reserve	Consoli	dated
	\$	\$
Balance at 1 July 2020	1,490,588	451,643
Options issued to advisors <sup>1</sup>	1,226,332	449,093
Options issued to Cannvalate Pty Ltd	-	244,403
Equity instruments issued to management and directors	600,043	345,449
At 30 June 2021	3,316,963	1,490,588

<sup>1</sup> 30,164,690 options were issued to brokers who supported the exercise of the IHLOB series of listed options and the associated shortfall.

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

#### 18. 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.

#### Fair value of options and performance rights granted

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-based payment arrangements were put into place during the period:

Options	Number	Grant Date <sup>2</sup>	Expiry Date	Exercise Price	Total fair value	Expensed fair value
Unlisted options (series 1)	10,000,000	20-Nov- 2020	20-Nov- 2023	\$0.15	\$659,400	\$133,687
Unlisted options (series 2)	10,000,000	20-Nov- 2020	20-Nov- 2023	\$0.25	\$539,500	\$109,378
Unlisted options (series 3)	10,000,000	25-Feb- 2021	20-Nov- 2023	\$0.20	\$1,361,800	\$170,566
Unlisted options (series 4)	10,000,000	25-Feb- 2021	20-Nov- 2023	\$0.25	\$1,261,500	\$158,003
Total options					•	\$571,634

The share options were issued to consultants providing investor relations to the Group.

The fair value of the equity-settled share options granted in the above table 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:

	Series 1 20-Nov-2023	Series 2 20-Nov-2023	Series 3 20-Nov-2023	Series 4 20-Nov-2023
Number	10,000,000	10,000,000	10,000,000	10,000,000
Dividend yield (%)	0%	0%	0%	0%
Expected volatility (%)	100%	100%	100%	100%
Risk-free interest rate (%)	2%	2%	2%	2%
Expected life of option (years)	3	3	2.5	2.5
Exercise price (cents)	15.0	25.0	20.0	25.0
Grant date share price (cents)	11.5	11.5	22	22
Vesting date	30-Nov-2023	30-Nov-2023	30-Nov-2023	30-Nov-2023

The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

### Share based payment expense

As at 30 June 2020 the Group had a number of securities on issue or unissued but granted that had either not completed all vesting conditions or had yet to reach performance hurdles. These included:

- (a) 88,000,000 unlisted options previously issued with various performance hurdles set for achievement prior to expiry on 1 December 2020. The performance hurdles were not met and the options lapsed. The amount previously expensed of \$72,656 has been reversed during the current year.
- (b) 1,166,666 ordinary shares approved by shareholders on 26 June 2020. Half of these vested upon the CEO continuing employment with the Company on 30 June 2021. The other half vests upon the CEO continuing employment with the Company at 30 June 2022.
- (c) 1,500,000 options with a strike price of \$0.05 (750,000 expiring 30 June 2025 and 750,000 expiring 30 June 2026) were issued along with the ordinary shares, with the same vesting conditions as in (b).
- (d) 2,952,619 ordinary shares vesting in three tranches upon CEO continued employment at 30 June 2021, 30 June 2022 and 30 June 2023.
- (e) 2,250,000 unlisted shares options vesting in three tranches as in (d).
- (f) 18,266,328 value-based performance rights with an expiry date of 22 November 2021, achieved the milestone attached during the year and were converted to ordinary shares during the year. The full expense has been recognised accordingly.
- (g) 12,037,265 value-based performance rights with milestone achieved during the year, and expensed in full accordingly.
- (h) 2,000,000 milestone-based performance rights subject to performance hurdles to be met between January and March 2021 were forfeited during the year as those hurdles were not met.
- (i) 200,000,000 unlisted options vesting upon the achievement of a share price of \$0.20, expiring on 30 September 2021.

Expensed during the current year:

Description	Expense 30 June 2020	Current year expense/(reversal)	To be expensed
	\$	\$	\$
88,000,000 unlisted options <sup>1</sup>	72,656	(72,656)	-
1,166,666 ordinary shares	456	41,620	13,924
1,500,000 unlisted share options	438	39,938	13,801
2,952,619 ordinary shares	961	87,702	56,015
2,250,000 unlisted share options	531	48,452	23,295
18,266,328 value-based performance rights	127,235	190,059	-
12,037,265 value-based performance rights	60,964	91,066	-
2,000,000 milestone-based performance rights	1,341	(1,341)	-
200,000,000 unlisted share options	131,096	175,203	-
Total		600,043	

<sup>1</sup> These options lapsed during the year. The value of the lapsed options, previously issued to settle outstanding invoices, was \$72,656.

Refer note 16(b) for all options in place during the year.

The weighted average contractual life of the options at 30 June 2021 was 0.5 years.

#### 19. Remuneration of auditors

Audit or review of the financial reports of the company	Consoli	dated
Amounts received & receivable by the auditor:	2021 \$	2020 \$
Audit services – HLB Mann Judd	43,000	37,000
Audit services – Withum Smith & Brown (US auditor)	-	-
Other services – Withum Smith & Brown (US auditor)	287,975	-
	330,975	37,000

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 audit of US GAAP compliant financial statements, along with advisory work in relation to the listing of securities.

#### 20. 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.

Details of the significant accounting policies and methods adopted, including the criteria for recognition, the basis of measurement and the basis on which income and expenses are recognised, in respect of each class of financial asset, financial liability and equity instrument are disclosed in note 1 to the financial statements.

#### (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.

906,145

### (b) Sensitivity analysis

During 2021, 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 recognised 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 2021 were as follows:

906,145

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
he Group's contractual I	ichilitics at 20 June	~~~~			
ne Group S contractuar i	abilities at 30 June	2020 were as	s follows:		
Description	Less than 1 month	2020 were as 1 to 3 months	s follows: 3 months to 1 year	1 to 5 years	Total
•	Less than 1	1 to 3	3 months to	1 to 5 years \$	Total \$

#### (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 past activities, being mineral exploration, 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 and unsecured convertible notes. Accordingly, the objective of the Group's capital risk management is to balance the current working capital position against the requirements to meet exploration 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.

### 21. Commitments and contingencies

#### **Operating lease commitments – group as lessee**

The Company leases premises on a short term basis, and has no material commitments arising from lease arrangements.

#### 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.

## 22. 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

### Key management personnel compensation

	Consolidated		
	2021	2020	
	\$	\$	
Short-term employee benefits	761,231	638,201	
Post-employment benefits	38,877	29,985	
Share based payments	672,699	565,448	
Total KMP compensation	1,472,807	1,233,634	

### 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, \$97,976 (2019: \$145,200) 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.

### 23. Details of the controlled entity

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 was incorporated in Australia on 30 November 2018 and IHL owns 100% of the issued ordinary shares in IXPL (2020: 100%).
- PXPL was incorporated on 30 November 2020 in Australia and IHL owns 100% of the issued ordinary shares in PXPL.
- On 30 June 2020, the Group disposed entirely of its 100% subsidiary Gameday International Pty Ltd, ('Gameday').

### 24. Events Subsequent to Reporting Date

On 21 July 2021, the Company issued 239,103 ordinary shares upon the exercise of unlisted options by option holders with an exercise price of \$0.08 per share, receiving \$19,128 upon conversion.

The Company issued a further 2,739,662 ordinary shares on the exercise of of "IHLAH" share options at an exercise price of \$0.08 per share on 16 August 2021, raising \$219,713.

On 18 August 2021 the Company announced that its public filing of Form F-1 with the Securities Exchange Commission ("SEC") in the US, in preparation for the for a proposed listing on the NASDAQ. An extraordinary General Meeting has been called on 17 September 2021 to put a resolution to shareholders to issue up to 180 million ordinary shares in relation to the proposed Initial Public Offering ("IPO") in the US.

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

### 25. Parent entity disclosures

The individual financial statements for the parent entity show the following aggregate amounts. The information presented has been prepared using accounting policies as discussed in Note 1.

Statement of financial position	2021	2020
	\$	\$
Current assets	9,222,528	3,573,665
Non-current assets		-
Total assets	9,222,528	3,573,665
Current liabilities	(668,527)	(504,228)
Non-current liabilities		-
Total liabilities	(668,527)	(504,228)
Net assets	8,554,001	2,237,151
Issued capital	45,938,576	34,192,043
Reserves	3,316,963	1,490,588
Accumulated losses	(40,701,538)	(32,613,194)
Shareholders' equity	8,554,001	2,237,151
Statement of profit or loss and other comprehensive incom	ne	
Loss after income tax	(8,088,344)	(12,115,578)
Total comprehensive loss	(8,088,344)	(12,115,578)

### **Contingencies of the Parent Entity**

There are no contingent liabilities involving the parent entity (2020: Nil).

### **Guarantees of the Parent Entity**

There are no guarantees involving the parent entity (2020: Nil)

### **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 2021 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 2021.

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

Troy Valentine Chairman 30 August 2021



### INDEPENDENT AUDITOR'S REPORT

To the members of Incannex Healthcare Limited

### Report on the Audit of the Financial Report

#### Opinion

We have audited the financial report of Incannex Healthcare Limited ("the Company") and its controlled entities ("the Group"), which comprises the consolidated statement of financial position as at 30 June 2021, 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, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- a) giving a true and fair view of the Group's financial position as at 30 June 2021 and of its financial performance for the year then ended; 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 are independent of the Group 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* ("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.

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

#### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were 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 these matters.

We have determined the matters described below to be the key audit matters to be communicated in our report.

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#### HLB Mann Judd (WA Partnership) ABN 22 193 232 714

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Key Audit Matter	How our audit addressed the key audit matter
Revenue Recognition Refer to Note 3 <i>Revenue</i>	
A substantial amount of the Group's revenue relates to the sale of medical cannabinoid products and oils. Revenue recognition was a key audit matter due to the importance of the matter to users' understanding of the financial report.	<ul> <li>Our procedures included but were not limited to:</li> <li>We evaluated management's processes and key controls regarding accounting for the Group's sales revenues;</li> <li>We ensured that the Group's accounting policies comply with Australian Accounting Standards; and</li> <li>We performed testing over a sample of revenue transactions and agreed these transactions to supporting evidence.</li> </ul>
Valuation of Share Based Payments Refer to Note 18 Share based payments	
The securities issued to directors, advisors and brokers as part of their remuneration was a complex area of accounting and valuation. The securities issued to directors, advisors and brokers included market-based performance rights and non-market-based options, requiring different accounting methodologies and valuation techniques.	<ul> <li>Our procedures included but were not limited to:</li> <li>We assessed management's valuation, classification and calculation of each category of share based payments; and</li> <li>We ensured that the accounting for, and disclosure of, the share based payments complied with Australian Accounting Standards.</li> </ul>
Valuation of share based payments was a key audit matter due to the complex nature of the valuation principles and the material amount of the resulting expense.	

Information other than the financial report and auditor's report thereon

The directors are responsible for the other information. The other information comprises the information included in the Group's annual financial report for the year ended 30 June 2021, 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 accordingly 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.

### Responsibilities of the directors 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 ability of the Group 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 Group 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 the 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 the 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 Group'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 Group'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 Group 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.

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, related safeguards.

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**

### **Opinion on the Remuneration Report**

We have audited the Remuneration Report included within the directors' report for the year ended 30 June 2021.

In our opinion, the Remuneration Report of Incannex Healthcare Limited for the year ended 30 June 2021 complies with section 300A of the *Corporations Act 2001*.

### Responsibilities

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.

HLB Mann Judd

HLB Mann Judd Chartered Accountants

Perth, Western Australia 30 August 2021

Arallondo L Di Giallonardo

Partner

### CORPORATE GOVERNANCE STATEMENT

Incannex Healthcare Limited, ("IHL" or "the Company") and its controlled entities (the "Group") have adopted the corporate governance framework and practices set out in this statement. The Board of the Company is responsible for its corporate governance, that is, the system by which the Group is managed. The corporate governance framework and practices have been in place throughout the financial year and comply with the third edition of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations ("Recommendations"), unless otherwise stated below.

This statement has been approved by the Board, and the information in the statement remains current as at 30 August 2021. Company policies and charters are available in the 'Investors' section of the Company's website at <a href="http://www.incannex.com.au">www.incannex.com.au</a>

### Principle 1: Lay Solid Foundations for Management and Oversight

#### 1.1 Role of the Board and Management

The Board is responsible for evaluating and setting the strategic direction for the Group, establishing goals formanagement and monitoring the achievement of those goals.

The Board has responsibility for the following:

- appointing and removing the Chief Executive Officer ("CEO") and Managing Director, Chief Financial Officer ("CFO"), Company Secretary and any other executives and approving their remuneration;
- determining the strategic direction of the Group and measuring performance of management against approved strategies;
- review of the adequacy of resources for management to properly carry out approved strategies and business plans;
- adopting operating and capital expenditure budgets at the commencement of each financial year, approving acquisitions and divestitures, and monitoring progress by both financial and nonfinancial key performance indicators;
- monitoring the Group's medium-term capital and cash flow requirements;
- approving and monitoring financial and other reporting to regulatory bodies, shareholders and other organisations;
- determining that satisfactory arrangements are in place for auditing the Group's financial affairs;
- reviewing and ratifying systems of risk management and internal compliance and control, codes
  of conduct and compliance with legislative requirements; and
- ensuring that policies and compliance systems consistent with the Group's objectives and best
  practice are in place and that the Company and its officers act legally, ethically and responsibly on all
  matters.

The Board's role and the Group's corporate governance practices are continually reviewed and improved as required.

#### 1.2 Information on New Directors

The Company has access to an external supplier to undertake appropriate checks on any potential director appointments. Under the Company's Constitution, all directors appointed throughout the year as an additional director or to fill a casual vacancy hold office to the AGM. Current directors hold office and are required to beconsidered by Shareholders for re-election under the Listing Rules.

All directors, whether appointed throughout the year as an additional director or to fill a casual vacancy or who are due for election under the Listing Rules, are disclosed in the Notice of AGM, with all material information in its possession relevant to a decision on whether or not to elect or re-elect a director. The company's constitution provides that at each annual general meeting, one third of the Board (other than any managing director in office from time to time) or, if their number is not a multiple of three, the number nearest to one third, must retire and, if the retiring directors so chose, may offer themselves for re-election.

#### 1.3 Contracts with Directors

On appointment, directors are provided with a formal letter of appointment and executive management with written employment agreements incorporating job descriptions (where relevant).

### 1.4 Professional Advice

The Board has determined that individual directors have the right in connection with their duties and responsibilities as directors, to seek independent professional advice at the Group's expense. The engagement of an outside adviser is subject to prior approval of the Chairman, and this will not be withheld unreasonably. If appropriate, any advice so received will be made available to all Board members.

The finance function is outsourced to an external consultant with appropriate skills. The company secretarial function is currently performed by Madhukar Bhalla. The Company Secretary is accountable to the Board through the Chairman on corporate governance matters pertaining to the company secretarial role. All directors have access to the Company Secretary.

### 1.5 Diversity

Recommendation 1.5 is that the Company should establish and disclose a diversity policy. Due to the Company's size and nature of operations, the Board has not yet implemented a diversity policy, but the Board recognises the value of diversity and the opportunities that it brings. As the Company grows and positions become available, the Board remains conscious of the requirement to establish a diversity policy and will seek to promote and increase diversity.

Recommendation 1.5 also states that the Company should report against a set of measurable objectives for achieving gender diversity. Due to the Company's size and nature of operations, the Board has not yet established measurable objectives for achieving gender diversity.

The Company currently has three permanent full-time employees (one male and two female) and uses the services of a number of consultants. There are four directors on the Board, all of whom are male.

### 1.6 Performance Review – Board and Directors

Due to the size of the Company and the Board, an informal self-assessment is normally undertaken in relation to the Board's collective performance and the performance of the Chairman and individual directors during each financial year. There are currently no formal policies in place for these evaluations. The Board, its committees and non-executive directors continually monitors its performance during the year in accordance with the processes described above.

Recommendation 1.6 includes the requirement to disclose whether a performance evaluation for the Board and Directors has taken place in the reporting period - a formal self-assessment was performed during the 2021 financial year.

#### 1.7 Performance Review – senior executives

Arrangements put in place by the Board to monitor the performance of the Group's executives include:

- a review by the Board of the Group's financial performance;
- annual performance appraisal meetings, incorporating analysis of key performance indicators with each individual, to ensure that the level of reward is aligned with respective responsibilities and individual contributions made to the success of the Group;
- an analysis of the Group's prospects and projects; and
- a review of feedback obtained from third parties, including advisors.

Recommendation 1.7 includes a requirement to disclose whether a performance evaluation for senior executives has taken place in the reporting period - performance evaluation for senior executives was undertaken during the 2021 financial year.

#### Principle 2: Structure of the Board to Add Value

#### 2.1 Nomination Committee

Recommendation 2.1 is that the Board should establish a nomination committee. The Board considers that the Group is not currently of a size, nor are its affairs of such complexity to justify the formation of a nomination committee at this time. The Board as a whole considers the following factors when selecting new directors and when recommending directors to shareholders for appointment or re-election:

- the aim of having a majority of independent directors on the Board and of having an independent non-executive chairman;
- the aim of having an independent director, other than the Board chairman, as the chairman of the Audit and Risk Management Committee;
- that between them, the directors have the appropriate skill base and range of expertise, experience and diversity to discharge the Board's mandate;

- that each individual director has sufficient time to meet his/her commitments as a director of the Company;
- the duration of each existing director's tenure, noting the retirement provisions of the Constitution as set out below; and
- whether the size of the Board is appropriate to facilitate effective discussions and efficient decisionmaking.

Where appropriate, independent consultants will be engaged to identify possible new candidates for the Board. To date, new candidates to join the Board have predominantly been sought through referrals, rather than through professional intermediaries.

Directors are initially appointed by the full Board, subject to election by shareholders at the next annual general meeting. Under the Company's Constitution a director (other than the managing director and only one managing director where the position is jointly held) is subject to reappointment by shareholders not later than the third anniversary following his/her last appointment. The nomination of existing directors for reappointment is not automatic and is contingent on performance and on the current and future needs of the Company.

### 2.2 Board Skills Matrix

The Board has developed a Board skills matrix, to simplify the process for identifying any 'gaps' in the Board's skills, expertise and experience. As part of the review of the skills matrix the Board monitor the skills, expertise and experience that are relevant to the Company and assesses those requirements against the collective attributes of the directors. The Board skills matrix will be reviewed by the directors on an annual basis.

Details of the Directors' skills, experience, expertise and attendance at meetings are set out in the Directors' Report in each year's Annual Report.

#### 2.3/2.4 Independent Directors

During the financial year ended 30 June 2021, the Company had the following Board members, who served as directors throughout.

- Mr Troy Valentine Non-Executive Chairman (appointed 11 December 2017)
- Mr Peter Widdows Non-Executive Director (appointed 1 March 2018)

On 24 July 2019, Mr Alistair Blake (Executive Director - appointed 20 October 2016) resigned from the Board, and on that same day, the following appointments to the Board were made:

- Dr Sud Agarwal Non-Executive Director (appointed 24 July 2019)
- Mr Joel Latham Managing Director (appointed 24 July 2019)

The Board currently consists of one executive and three Non-executive Directors.

Details of the directors' skills, experience, expertise, special responsibilities, attendance at Board meetings and dates of appointment are set out in the directors' report.

In assessing the independence of the directors, the Board has defined an independent director as a director who:

- is non-executive;
- is not a substantial shareholder (i.e. greater than 5%) of the Company or an officer of, or otherwise associated directly with, a substantial shareholder of the Company;
- has not within the last three years been employed in an executive capacity by the Company or another Group member;
- has not within the last three years been a principal or employee of a material professional adviser or a material consultant to the Company or another Group member, or an employee materially associated with the service provided;
- is not a material supplier or customer of the Company or another Group member, or an officer of or otherwise associated, directly or indirectly, with a material supplier or customer;
- has no material contractual relationship with the Company or another Group member other than as a director of the Company; and
- is free from any interest and any business or other relationship which could, or could reasonably be perceived to, materially interfere with the director's ability to act in the best interests of the Company.

Materiality for these purposes is determined on both quantitative and qualitative bases. An amount which is greater than five percent of either the net assets of the Company or an individual director's net worth is considered material for these purposes.

Troy Valentine is an independent director.

Peter Widdows is deemed to be an independent director.

Sud Agarwal is deemed to be a non-independent director.

Joel Latham is the Group Managing Director and Chief Executive Officer and is therefore not independent.

The Company's Constitution provides that the number of directors shall not be less than three and not more than seven. The Board considers that the Company is not currently of a size, nor are its affairs of such complexity to justify the appointment and further expense of additional independent non-executive directors.

The Board believes that the four individuals on the Board can, and do, make independent judgments and act in the best interests of shareholders.

In accordance with the Corporations Act 2001 and the Company's Constitution, directors must keep the Board advised, on an ongoing basis, of any interest that could potentially conflict with those of the Group. Where theBoard believes that a significant conflict exists, the director concerned does not receive the relevant Board papers and is not present at the meeting whilst the item is considered.

#### 2.5 Chairman

Troy Valentine performs the role of chairman.

The Chairman's responsibilities include leadership of the Board and the efficient organisation and conduct of the functioning of the Board. The Board generally manages the day-to-day affairs of the Group.

#### 2.6 Director Induction

The Board implements an induction program for new Directors which involves providing information about the company, its constitution and policies and practices. The Board is continually informed by Senior Managementof key developments in the Company's business and the industry in which the Company operates.

#### Principle 3. Act ethically and responsibly

### 3.1 Code of Conduct

The Group has a Code of Business Conduct in place which provides guidelines aimed at maintaining high ethical standards, corporate behaviour and accountability within the Group.

All Group personnel and directors are expected to:

- respect the law and act in accordance with it;
- respect confidentiality and not misuse Group information, assets or facilities;
- value and maintain professionalism;
- avoid real or perceived conflicts of interest;
- act in the best interests of shareholders;
- by their actions contribute to the Group's reputation as a good corporate citizen, which seeks therespect of the community and environment in which it operates;
- perform their duties in ways that minimise environmental impacts and maximise workplace safety;
- exercise fairness, courtesy, respect, consideration and sensitivity in all dealings within their workplaceand with customers, suppliers and the public generally; and
- act with honesty, integrity, decency and responsibility at all times.

Any member of Group personnel that breaches the Code of Ethics and Conduct may face disciplinary action. If a member of Group personnel suspects that a breach of the Code of Ethics and Conduct has occurred or will occur, he or she must report that breach to management. No member of Group personnel will be disadvantaged or prejudiced if he or she reports in good faith a suspected breach. All reports will be acted upon and kept confidential.

### Principle 4. Safeguard Integrity in Corporate Reporting

### 4.1 Audit Committee

Recommendation 4.1 is that the Board should establish an Audit and Risk Management Committee. The Board considers that the Group is not currently of a size, nor are its affairs of such complexity to justify the formation of an audit committee at this time. During the year, the full Board reviews the integrity of the Company's financial reporting and the processes to ensure the independence and competence of the external auditors.

The Board currently fulfils the responsibilities which are usually assigned to an audit committee including:

- considering whether the Company's financial statements reflect the understanding of the Committee members of, and otherwise provide a true and fair view of, the financial position and performance of the Company;
- ensuring that the quality of financial controls is appropriate for the business of the Company;
- considering the appointment or removal of the external auditor, the rotation of the external audit partner and approving the remuneration and terms of engagement of the external auditor;
- monitoring and reviewing the external auditor's independence, objectivity and performance, taking intoconsideration relevant professional and regulatory requirements; and
- reviewing the Company's risk management and internal control systems.

#### 4.2 CEO/CFO declarations

The Board has received a written assurance from each of the Chief Executive Officer and Chief Financial Officer for each financial reporting period that in their opinion, the declaration provided by them in accordancewith section 295A of the Corporations Act is founded on a sound system of risk management and internal control and that the system is operating effectively in all material respects in relation to financial reporting risks.

#### 4.3 External Auditors present at the Annual Meeting

The Company's policy is to appoint external auditors who clearly demonstrate quality and independence. The performance of the external auditor is considered annually and applications for tender for external audit services are requested as deemed appropriate, taking into consideration assessment of performance, existingvalue and tender costs. The audit engagement partner is rotated periodically, as required by the CorporationsAct.

A representative from the external auditor is invited to attend each annual general meeting to answer any questions concerning the audit of the Group and the contents of the auditor's report.

#### Principle 5. Make Timely and Balanced Disclosure

#### 5.1 Market Disclosure Policy

The Market Disclosure Policy requires executive management to determine when a market release is required to comply with the ASX Listing Rule continuous disclosure requirements. The Policy sets out details of accountability for the preparation and approval of ASX releases, and is available on the Company's website.

#### Principle 6. Respect the Rights of Shareholders

#### 6.1 Website Information

The Company discloses information about itself, ASX announcements, its Corporate Governance Statement and all its Corporate Governance Policies on the Company's website.

#### 6.2 Investor Relations

The Group places considerable importance on effective communications with shareholders.

The Group communicates with shareholders and other stakeholders in an open, regular and timely manner, so that the market has sufficient information to make informed investment decisions on the operations and results of the Group. The following communications are posted on the Company's website:

- ASX Quarterly Cash Flow Reports;
- Half Yearly Report;
- presentations at the Annual General Meeting/General Meetings;

- Annual Report; and
- other announcements lodged with ASX.

### 6.3 **Participation at Shareholder Meetings**

The Board encourages full participation of shareholders at the Annual General Meeting. Shareholders who areunable to attend general meetings are encouraged to lodge proxy appointments in advance of the meeting.

### 6.4 Electronic Communications

Shareholders may elect to receive electronic notifications when the Annual Report is available on the Company's website, and may electronically lodge proxy instructions for items of business to be considered atgeneral meetings.

### Principle 7. Recognise and Manage Risk

### 7.1 Risk Committee

Recommendation 7.1 is that the Board should establish a committee to oversee risk. The Board considers that the Group is not currently of a size, nor are its affairs of such complexity to justify the formation of a risk committee at this time.

The Board currently fulfils the responsibilities which are usually assigned to a risk committee. Senior executives and the Board regularly consider strategic and operational areas of risk for the Group and records any remedialaction the Group has taken in the management of those risks.

### 7.2 Risk Management Review

Recommendation 7.2 is that the Board or a Committee should review the risk management framework at leastannually. During the year, ongoing monitoring, mitigating and reporting on material risks by senior executives and the Board took place in accordance with the processes disclosed.

The Board has established a framework for the management of the Group including a system of internal controls, a business risk management process and the establishment of appropriate ethical standards. The identification and effective management of risk, including calculated risk-taking, is viewed as an essential part of the Group's approach to creating long-term shareholder value.

Management is responsible for designing, implementing and reporting on the adequacy of the Group's risk management and internal control system.

Key elements of the Group's internal control systems include:

- the Code of Conduct, which sets out an ethical and legal framework for all employees in the conductof the Group's business; and
- financial and reporting systems to provide timely, relevant and reliable information to managementand the Board.

During the year and up to the date of this statement, management and the Company Secretary reported directlyto the Board on the Group's key risks and the effectiveness of the Company's management of those risks.

### 7.3 Internal Audit Function

The Board, has determined not to have an internal audit function due to the size of the Company.

The Company's external auditors are engaged to perform a half year review and full year audit as required under the Corporations Act 2001. Senior executives and the Board have regular meetings and contact with the external auditors during the year and for the review and audits.

### 7.4 Material Exposure to Risk

Recommendation 7.4 is that the Board should disclose whether it has any material exposure to economic, environmental and social sustainability risks and if so, how it manages those risks. The Group believes that the following operational risks are inherent in the industry in which the Group operates, having regard to the Group's circumstances (including financial resources, prospects and size):

- fluctuations in commodity prices and exchange rates;
- accuracy of mineral reserve and resource estimates;
- reliance on licenses, permits and approvals from governmental authorities;

- ability to obtain additional financing;
- acquisition of new business opportunities; and
- changed operating, market or regulatory environments.

These risk areas are provided here to assist investors to understand better the nature of the risks faced by theGroup, and are not necessarily an exhaustive list.

#### Principle 8. Remunerate Fairly and Responsibly

#### 8.1 Remuneration Committee

Recommendation 8.1 is that the Board should establish a remuneration committee. The Board considers that the Company is not currently of a size, nor are its affairs of such complexity to justify the formation of a remuneration committee. The Board as a whole is responsible for the remuneration arrangements for directors and executives of the Company.

Details of the Group's remuneration policy are set out in the remuneration report.

### 8.2 Remuneration Disclosure for Non-Executive and Executive Directors

The remuneration of non-executive directors is determined by the Board as a whole having regard to the levelof fees paid to non-executive directors by other companies of similar size in the industry. Due to the size of theCompany, the structure of both executive and non-executive directors' remuneration includes a long-term incentive component, linked to the performance of the Group.

The non-executive directors receive no retirement benefits, other than statutory superannuation contributions. Any increase in the maximum total remuneration of the non-executive directors of the Company, which is set at \$500,000 is subject to the approval of shareholders. Further information on directors' and executives' remuneration is set out in the directors' report under the heading Remuneration Report in the Directors' Report in each year's Annual Report.

Any directors or IHL personnel participating in equity-based remuneration schemes are prohibited from entering into transactions in associated products which limit the economic risk of their unvested entitlements.

#### 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 27 August 2021)

Position	Holder Name	Number Held	Percentage
1	MR RAYMOND LAURENCE CARROLL	45,250,000	4.20%
2	DR SUDHANSHU AGARWAL	34,303,593	3.18%
3	CANNVALATE PTY LTD	32,000,000	2.97%
4	MR ANTHONY MICHAEL MALYNIAK <ejm a="" c=""></ejm>	25,650,000	2.38%
5	BAGBO PTY LTD	16,556,198	1.54%
6	MR BRIAN PETER BYASS	15,800,000	1.47%
7	MR PETER WIDDOWS	15,315,799	1.42%
8	SLADE TECHNOLOGIES PTY LTD <embrey a="" c="" f="" family="" s=""></embrey>	15,100,000	1.40%
9	MR JOEL BRADLEY LATHAM	13,829,129	1.28%
10	ALIGNMENT CAPITAL PTY LTD	13,194,248	1.22%
11	CIPATER PTY LTD	12,765,000	1.18%
12	MR KAIDE WANG	11,601,607	1.08%
13	JAPL NOMINEES PTY LTD < JAPL INVESTMENT A/C>	10,014,370	0.93%
14	ELLAZ PTY LTD <the a="" c="" family="" ripper=""></the>	10,000,000	0.93%
15	CITICORP NOMINEES PTY LIMITED	9,686,241	0.90%
16	MR PETER FRANCIS SCANLAN	9,500,000	0.88%
17	MR SAM BOAKE	9,001,493	0.84%
18	VBS EXCHANGE PTY LTD	9,000,000	0.83%
19	PELRUS PTY LTD	7,530,000	0.70%
20	MS NIOMIE ESTHER VARADY	7,185,508	0.67%
	Total	323,283,186	29.99%

#### **DISTRIBUTION OF SHAREHOLDERS (as at 27 August 2021)**

Range	Total Holders	Units	% of Total
1 -1,000	104	25,583	0.00%
1,001 - 5,000	2,305	7,091,829	0.66%
5,001 - 10,000	1,454	11,280,326	1.05%
10,001 -100,000	2,873	102,220,552	9.48%
100,001 and above	1,062	957,421,140	88.81%
Totals	7,798	1,078,039,430	100.00%

There were 120 shareholders holding less than a marketable parcel (less than 1,285 shares at \$ 0.385) at 27 August 2021 – a total of 44,677 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 27 August 2021:

Class	Number
All classes of OPTIONS	326,437,328