UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)
☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number: 001-41106

Incannex Healthcare Limited

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Suite 105, 8 Century Circuit
Norwest 2153, NSW
Australia
(Address of principal executive offices)

Joel Latham, Chief Executive Officer
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Norwest 2153, NSW
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Phone: +61 425 703 805 E-mail: joel@incannex.com.au
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, as represented by American Depositary Shares	IXHL	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act. **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. **None**

The number of ordinary shares outstanding as of June 30, 2022, was 1,292,334,028.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Emerging growth company	☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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INTRODUCTION

Incannex Healthcare Limited was incorporated under the laws of Australia in 2001. Our ordinary shares have been listed on the Australian Securities Exchange ("ASX") since 2016 and, since February 2022, have been listed on the Nasdaq Global Market in the form of American Depositary Shares ("ADSs), with each ADS representing 25 ordinary shares. Deutsche Bank Trust Company Americas acts as depositary for the ADSs.

As used in this Annual Report on Form 20-F, the terms "we," "us," "our", "Incannex" and the "Company" mean Incannex Healthcare Limited and its subsidiaries, unless otherwise indicated.

FINANCIAL AND OTHER INFORMATION

Our consolidated financial statements appearing in this Annual Report on Form 20-F are prepared in Australian dollars and in accordance with the International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). Our consolidated financial statements appearing in this Annual Report on Form 20-F comply with both the IFRS and Australian Accounting Standards. In this Annual Report, all references to "U.S. dollars" or "US$" are to the currency of the United States and all references to "Australian dollars" or "$" or "A$" are to the currency of Australia.

In this Annual Report, the term "fiscal" refers to the fiscal year commencing July 1 and ending June 30 of the following year.

Statements made in this Annual Report on Form 20-F concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this Annual Report or to any registration statement that we previously filed, you may read the document itself for a complete description of its terms.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Except for the historical information contained in this Annual Report on Form 20-F, the statements contained in this Annual Report on Form 20-F are "forward-looking statements" that reflect our current view with respect to future events and financial results. We urge you to consider that statements which use the terms "anticipate," "believe," "do not believe," "expect," "plan," "intend," "estimate," and similar expressions are intended to identify forward-looking statements and these forward-looking statements, include, without limitation, any statements relating to:

- our product development and business strategy, including the potential size of the markets for our products and future development and/or expansion of our products and therapies in our markets;
- our research and development activities, including clinical testing and manufacturing and the related costs and timing;
- the impact that a pandemic could have on business operations;
- the sufficiency of our cash resources;
- our ability to commercialize products and generate product revenues;
- our ability to raise additional funding when needed;
- any statements concerning anticipated regulatory activities or licensing or collaborative arrangements, including our ability to obtain regulatory clearances;
- our research and development expenses;
- our intellectual property; and
- any statement of assumptions underlying any of the foregoing.

We remind investors that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, our achievements or industry results, to be materially different from any future results, performance, levels of activity, or our achievements expressed or implied by such forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly release any update or revision to any forward-looking statements to reflect new information, future events or circumstances, or otherwise after the date hereof. Please see the Risk Factors section that appears in "Item 3. Key Information – D. Risk Factors."

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not applicable.

B. Advisers

Not applicable.

C. Auditors

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

The following risks relate specifically to our business and should be considered carefully. Our business, financial condition and results of operations could be harmed by any of the following risks. As a result, the trading price of our ordinary shares and our American Depositary Shares, or ADSs, could decline and the holders could lose part or all of their investment.

Risks Related to Our Business

We have a history of operating losses and may not achieve or maintain profitability in the future.

We have experienced significant recurring operating losses and negative cash flows from operating activities since inception. For example, for the fiscal years ended June 30, 2022 and 2021, we had total comprehensive losses of A$14.9 million and A$11.4 million, respectively, and we had negative cash flows from operating activities of A$12.8 million and A$6.9 million, respectively. As of June 30, 2022, we had accumulated losses of A$58.8 million.

We are a clinical stage pharmaceutical development company and the success of our drug candidates is therefore uncertain. We focus on medicinal synthetic cannabidiol pharmaceutical products and psychedelic medicine therapies.

We expect to continue to incur losses from operations for the foreseeable future and expect the costs of drug development to increase in the future as more patients are recruited for clinical trials. In particular, we expect to continue to incur significant losses in the development of our drug candidates. Because of the numerous risks and uncertainties associated with the development, manufacturing, sales and marketing of our drug candidates, we may experience larger than expected future losses and may never become profitable.

Moreover, there is a substantial risk that we, or our development partners, may not be able to complete the development of our current drug candidates or develop other pharmaceutical products. It is possible that none of them will be successfully commercialized, which could prevent us from ever achieving profitability.

Our research and development activities could be adversely impacted if our funding sources are insufficient.

We anticipate that the costs related to the development of our clinical trials will increase and we will require additional funds to achieve our long-term goals of commercialization and further development of our drug candidates. In addition, we will require funds to pursue regulatory applications, defend intellectual property rights, contract manufacturing capacity, develop marketing and sales capability and fund operating expenses. We intend to seek such additional funding through public or private financings and/or through licensing of our assets or other arrangements with corporate partners. However, such financing, licensing opportunities or other arrangements may not be available from any sources on acceptable terms, or at all. Any shortfall in funding could result in us having to curtail or cease our research and development activities, thereby adversely affecting our business, financial condition and results of operations.

In addition, because of the numerous risks and uncertainties associated with the development of our drug candidates, we are unable to predict the timing or amount of increased research and development costs, or when, or if, we will be able to achieve or maintain profitability. Our costs could significantly increase beyond current expectations if the applicable regulatory authorities require further studies in addition to those currently anticipated. In any case, even if our drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of such drug candidates and there can be no guarantee that we will ever generate significant revenues.

We currently have no source of product revenue and may never become profitable.

None of our drug candidates has been approved for commercial sale and we expect it to be several years before any of them are approved, if ever, and we are then able to commence sales of our drug candidates. To date, we have not generated any revenue from the licensing or commercialization of our drug candidates and do not expect to receive revenue from them for a number of years, if ever. We will not be able to generate product revenue unless and until our drug candidates, alone or with future partners, successfully completes clinical trials, receives regulatory approval and is successfully commercialized. Although we may seek to obtain revenue from collaboration or licensing agreements with third parties, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements.

We will require additional financing and may be unable to raise sufficient capital, which could have a material impact on our research and development programs or commercialization of our drug candidates.

We have historically devoted most of our financial resources to research and development, including pre-clinical and clinical development activities. To date, we have financed a significant amount of our operations through equity financings. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. The amount of such future net losses, as well as the possibility of future profitability, will also depend on our success in developing and commercializing products that generate significant revenue. Our failure to become and remain profitable would depress the value of our ADSs and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We anticipate that our expenses will increase substantially for the foreseeable future if, and as, we:

- continue our research and preclinical and clinical development of our drug candidates;
- expand the scope of our current proposed clinical studies for our drug candidates;
- initiate additional preclinical, clinical or other studies for our drug candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for our drug candidates that successfully complete clinical studies;
- seek to identify and validate additional drug candidates;
- acquire or in-license other drug candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a publicly quoted company and our product development and planned future commercialization efforts;
- add an internal sales force; and
- experience any delays or encounter issues with any of the above.

Until our drug candidates become commercially available, we will need to obtain additional funding in connection with the further development of our drug candidates. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. As such, additional financing may not be available to us when needed, on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or obtain funds by entering agreements on unattractive terms.

Furthermore, any additional equity fundraising in the capital markets may be dilutive for shareholders and any debt-based funding may bind us to restrictive covenants and curb our operating activities and ability to pay potential future dividends even when profitable. We cannot guarantee that future financing will be available in sufficient amounts or on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our ADSs to fall.

If we are unable to secure sufficient capital to fund our operations, then we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. For example, strategic collaborations could require us to share commercial rights to our drug candidates with third parties in ways that we do not intend currently or on terms that may not be favorable to us. Moreover, we could also have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us.

We may find it difficult to enroll patients in our clinical trials and patients could discontinue their participation in our clinical trials, which could delay or prevent our current and any future clinical trials of our drug candidates and make those trials more expensive to undertake.

Identifying and qualifying patients to participate in current and any future clinical trials of our drug candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our drug candidates. Patients may be unwilling to participate in any future clinical trials because of negative publicity from adverse events in the biotechnology industry. Patients could be unavailable for other reasons, including competitive clinical trials for similar patient populations, and the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed. If we have difficulty enrolling a sufficient number of patients to conduct any future clinical trials as planned, we may need to delay, limit or discontinue those clinical trials. Clinical trial delays could result in increased costs, slower product development, setbacks in testing the safety and effectiveness of our technology or discontinuation of the clinical trials altogether.

Any failure to implement our business strategy could negatively impact our business, financial condition and results of operations.

The development and commercialization of our drug candidates is subject to many risks, including:

- additional clinical or pre-clinical trials may be required beyond what we currently expect;
- regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- regulatory authorities may disagree with our proposed design of future clinical trials;
- regulatory authorities may delay approval of our drug candidates, thus preventing milestone payments from our collaboration partners;
- regulatory authorities may not accept data generated at our clinical study sites;
- we may be unable to obtain and maintain regulatory approval of our drug candidate in any jurisdiction;
- the prevalence and severity of any side effects of any drug candidate could delay or prevent commercialization, limit the indications for any approved drug candidate, require the establishment of a risk evaluation and mitigation strategy, or cause an approved drug candidate to be taken off the market;
- regulatory authorities may identify deficiencies in manufacturing processes;
- regulatory authorities may change their approval policies or adopt new regulations;
- the third party manufacturers we expect to depend on to supply or manufacture our drug candidates may not produce adequate supply;

- we, or our third party manufacturers, may not be able to source or produce current Good Manufacturing Practice ("cGMP") materials for the production of our drug candidates;

- we may not be able to manufacture our drug candidates at a cost or in quantities necessary to make commercially successful products;

- we may not be able to obtain adequate supply of our drug candidates for our clinical trials;

- we may experience delays in the commencement of, enrolment of patients in and timing of our clinical trials;

- we may not be able to demonstrate that our drug candidates are safe and effective as a treatment for its indications to the satisfaction of regulatory authorities, and we may not be able to achieve and maintain compliance with all regulatory requirements applicable to our drug candidates;

- we may not be able to maintain a continued acceptable safety profile of our products following approval;

- we may be unable to establish or maintain collaborations, licensing or other arrangements;

- the market may not accept our drug candidates;

- we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations, and the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations will affect our profitability;

- we may experience competition from existing products or new products that may emerge;

- we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our drug candidates; and

- we may not be able to obtain and maintain coverage and adequate reimbursement from third party payors.

If any of these risks materializes, we could experience significant delays or an inability to successfully develop and commercialize our drug candidates we or our partners may develop, which would have a material adverse effect on our business, financial condition and results of operations.

Positive results from preclinical studies of our drug candidates are not necessarily predictive of the results of our planned clinical trials of our drug candidates.

Positive results in preclinical proof of concept and animal studies of our drug candidates may not result in positive results in clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early-stage clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks can be caused by preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their drug candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval. If we fail to produce positive results in our clinical trials of our drug candidates, the development timeline and regulatory approval and commercialization prospects for our drug candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

Ongoing and future clinical trials of drug candidates may not show sufficient safety and efficacy to obtain requisite regulatory approvals for commercial sale.

Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a drug candidate but rather to test safety and to understand the drug candidate's side effects at various doses and schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. Further, Phase III clinical trials may not show sufficient safety or efficacy to obtain regulatory approval for marketing. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could require that the clinical trial be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the drug candidate involved, as well as other factors. If we suffer any significant delays, quality issues, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue the development of our drug candidates or generate revenue and our business may be severely harmed.

If we do not obtain the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

The clinical development, manufacturing, sales and marketing of our drug candidates are subject to extensive regulation by regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere. Despite the substantial time and expense invested in preparation and submission of a Biologic License Application or equivalents in other jurisdictions, regulatory approval is never guaranteed. The number, size and design of preclinical studies and clinical trials that will be required will vary depending on the product, the disease or condition for which the product is intended to be used and the regulations and guidance documents applicable to any particular product. Additionally, during the review process and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether our products have abuse potential, which may delay approval and any potential controlled substance scheduling processes. The FDA or other regulators can delay, limit or deny approval of a product for many reasons, including, but not limited to, the fact that regulators may not approve our or a third-party manufacturer's processes or facilities or that new laws may be enacted or regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product.

Successful results in clinical trials and in the subsequent application for marketing approval are not guaranteed. If we are unable to obtain regulatory approvals, we will not be able to generate revenue from our drug candidates. Even if we receive regulatory approval for any of our drug candidates, our profitability will depend on our ability to generate revenues from their sale or the licensing of our technology.

Even if our drug candidates receive regulatory approval, we may still face development and regulatory difficulties that may delay or impair future sales of drug candidates.

Even if we or our licensing partners receive regulatory approval to sell any drug candidates, the relevant regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labelling, packaging, adverse event reporting, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies. In addition, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. In addition, new statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates.

We have limited manufacturing experience with our drug candidates.

We have no manufacturing capabilities and are dependent on third parties for cost effective manufacture and manufacturing process development of our drug candidates. Problems with third-party manufacturers or the manufacturing process, or the scaling up of manufacturing activities as such may delay clinical trials and commercialization of our drug candidates.

To the extent we rely significantly on contractors, we will be exposed to risks related to the business and operational conditions of our contractors.

We are a small company, with few internal staff and limited facilities. We are and will be required to rely on a variety of contractors to manufacture and transport our drug candidates, to perform clinical testing and to prepare regulatory dossiers. Adverse events that affect one or more of our contractors could adversely affect us, such as:

- a contractor is unable to retain key staff that have been working on our drug candidates;
- a contractor is unable to sustain operations due to financial or other business issues;
- a contractor loses their permits or licenses that may be required to manufacture our drug candidates; or
- errors, negligence or misconduct that occur within a contractor may adversely affect our business.

We depend on, and will continue to depend on, collaboration and strategic alliances with third partners. To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into partnerships and strategic alliances with other pharmaceutical companies or other industry participants.

Any partnerships or alliance we have or may have in the future may be terminated for reasons beyond our control or we may not be able to negotiate future alliances on acceptable terms, if at all. These arrangements may result in us receiving less revenue than if we sold our products directly, may place the development, sales and marketing of our products outside of our control, may require us to relinquish important rights or may otherwise be on unfavorable terms. Collaborative arrangements or strategic alliances will also subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partner/collaborators may devote to the drug candidates;
- strategic partner/collaborators may experience financial difficulties;
- the failure to successfully collaborate with third parties may delay, prevent or otherwise impair the development or commercialization of our drug candidates or revenue expectations;
- products being developed by partners/collaborators may never reach commercial stage resulting in reduced or even no milestone or royalty payments;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete their obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing drug candidates.

Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party supply and manufacturing partners to manufacture and supply the materials for our research and development and preclinical and clinical study supplies. We do not own manufacturing facilities or supply sources for such materials.

There can be no assurance that our supply of research and development, preclinical and clinical development biologics and other materials will not be limited, interrupted or restricted in certain geographic regions, be of satisfactory quality or continue to be available at acceptable prices. Replacement of a third-party manufacturer could require significant effort, cost and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a drug candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which would be costly and delay any future clinical trials.

Further, if any third-party provider fails to meet its obligations to manufacture our products, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any therapies, if approved, could be stopped, delayed or made commercially unviable, less profitable or may result in enforcement actions against us.

Our research and development efforts will be jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

Changes in our senior management could be disruptive to our business and may adversely affect our operations. For example, when we have changes in senior management positions, we may elect to adopt different business strategies or plans. Any new strategies or plans, if adopted, may not be successful and if any new strategies or plans do not produce the desired results, our business may suffer.

Moreover, competition among biotechnology and pharmaceutical companies for qualified employees is intense and as such we may not be able to attract and retain personnel critical to our success. Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our product development and commercialization activities.

In addition, biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our drug candidates may be or become uncompetitive. To remain competitive, we must employ and retain suitably qualified staff that are continuously educated to keep pace with changing technology, but may not be in a position to do so.

We may encounter difficulties in managing our growth, which could negatively impact our operations.

As we advance our clinical development programs for drug candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. We will also need to establish commercial capabilities in order to commercialize any drug candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management’s attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

In addition, in order to continue to meet our obligations as a publicly listed company in both Australia and the United States and to support our anticipated long-term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be harmed.

The integration of APIRx with our business operations could undermine our results of operations.

In August 2022, we completed the acquisition of 100% of APIRx Pharmaceutical USA, LLC (the "Acquisition"). However, our ability to successfully integrate APIRx, will depend on the timely integration and consolidation of operations, facilities, procedures, policies and technologies, and the harmonization of differences in the business cultures between APIRx and us. Such integration and consolidation could be complex and time consuming, will involve additional expense and could disrupt our business and divert management's attention from ongoing business concerns and our clinical trials. Any failure to successfully integrate the business, operations and employees of APIRx could undermine our results of operations.

We may be unable to achieve the expected synergies following the Acquisition.

We believe that the Acquisition will provide us with the opportunity to achieve synergies between Incannex's clinical trials and APIRx's clinical projects. The synergies we expect to realize from the Acquisition are, necessarily, based on projections and assumptions about the combined businesses and assume the successful integration of APIRx's operations into our business and operations. Our projections and assumptions concerning the Acquisition could prove to be inaccurate, however, and we may not successfully integrate APIRx and our operations in a timely manner, or at all. We could also be exposed to unexpected contingencies or liabilities of APIRx or litigation regarding APIRx's intellectual property portfolio. If we do not realize the anticipated synergies from the Acquisition, our growth strategy and future profitability could be adversely affected.

Future potential sales of our drug candidates may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

There is a risk that our drug candidates may not gain market acceptance among physicians, patients and the medical community, even if they are approved by the regulatory authorities. The degree of market acceptance of any of our approved drug candidates will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive products;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our drug candidates;
- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

As controlled substances, the products may generate public controversy. Physicians, patients, payers or the medical community may be unwilling to accept, use or recommend our drug candidates which would adversely affect our potential revenues and future profitability. Adverse publicity or public perception regarding cannabis and psilocybin to our investigational therapies using these substances may negatively influence the success of these therapies.

We face competition from entities that may develop drug candidates for our target disease indications, including companies developing novel treatments and technology platforms based on modalities and technology similar to ours.

The development and commercialization of drug candidates is highly competitive. Multinational pharmaceutical companies and specialized biotechnology companies could develop drug candidates and processes competitive with our drug candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community, patients and third-party payers, and any new treatments that enter the market.

There may be a significant number of products that are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing, and may in the future try to develop, drug candidates.

Multinational pharmaceutical companies and specialized biotechnology companies could have significantly greater financial, technical, manufacturing, marketing, sales and supply resources and experience than we have. If we successfully obtain approval for any drug candidate, we could face competition based on many different factors, including the safety and effectiveness of our drug candidates, the ease with which our drug candidates can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these drug candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position.

Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or non-competitive before we recover the expense of developing and commercializing our drug candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

If healthcare insurers and other organizations do not pay for our drug candidates or impose limits on reimbursement, our future business may suffer.

Our drug candidates may be rejected by the market due to many factors, including cost. The continuing efforts of governments, insurance companies and other payers of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability. In Australia and certain foreign markets, the pricing of pharmaceutical products is subject to government control. We expect initiatives for similar government control to continue in the United States and elsewhere. The adoption of any such legislative or regulatory proposals could harm our business and prospects.

Successful commercialization of our drug candidates will depend in part on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health insurers and other organizations. Our drug candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Third-party payers are increasingly challenging the price of medical products and treatment. If third-party coverage is not available for our drug candidates the market acceptance of these drug candidates will be reduced. Cost-control initiatives could decrease the price we might establish for drug candidates, which could result in product revenues lower than anticipated. If the price for our drug candidates decreases or if governmental and other third-party payers do not provide adequate coverage and reimbursement levels our potential revenue and prospects for profitability will suffer.

We could become exposed to product liability claims that could adversely affect our business.

The testing, marketing and sale of therapeutic products entails an inherent risk of product liability. We rely on a number of third-party researchers and contractors to produce, collect, and analyze data regarding the safety and efficacy of our drug candidates. We also have quality control and quality assurance in place to mitigate these risks, as well as professional liability and clinical trial insurance to cover financial damages in the event that human testing is done incorrectly or the data is analyzed incorrectly.

Notwithstanding our control procedures, we may face product liability exposure related to the testing of our drug candidates in human clinical trials. If any of our drug candidates are approved for sale, we may face exposure to claims by an even greater number of persons than were involved in the clinical trials once marketing, distribution and sales of our drug candidates begin. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize drug candidates.

With respect to product liability claims, we could face additional liability beyond insurance limits if testing mistakes were to endanger any human subjects. In addition, if a claim is made against us in conjunction with these research testing activities, the market price of our ADSs may be negatively affected.

The outbreak of a pandemic could adversely impact our business, including our non-clinical studies and clinical trials.

Public health crises such as pandemics or similar outbreaks might adversely impact our business. In December 2019, a novel strain of coronavirus ("COVID-19") surfaced in China and then spread to most countries in the world.

As a result of the COVID-19 outbreak, or any future pandemic, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting a virus, being forced to quarantine, or not wanting to attend hospital visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by national, state or local governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA, the European Medicines Agency, the Australian Therapeutic Goods Administration or other foreign regulatory agencies, which may impact approval timelines;

- interruption of, or delays in receiving, supplies of our drug candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in our supply chain or distribution vendors' ability to ship drug candidates; and

- limitations on employee resources that would otherwise be focused on the conduct of our non-clinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of our drug candidates and the Active Pharmaceutical Ingredient ("API") used to manufacture them will require import and export licenses. In the United States, the FDA, U.S. Customs and Border Protection, and the U.S. Drug Enforcement Administration (the "DEA"); in Canada, the Canada Border Services Agency, Health Canada; in Europe, the European Medicines Agency (the "EMA") and the European Commission; in Australia and New Zealand, the Australian Customs and Board Protection Service, the Therapeutic Goods Administration (the "TGA"), the New Zealand Medicines and Medical Device Safety Authority and the New Zealand Customs Service; and in other countries, similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export processes require the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country.

We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of API and our drug candidates may be held up or lost in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our drug candidates. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our drug candidates could have a material adverse effect on our business, results of operations and financial condition.

Our drug candidates will be subject to controlled substance laws and regulations. Failure to receive necessary approvals may delay the launch of our drug candidates and failure to comply with these laws and regulations may adversely affect the results of our business operations.

Our drug candidates contain controlled substances as defined in the Controlled Substance Act (the "CSA"). Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have not currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

As a synthetic cannabinoids pharmaceutical product with psychedelic agents, our drug candidates are likely to be scheduled as Schedule II or III controlled substance. We will need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the products to pharmacies and other healthcare providers, and these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If any of our drug candidates is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems, and they must adhere to additional recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

We intend to manufacture the commercial supply of our drug candidates outside of the United States. If any of our products are approved by the FDA and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains from the DEA an importer registration and files an application with the DEA for an import permit for each import. The failure to identify an importer or obtain the necessary import authority could affect the availability of our drug candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted. The failure to maintain the necessary registrations or comply with applicable laws could delay the commercialization of our drug candidates and could delay the completion of the clinical studies. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, could result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. In addition, if the FDA, DEA, or any foreign regulatory authority determines that our drug candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of which could increase the cost and/or delay the launch of our drug candidates.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our drug candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

We intend to contract manufacturers in Australia to produce the drug product for our clinical trials and the API for our drug candidates. In addition, we may decide to develop, manufacture or commercialize our drug candidates in additional countries. As a result, we will also be subject to controlled substance laws and regulations from the TGA in Australia and from other regulatory agencies in other countries where we develop, manufacture or commercialize our drug candidates in the future. We plan to submit New Drug Applications (“NDAs”) for our drug candidates to the FDA upon completion of all requisite clinical trials and may require additional DEA scheduling decisions at such time as well.

Changes in U.S. healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may harm our business and results of operations.

There have been, and likely will continue to be, several executive, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities eligible for the program; (5) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (6) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (8) created a licensure framework for follow-on biologic products; and (9) established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. We continue to monitor any changes or challenges to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2030, unless additional Congressional action is taken. Subsequently, the American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws could result in additional reductions in Medicare and other healthcare funding, which may materially negatively affect customer demand and affordability for our drug candidates and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug candidates that we successfully commercialize or put pressure on our product pricing.

In addition, proposed federal and state legislation may increase competition as it relates to cannabis derived products. Under the Cannabis Administration and Opportunity Act, the U.S. Senate proposed legalizing the use of hemp-derived CBD in dietary supplements by amending the Federal Food, Drug, and Cosmetic Act (the "FDCA"). The Hemp Access and Consumer Safety Act of 2021 (SB 1698) also permits hemp-derived CBD to be used in dietary supplements. States are considering the reimbursement of medical marijuana. As the availability and reimbursement of cannabis-derived products potentially expand, the pharmaceutical industry may directly compete with state-regulated cannabis businesses for market share.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and put additional downward pressure on the price that we receive for any approved product. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technology.

Our success is to a certain degree also dependent on our ability to obtain and maintain protection of our intellectual property portfolio, including the assets acquired through the Acquisition or, where applicable, to receive/maintain orphan drug designation/status and resulting marketing exclusivity for our drug candidates.

We may be materially adversely affected by our failure or inability to protect our intellectual property rights. Without the granting of these rights, the ability to pursue damages for infringement would be limited. Similarly, any know-how that is proprietary or particular to our technologies may be subject to risk of disclosure by employees or consultants despite having confidentiality agreements in place.

Any future success will depend in part on whether we can obtain and maintain patents to protect our own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of third parties. Biotechnology patent matters can involve complex legal and scientific questions, and it is impossible to predict the outcome of biotechnology and pharmaceutical patent claims. Any of our future patent applications may not be approved, or we may not develop additional products or processes that are patentable. Some countries in which we may sell our drug candidate or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the United Kingdom, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Even if we are able to obtain patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

Moreover, any of our pending applications may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, the Intellectual Property Office, or IPO, in the United Kingdom, the Australian Patent and Trademark Office and/or any patents issuing thereon may become involved in opposition, derivation, reexamination, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop and commercialize drug candidates.

The issuance of a patent is not conclusive as to the inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States, the European Union, Australia and elsewhere. Such challenges may result in loss of ownership or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the European Union, Australia and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our drug candidates, such that we could be required to litigate with or obtain licenses from third parties in order to develop or market our drug candidates.

Our commercial success may depend upon our future ability and the ability of our potential collaborators to develop, manufacture, market and sell our drug candidates without infringing valid intellectual property rights of third parties. If a third-party intellectual property right exists it may require the pursuit of litigation or administrative proceedings to nullify or invalidate the third-party intellectual property right concerned, or entry into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders, including our competitors, may bring infringement claims against us. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims or otherwise resolve such claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our drug candidate.

If we fail to settle or otherwise resolve any such dispute, in addition to being forced to pay damages, we or our potential collaborators may be prohibited from commercializing any drug candidates we may develop that are held to be infringing, for the duration of the patent term. We might, if possible, also be forced to redesign our formulations so that we no longer infringe such third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we collaborate with various organizations and academic institutions on the advancement of our technology and drug candidates, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our drug candidates.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us. In other cases, we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the United State Patent and Trademark Office and other governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various corresponding governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We may become involved in lawsuits to protect and defend our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property and we may inadvertently infringe the patent or intellectual property of others. To counter infringement or unauthorized use, we may be required to file claims, and any related litigation and/or prosecution of such claims can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid in whole or in part, unenforceable, or construe the patent's claims narrowly allowing the other party to commercialize competing products on the grounds that our patents do not cover such products.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. The effects of patent litigation or other proceedings could therefore have a material adverse effect on our ability to compete in the marketplace.

Confidentiality and invention assignment agreements with our employees, advisors and consultants may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, advisors and consultants to enter into confidentiality and invention assignment agreements with us. However, current or former employees, advisors and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality and invention assignment agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality and invention assignment agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to ours but that are not covered by our intellectual property rights.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license.
- It is possible that any pending patent applications that we have filed, or will file, will not lead to issued patents.
- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- Ownership of our patents or patent applications may be challenged by third parties.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

We may face difficulties with protecting our intellectual property in certain jurisdictions, which may diminish the value of our intellectual property rights in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries in Europe and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are, or any of our licensors is, forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position or commercial advantage may be impaired and our business and results of operations may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and any future drug candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in non-U.S. jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and a change allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions. The Leahy-Smith Act and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have harm our business, financial condition and results of operations.

Price controls may be imposed in non-U.S. markets, which may negatively affect our future profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our drug candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be harmed.

Risks Relating to Ownership of the ADSs

The trading price of the ADSs may be volatile, and purchasers of the ADSs could incur substantial losses.

The market price of our ordinary shares historically has been, and we expect our ordinary shares and ADSs will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due to factors specific to us, to changes in analysts' recommendations and earnings estimates, to arbitrage between our Australian-listed ordinary shares and our Nasdaq-listed ADSs, to changes in exchange rates, or to factors affecting the biopharmaceutical industry or the securities markets in general. Market fluctuations, as well as general political and economic conditions, such as a recession, interest rate or currency fluctuations, could adversely affect the market price of our securities.

We may experience a material decline in the market price of our shares, regardless of our operating performance. Therefore, a holder of our ADSs may not be able to sell those ADSs at or above the price paid by such holder for such ADSs. Price declines in our ADSs could result from a variety of factors, including many outside our control. These factors include:

- the results of pre-clinical testing and clinical trials by us and our competitors;
- unforeseen safety issues or adverse side effects resulting from the clinical trials or the commercial use of our drug candidate;

- regulatory actions in respect of any of our drug candidates or the products of any of our competitors;
- announcements of the introduction of new products by us or our competitors;
- market conditions, including market conditions in the pharmaceutical and biotechnology sectors;
- increases in our costs or decreases in our revenues due to unfavorable movements in foreign currency exchange rates;
- developments or litigation concerning patents, licenses and other intellectual property rights;
- litigation or public concern about the safety of our drug candidates;
- changes in recommendations or earnings estimates by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- additions or departures of key personnel;
- changes in third party reimbursement policies; and
- developments concerning current or future strategic alliances or acquisitions.

In addition, volatility and low market price of our ADSs may adversely impact investors' interest in our securities. A decline in investors' interest may prompt further volatility and decrease in market price.

If we are or become a passive foreign investment company ("PFIC"), then that would subject our U.S. shareholders to adverse tax rules.

Holders of our ADSs who are U.S. taxpayers will be subject to particular income tax rules if we are a PFIC. These rules could result in a reduction in the after-tax return to a "U.S. Holder" of our ADSs and reduce the value of our ADSs. For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income.

If we are classified as a PFIC in any year that a U.S. Holder owns ADSs, the U.S. Holder will generally continue to be treated as holding ADSs of a PFIC in all subsequent years, notwithstanding that we are not classified as a PFIC in a subsequent year. Dividends received by the U.S. Holder and gains realized from the sale of our ADSs would be taxed as ordinary income and subject to an interest charge. We urge U.S. investors to consult their own tax advisors about the application of the PFIC rules and certain elections that may help to minimize adverse U.S. federal income tax consequences in their particular circumstances. For further information, see Item 10.E – Additional Information – Taxation – U.S. Taxation.

The requirements of being a public company may strain our resources and divert management's attention.

As a publicly-traded company in the United States, Incannex is subject to the reporting requirements of the U.S. Securities Exchange Act of 1934 (the "Exchange Act"), the Sarbanes-Oxley Act and applicable securities rules and regulations. Compliance with these laws will increase our legal and compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires that we file this annual report on Form 20-F and certain other reports. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required. As a result, management's attention could be diverted from other business concerns and, thus, adversely affect our business and results of operations.

The Sarbanes-Oxley Act requires that we assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures. If we identify material weaknesses or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be restated, we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the market price of our securities could decline.

We could become subject to the auditor attestation requirement under the Sarbanes-Oxley Act even if we have little or no revenue, thus imposing significant cost and administrative burden on us.

We currently qualify as an "emerging growth company" and, as a result, are exempt from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of internal controls over financial reporting. We expect to remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of our first public offering in the United States. Once we cease to be an emerging growth company and the aggregate worldwide market value of our voting equity held by non-affiliates exceeds US$75 million as of our most recently completed second fiscal quarter, then we will be subject to the auditor attestation requirement in the assessment of the internal controls over financial reporting.

While the U.S. Securities and Exchange Commission ("SEC") has acknowledged the significant cost of the auditor attestation requirement for small companies and provided an exemption for U.S. "smaller reporting companies" with less than US$100 million in revenue, the SEC has decided not to similarly exempt foreign private issuers (such as Incannex) unless they comply with the reporting requirements for U.S. companies, including presenting financial statements in accordance with U.S. generally accepted accounting principles. Given the significant cost and administrative burden resulting from inconsistent reporting obligations under the rules of the SEC and ASX, it may not be feasible for us to comply with the SEC's reporting requirements for U.S. companies in the event Incannex were to cease being an "emerging growth company" and have aggregate worldwide market value of our voting equity held by non-affiliates exceeding US$75 million.

In such event, we could be obligated to incur significant compliance costs (which in 2019 the SEC estimated to be US$210,000 per annum to comply with the attestation requirement under Section 404 of the Sarbanes-Oxley Act) and administrative burden given our limited number of personnel. If such costs were to become too significant, we could reconsider our listing on Nasdaq because, as the SEC has acknowledged, the savings for a small company could be put to more productive use such as developing the company.

Our issuance of additional ordinary shares in connection with financings, acquisitions, investments, or otherwise will dilute all other ADS holders.

We expect to issue additional ordinary shares in the future that will result in dilution to all other ADS holders. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. While we will be subject to the constraints of the ASX Listing Rules regarding the percentage of our capital that we are able to issue within a 12-month period (subject to applicable exceptions), any such issuances of additional ordinary shares may cause ADS holders to experience significant dilution of their ownership interests and the per ADS value of our ADSs to decline.

As long as we remain subject to the rules of the ASX, we may be unable to conduct certain types of capital raisings without shareholder approval if such capital raising would result in an equity issuance above regulatory thresholds and, consequently, we could be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite shareholder approvals.

Our ability to access equity capital is limited by ASX Listing Rule 7.1, which provides that a company may not, subject to certain exceptions for certain types of offering (*e.g.*, rights offers) or approval by shareholders, issue or agree to issue during any consecutive 12-month period any equity securities, or other securities with rights to conversion to equity, if the number of those securities in aggregate would exceed 15% of the number of ordinary securities on issue at the commencement of that 12-month period.

Our equity issuances will be limited by ASX Listing Rule 7.1 as long as we continue to be listed on the ASX and this constraint may prevent us from raising the full amount of equity capital needed for operations without prior shareholder approval or structuring the capital raising within one of the exceptions to this limitation such as a rights offer.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

Our ordinary shares are quoted in Australian dollars on the ASX and the ADSs will be quoted in U.S. dollars. Any significant change in the value of the Australian dollar could have a negative effect on the value of the ADSs in U.S. dollars. In addition, if the Australian dollar weakens against the U.S. dollar, then, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. To the extent that we need to convert U.S. dollars we receive into Australian dollars for our operations, appreciation of the Australian dollar against the U.S. dollar would have a negative effect on the Australian dollar amount we would receive from the conversion. Consequently, appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

Our ADS holders are not shareholders and do not have shareholder rights.

Deutsche Bank, as depositary, registers and delivers our American Depositary Shares, or ADSs. Our ADS holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADSs. Holders of our ADSs will have ADS holder rights. A deposit agreement among us, the depositary and our ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. For a description of ADS holder rights, see "Description of Securities" in this Annual Report.

Our shareholders have shareholder rights. Australian law and our constitution govern shareholder rights. For a description of our shareholders' rights, see "Memorandum and Articles of Association" in this Annual Report. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares.

Our ADS holders do not have the same voting rights as our shareholders. ADS holders may exercise voting rights with respect to the underlying ordinary shares only in accordance with the provisions of the deposit agreement. Under the deposit agreement, ADS holders vote by giving voting instructions to the depositary. Upon receipt of instructions, the depositary will try to vote in accordance with those instructions. Otherwise, ADS holders will not be able to vote unless they withdraw the ordinary shares underlying their ADSs.

If we ask for our ADS holders' instructions, the depositary will notify our ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as practical, subject to Australian law and the provisions of the depositary agreement, to vote the shares as our ADS holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADS holders. We cannot assure our ADS holders that they will learn of ordinary shareholders' meetings and receive the voting materials in time to instruct the depositary or withdraw the underlying ordinary shares. This means that there is a risk that our ADS holders may not be able to exercise voting rights and there may be nothing they can do if their shares are not voted as they requested.

Our ADS holders do not have the same rights to receive dividends or other distributions as our shareholders.

Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends in the foreseeable future). Dividends may be paid on shares of one class but not another and at different rates for different classes. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to our ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Our ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADS holders amounts distributed by us as a dividend or distribution.

There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADSs.

The deposit agreement with the depositary generally requires the depositary to convert foreign currency it receives in respect of deposited securities into U.S. dollars and distribute the U.S. dollars to ADS holders, provided the depositary can do so on a reasonable basis. If it does not convert foreign currency, the depositary may distribute the foreign currency only to those ADS holders to whom it is possible to do so. If a distribution is payable by us in Australian dollars, the depositary will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, our ADS holders may lose some of the value of the distribution. The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. This means that our ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could augur less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law.

In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the Depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the Depositary in connection with matters arising under the deposit agreement or the ADSs, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the Depositary.

If a lawsuit is brought against us and/or the Depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may determine different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

As the jury trial waiver relates to claims arising out of or relating to the ADSs or the deposit agreement, we believe that the waiver would likely continue to apply to purchasers of ADSs in secondary transactions. In addition, we believe that the waiver would likely continue to apply to ADS holders or beneficial owners who withdraw the ordinary shares from the ADS facility with respect to claims arising before the cancellation of the ADSs and the withdrawal of the ordinary shares, and the waiver would likely not apply to ADS holders or beneficial owners who subsequently withdraw the ordinary shares represented by ADSs from the ADS facility with respect to claims arising after the withdrawal. However, to our knowledge, there has been no case law on the applicability of the jury trial waiver to ADS holders or beneficial owners who withdraw the ordinary shares represented by the ADSs from the ADS facility. Nevertheless, if this jury trial waiver is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or the ADSs serves as a waiver by any owner or holder of ADSs or by us or the Depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Risks Relating to Our Location in Australia

Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.

Incannex is incorporated in Australia and is subject to the takeover laws of Australia and the Corporations Act 2001 (Commonwealth of Australia). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares (including through the acquisition of ADSs) if the acquisition of that interest will lead to a person's or someone else's voting power in us increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%. Exceptions to the general prohibition include circumstances where the person makes a formal takeover bid for us, if the person obtains shareholder approval for the acquisition or if the person acquires less than 3% of the voting power of us in any rolling six-month period. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.

Holders of our ordinary shares or ADSs may have difficulty in effecting service of process in the United States or enforcing judgments obtained in the United States.

Holders of our ordinary shares or ADSs may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the U.S., liabilities under U.S. securities laws. In particular, if such a holder sought to bring proceedings in Australia based on U.S. securities laws, the Australian court might consider:

- that it did not have jurisdiction;
- that it was not an appropriate forum for such proceedings;
- that, applying Australian conflict of laws rule, U.S. law did not apply to the relationship between holders of our ordinary shares or ADSs and us or our directors and officers; and/or
- that the U.S. securities laws were of a public or penal nature and should not be enforced by the Australian court.

Holders of our ordinary shares and ADSs may also have difficulties enforcing in courts outside the U.S. judgments obtained in the U.S. courts against any of our directors and executive officers or us, including actions under the civil liability provisions of the U.S. securities laws.

As a foreign private issuer whose shares are listed on the Nasdaq Global Market, we may follow certain home country corporate governance practices instead of certain Nasdaq requirements.

As a "foreign private issuer" (as defined in the SEC's rules) whose ADSs are listed on the Nasdaq Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of The Nasdaq Marketplace Rules. As an Australian company, we may follow home country practice in Australia with regard to the composition of the board of directors and director nomination process. In addition, we may follow Australian law instead of the Nasdaq Marketplace Rules that require that we obtain shareholder approval for certain events. Accordingly, our U.S. shareholders may not be afforded the same protection as provided under Nasdaq's corporate governance rules that are applicable to U.S. companies.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

As a foreign private issuer, we are not subject to the same disclosure requirements applicable to U.S. public companies. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies under the Exchange Act. In addition, our senior management and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies that file quarterly reports on Form 10-Q. Therefore, our U.S. shareholders will not receive the same level of disclosure from us that is applicable to U.S. companies.

Any loss of our foreign private issuer status in the future could result in significant additional cost.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if 50% or more of our securities are held by U.S. residents and more than 50% of our senior management or directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer could be significantly more than costs we incur as a foreign private issuer. If we were to cease to be a foreign private issuer, then we would be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which forms are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required to prepare our financial statements in accordance with U.S. GAAP rather than IFRS. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we could lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of senior management named in this Annual Report.

Certain members of our senior management and board of directors named in this Annual Report are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. As a result, it may be impracticable to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the United States. An award for monetary damages under U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time.

As a result, our U.S. shareholders may have more difficulty in protecting their interests through actions against us, our management or our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States. In addition, as a company incorporated in Australia, the provisions of the Australian Corporations Act 2001 regulate the circumstances in which shareholder derivative actions may be commenced which may be different, and in many ways less permissive, than for companies incorporated in the United States.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal name is Incannex Healthcare Limited ("Incannex"). We were incorporated in Australia in April 2001 under the name Mount Magnet South Limited. In November 2016, we changed name to Impression Healthcare Limited, and in June 2020, to Incannex Healthcare Limited. Incannex was listed on the ASX in 2016 and on Nasdaq in February 2022.

Since 2019, we have been conducting research and development for medicinal cannabis pharmaceutical products and psychedelic medicine therapies for treatment of a range of indications.

In January 2019, the Department of Health of Victoria granted us licenses to sell or supply cannabinoid substances, and in particular cannabis, cannabidiol ("CBD"), tetrahydrocannabinols ("THC") and dronabinol.

In June 2020, we discontinued the sale of mouthguards for sports activities to focus our resources on cannabinoid sales and development activities. As a result, on June 30, 2020, we sold our wholly-owned subsidiary Gameday International Pty Ltd.

In June 2021, in order to focus on the development of our drug candidates, we terminated our distribution agreement for the sale of cannabinoid products and, as a result, have not had any sales of such products since then.

In August 2022, we acquired APIRx Pharmaceutical USA, LLC, which focuses on the research and development of prescription pharmaceutical cannabinoid medicines. We issued 218,169,497 ordinary shares, at a price of A$0.573 per share, in exchange for 100% of the equity interests in APIRx. Upon completion of the acquisition, the Founders of APIRx, Dr. George Anastassov and Mr Lekhram Changoer joined Incannex as a Director and our Chief Technology Officer, respectively. While APIRx owned intellectual property at the time of the acquisition, it did not have any other material assets or liabilities. The acquisition of APIRx presents Incannex with both long and short-term opportunities for significant value growth. APIRx has twenty-two (22) active clinical and pre-clinical research and development projects underpinned by an intellectual property portfolio that includes 19 granted patents and 23 pending patents. It holds a diverse portfolio of promising therapeutic candidates targeted at treating an extensive range of conditions including pain disorders, addiction disorders, mental illnesses, gastrointestinal diseases, gum disease, skin conditions and ophthalmic conditions. The indications being pursued represented an aggregate addressable market of US$400B per annum.

Our registered office is located at Suite 105, 8 Century Circuit, Norwest 2153, NSW Australia and our telephone number is +61 409 840 786. Our agent for service of process in the United States is Vcorp Services, LLC, (the "Process Agent"), now at 25 Robert Pitt Drive, Suite 204, Monsey, New York 10952. Our address on the Internet is www. incannex.com.au. The information on, or accessible through, our website is not part of this Annual Report on Form 20-F. All information we file with the U.S. Securities and Exchange Commission ("SEC") is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at www.sec.gov.

B. Business Overview

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

The recent acquisition of APIRx brings to Incannex a diverse portfolio of promising therapeutic candidates targeted at treating a broad range of conditions including pain, dementia, Parkinson's disease, restless leg syndrome, gastrointestinal diseases, periodontitis, addiction disorders, skin conditions and ophthalmic conditions.

The acquisition of APIRx strengthens our position in the area of cannabinoid and psychedelic treatment development. In particular, it:

- adds a large portfolio of intellectual property with granted and pending patents;
- significantly expands Incannex's addressable markets globally and addressable market sizes;
- further enhances Incannex's technical and drug development capability; and
- expands Incannex's drug delivery capability to include APIRx's patented delivery technologies.

Strategy

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

We develop targeted and scientifically validated fixed-dose combinations of cannabinoids with generic partners, unique formulations of 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 that also represent compelling commercial opportunities. In particular, we are developing three unique pharmaceutical compositions to target five indications: obstructive sleep apnea ("OSA"), traumatic brain injury and concussion ("TBI"), rheumatoid arthritis ("RA"), inflammatory bowel disease ("IBD") and inflammatory lung conditions ("ARDS", "COPD", Asthma, Bronchitis). We are also developing a treatment for generalized anxiety disorder ("GAD") utilising psilocybin combined with innovative psychotherapy methods. With the acquisition of APIRx we are also developing cannabinoid products to target an additional 22 indications. The most progressed of these are pain and spasticity associated with multiple sclerosis, irritable bowel syndrome, opioid addiction, smoking cessation, cannabis use disorder, vitiligo, atopic dermatitis and psoriasis. 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. Mark Bleackley (our Chief Scientific Officer), Dr George Anastassov (Non-executive director), Lekhram Changoer (our Chief Technical Officer), Rosemarie Walsh (our VP Clinical Operations), and Dr Paul Liknaitsky (psychedelic principal investigator from Monash University).

To achieve our goals, we intend to:

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

- **Take advantage of accelerated commercialization pathway options for our drug candidates**. We and our regulatory consultants believe that each of our drug candidates will qualify for one or more FDA expedited review programs (breakthrough designation, accelerated approval, priority review and/or fast track), as there are a limited amount of pharmaceutical drug treatments approved in the U.S. to treat the indications that we are targeting with our drug candidates, and the pharmaceutical treatments that do exist provide limited treatment and are costly. These expedited review programs often result in accelerated and less-costly regulatory pathways to approval compared with traditional regulatory pathways. We have not yet approached the FDA about the suitability of our products for these accelerated approval pathways and such designations do not guarantee accelerated review by the FDA.

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

- **Maintain a strong intellectual property portfolio**. We have developed a global intellectual property strategy to support our commercial objectives. We are monitoring the results of our research and development programs to identify new intellectual property that aligns with those commercial objectives. We intend to take a global approach to our intellectual property strategy and 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 and we own a further 19 granted and 23 pending patents resulting from the APIRx acquisition. Our patents approach aligns with our regulatory strategy, including the proposed submission of Pre-Investigational New Drug Application ("pre-IND") meeting requests to the FDA for our clinical programs.

Clinical Approach

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

Market Opportunity

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

Our 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. The estimated compound annual growth rate ("CAGR") for OSA detection and treatment using CPAP devices from 2021 to 2028 is 6.2%.

IHL-42X in Obstructive Sleep Apnea

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

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

We have recently completed a proof-of-concept Phase 2 clinical trial in Australia to support our IND application with FDA and to inform the clinical design of our future pivotal Phase 2 clinical trial, which will be conducted under the IND to assess the safety and efficacy of IHL-42X in patients with Obstructive Sleep Apnea. The IND for IHL-42X in treatment of OSA has not yet been submitted and although we have incorporated multiple facets into this study, including full monitoring by a CRO and CDISC data formatting.

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

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

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

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

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

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

- All doses of IHL-42X reduced AHI in patients with sleep apnoea compared to baseline (Table 1). This reduction was substantially greater than observed for placebo.

Average AHI data for baseline and each treatment period

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

- At the group level the difference relative to baseline with low dose and medium dose was statistically significant ($p<0.05$).

- When comparing directly to baseline within patients the difference in AHI compared to baseline between all three doses and placebo was statistically significant ($p<0.001$) (Table 2)

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

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

- Low dose IHL-42X reduced AHI by >50% relative to baseline in 62.5% of patients and by >80% in 25% of patients.

- Low dose IHL-42X reduced AHI to the greatest extent at both the group level and when comparing the within patient reduction relative to baseline.

- Low dose IHL-42X reduced AHI to a greater extent than predicted based on published data for dronabinol and acetazolamide alone (Table 3).

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

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

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

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

- all three doses of IHL-42X reduced ODI compared to baseline to a greater extent than placebo.

- For low and medium dose IHL-42X the difference in reduction in ODI relative to baseline compared to placebo was statistically significant ($p<0.05$).

Reduction in ODI compared to baseline during each treatment period.

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

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

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

Patient reported sleep quality during each treatment period

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

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

Sleep metrics captured by actigraphy

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

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

Proportion subjects of TEAEs reported for each treatment period

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

Total number of TEAEs reported during each treatment period

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

Incannex are finalizing the formulation of the IHL-42X fixed dose combination product and drafting an IND application for submission to the FDA. Once the IND is open a multisite, pivotal Phase 2 using the fixed dose combination product will commence. In parallel with the IND application Incannex will conduct a bioavailability and bioequivalence clinical trial in Australia to support the bridging to the reference listed drugs for dronabinol and acetazolamide in a future FDA application.

IHL-216A

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

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

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

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

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

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

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

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

The total global addressable market for TBI was estimated to be US$6.7 billion in 2020 and the anticipated CAGR for the market from 2021 to 2028 is 8.3%. There are currently no pharmacological treatments for the secondary neurological effects of TBI.

IHL-216A Formulation development for clinical trials

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

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

In August 2022, we engaged Curia Global, Inc. ("Curia") to further develop and manufacture GMP-grade IHL-216A. Curia, formerly AMRI, is a leading contract research, development and manufacturing organization providing products and services from R&D through commercial manufacturing to pharmaceutical and biopharmaceutical customers.

Vector's and Curia's engagement represents substantial progress in the development of IHL-216A and follows positive results from extensive proof-of-concept and optimization studies undertaken at Vectura. Curia is engaged to scale-up the fill-finish manufacture of IHL- 216A in compliance with Current Good Manufacturing Practice ("cGMP"). Curia will also generate data on the quality and stability of IHL-216A to support future regulatory filings, including a FDA pre-IND package and subsequent IND application. The first cGMP batch manufactured at Curia will be used in a phase 1 clinical trial. Incannex received feedback from the FDA on the proposed clinical development of IHL-216A in a pre-IND meeting in September 2022. We are currently taking on board the recommendations of the FDA to adjust the clinical development strategy and incorporate the FDA's suggestions on the Phase 1 clinical trial design.

In September 2022, via written pre-IND meeting correspondence, the FDA provided valuable, multidisciplinary feedback on the proposed clinical development of IHL-216A and acknowledged that treatment of TBI is a significant unmet medical need that requires innovative treatment solutions. The FDA also confirmed that FDA505(b)2 was the appropriate regulatory pathway for IHL-216A, whereby some of the information required for marketing approval may derive from studies already completed on the drug components of IHL-216A and in the public domain.

FDA provided critical guidance on the data requirements for opening an IND for IHL-216A, particularly related to the intricacies of developing an inhaled drug product and conducting clinical trials that involve an anaesthetic. Incannex is drafting a follow-up request for additional information on the FDA's recommendations and will provide an update to ASX and Nasdaq investor platforms when it has been received.

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

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

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

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

Post-mortem analysis of rat brains also detected synergy between CBD and isoflurane. Brains were fixed and sectioned prior to Nissl staining to identify neuronal damage. Nissl staining is a microscopy technique to visualise Nissl bodies. Healthy neurons typically have more Nissl bodies than damaged ones. Neuronal damage is indicated by the ratio of Nissl bodies to neurons across different sections of the hippocampus with a lower Nissl/neuron ratio indicative of increased neuronal damage. Synergy between CBD and isoflurane was detected in hippocampal regions *cornu ammonis* 1 (CA1) and *cornu ammonis* 2 (CA2). These regions of the brain are known to be important in the formation and storage of memories. In the study, the improvement in Nissl/Neuron ratio observed for IHL-216A treated animals was increased by 53% for CA1 and 60% for CA2 relative to CBD alone, 28% for CA1 and 145% for CA2 relative to isoflurane alone, and by 20% for CA1 and 53% for CA2 relative to the predicted effect of CBD and isoflurane combined. These results demonstrated that less neuronal damage was observed in the rats treated with IHL-216A relative to the predicted value.

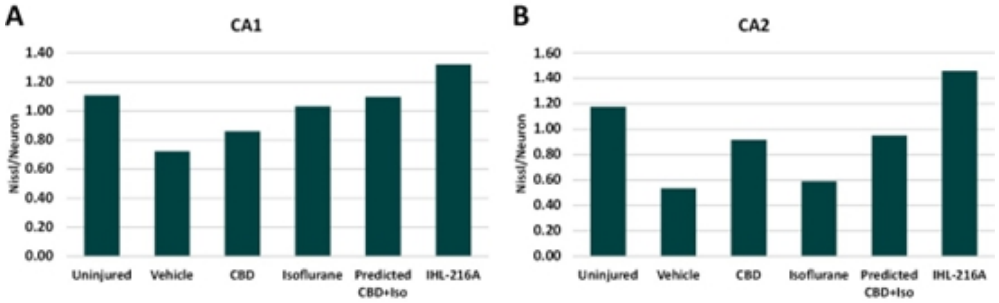


Figure 1. Synergistic activity of CBD and isoflurane (IHL-216A) in neuronal damage as assessed by Nissl staining. *Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for neuronal damage by post-mortem analysis of fixed brain sections by Nissl staining. Nissl staining permits the quantitation of the ratio of Nissl bodies to total neurons, a lower ratio being indicative of increased neuronal damage. The Nissl/neuron ratio observed in hippocampal regions (A) CA1 and (B) CA2 contralateral to the site of injury in the group treated with IHL-216A was greater than that predicted based on the groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=6, CBD n=6, isoflurane n=5, IHL-216A n=6. Neuroinflammation Marker — Iba1.*

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

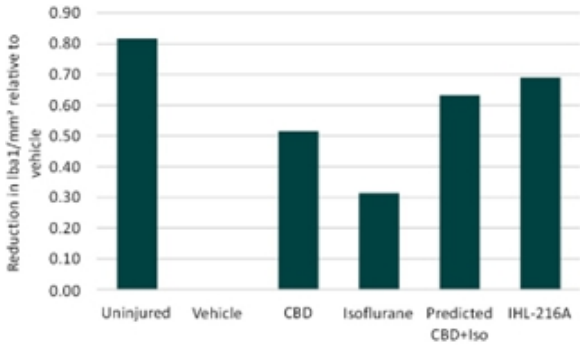


Figure 2. Synergistic activity of CBD and isoflurane (IHL-216A) in reducing levels of the neuroinflammatory marker Iba1. *Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for neuroinflammation through immunofluorescence analysis of the neuroinflammatory marker Iba1. Iba1 levels increase after TBI and a reduction in Iba1 is indicative of a reduction in neuroinflammation. Iba1 levels in brain sections ipsilateral to the site of injury in the group treated with IHL-216A were reduced more than would be predicted based on the reduction observed in groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=5, CBD n=6, isoflurane n=3, IHL-216A n=5.*

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

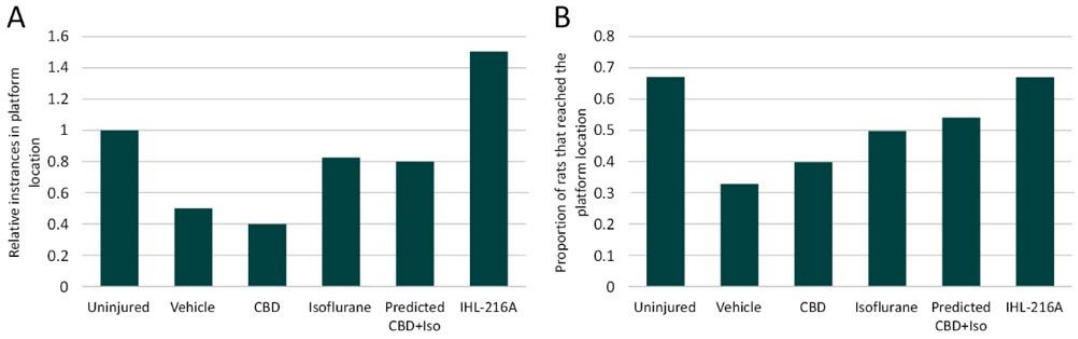
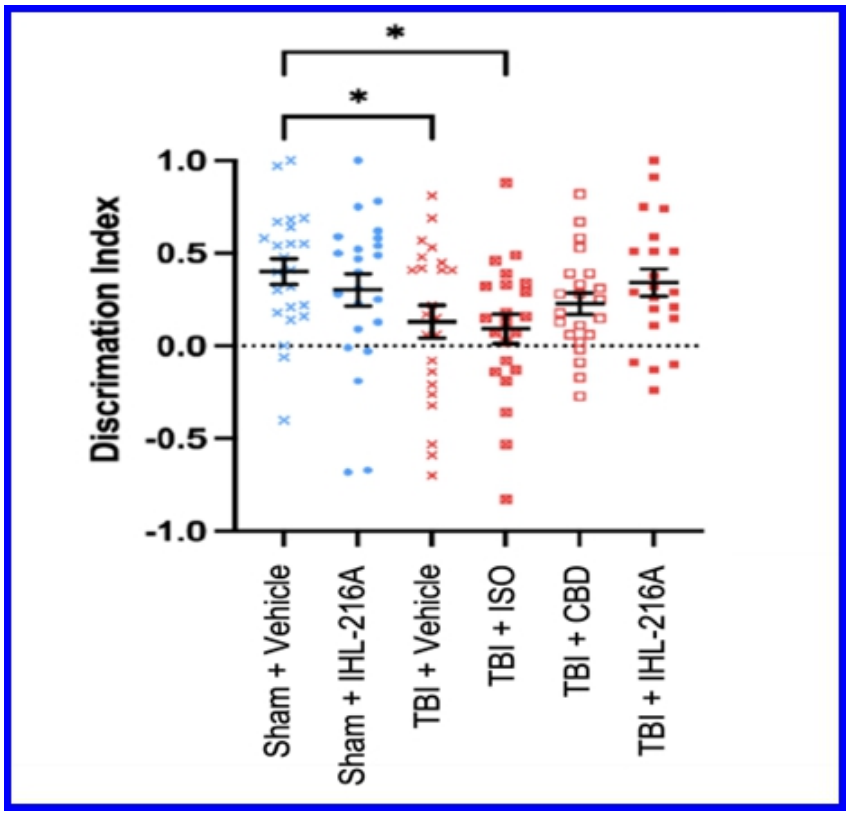


Figure 3. Synergistic activity of CBD and isoflurane (IHL-216A) in the Morris Water Maze assessment. *Rodents that had undergone TBI and treated with CBD and/or isoflurane or vehicle were assessed for spatial learning and memory using the Morris Water Maze. The observed performance with respect to both (A) relative instances of animal in platform location and (B) proportion of animals in that reached the platform location was better in the group treated with the CBD isoflurane combination (IHL-216A) than what was predicted based on the performance of the groups treated with each drug alone, which is indicative of synergy. Values are average of the respective treatment group. Group sizes: Uninjured n=6, vehicle n=6, CBD n=5, isoflurane n=6, IHL-216A n=6.*

Stage 2 pre-clinical study for IHL-216A

In May 2022, we announced that the stage 2 study had been completed and that IHL-216A was observed to have a strong neuroprotective effect in a widely, known model of sports concussion developed in collaboration with the NFL to accurately represent the type of brain injury that occurs in sports-related concussion. This study compared six groups of twenty-four Sprague Dawley rats When animals were tested in a Y-maze task, which assesses spatial memory by determining the animal's ability to discriminate between a novel (new) and familiar arm, twenty-four hours after injury, animals treated with IHL-216A were found to have no difference in discrimination index compared sham (uninjured) animals (mean difference= 0.0598, p=0.5855) (Figure 1). In contrast, injured animals treated with either vehicle or isoflurane alone after injury, the discrimination index was significantly reduced compared to sham animals (mean diff=0.2704, p=0.0498 and mean diff=0.3095, p=0.0245 respectively). The group treated with CBD alone had intermediate performance in the Y-maze between sham and vehicle treated animals (mean diff.0.1745, p==0.2933). These findings indicate that the defect in spatial memory observed at 1 day post injury is restored in animals treated with IHL-216A.



IHL-216A restores the deficit in Y-maze novel/familiar arm discrimination index assessment 24 h post TBI. A Y-maze was used to assess spatial memory 24 h after induction of TBI. Sham + Vehicle treated animals displayed a clear preference for the novel arm. This preference was reduced in TBI + vehicle animals, indicating that there is a deficit in novel arm discrimination associated with TBI. 10 Each group consisted of 24 rodents.

IHL-675A

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

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

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

In July 2022, we received approval from the Bellberry Human Research Ethics Committee ("HREC") for a phase 1 clinical trial investigating the proprietary multi-use of IHL-675A. The trial measured the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ). Three cohorts of 12 participants (n = 36) received either IHL-675A, CBD or HCQ and the assessments were identical across the three arms of the trial. Patient recruitment commenced in August 2022 and dosing was completed in September 2022. Participants will continue to be monitored until the end of October 2022, after which blood samples will be assessed for levels of CBD, HCQ and major metabolites to characterize the pharmacokinetics of each active pharmaceutical ingredient. The CSR will be available in Q1 2023.

In October 2022, we announced that dosing in the Phase 1 trial had been completed and no adverse events of concern had been reported. This announcement also included that the next steps were that the company has commenced arranging for a Phase 2 clinical trial investigating safety and efficacy in arthritis patients and preparations for a pre-IND meeting with the FDA on the use of IHL-675A for treatment of arthritis.

Subject to clinical success, the results of the phase 1 clinical trial will form part of three IND applications with the FDA for each of the initial three indications the Company is pursuing for IHL-675A. These indications are rheumatoid arthritis, inflammatory bowel disease and lung inflammation, representing major markets for Incannex to pursue with IHL-675A. Once the IND applications are evaluated and approved, we intend to conduct clinical trials partly or wholly in the United States.

Lung Inflammation (COPD, Asthma, ARDS and Bronchitis)

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

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

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

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

Rheumatoid Arthritis

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

HCQ is approved for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate and marketed as Plaquenil.

Inflammatory Bowel Disease

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

- Ulcerative colitis. This condition involves inflammation and sores (ulcers) along the superficial lining of the large intestine (colon) and rectum.

- Crohn's disease. This type of IBD is characterized by inflammation of the lining of the digestive tract, which often can involve the deeper layers of the digestive tract.

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

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

Preclinical in vitro study of IHL-675A against inflammation

On November 5, 2020, we released the results of our first in vitro study to investigate the synergistic activity of IHL-675A to inhibit inflammation. To test the anti-inflammatory potential of IHL-675A, human 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 $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$, is subtracted from the observed inhibition to yield an EOB score. An EOB score of greater than zero indicates that the combination is synergistic. None of the below data has been analysed for statistical significance.

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

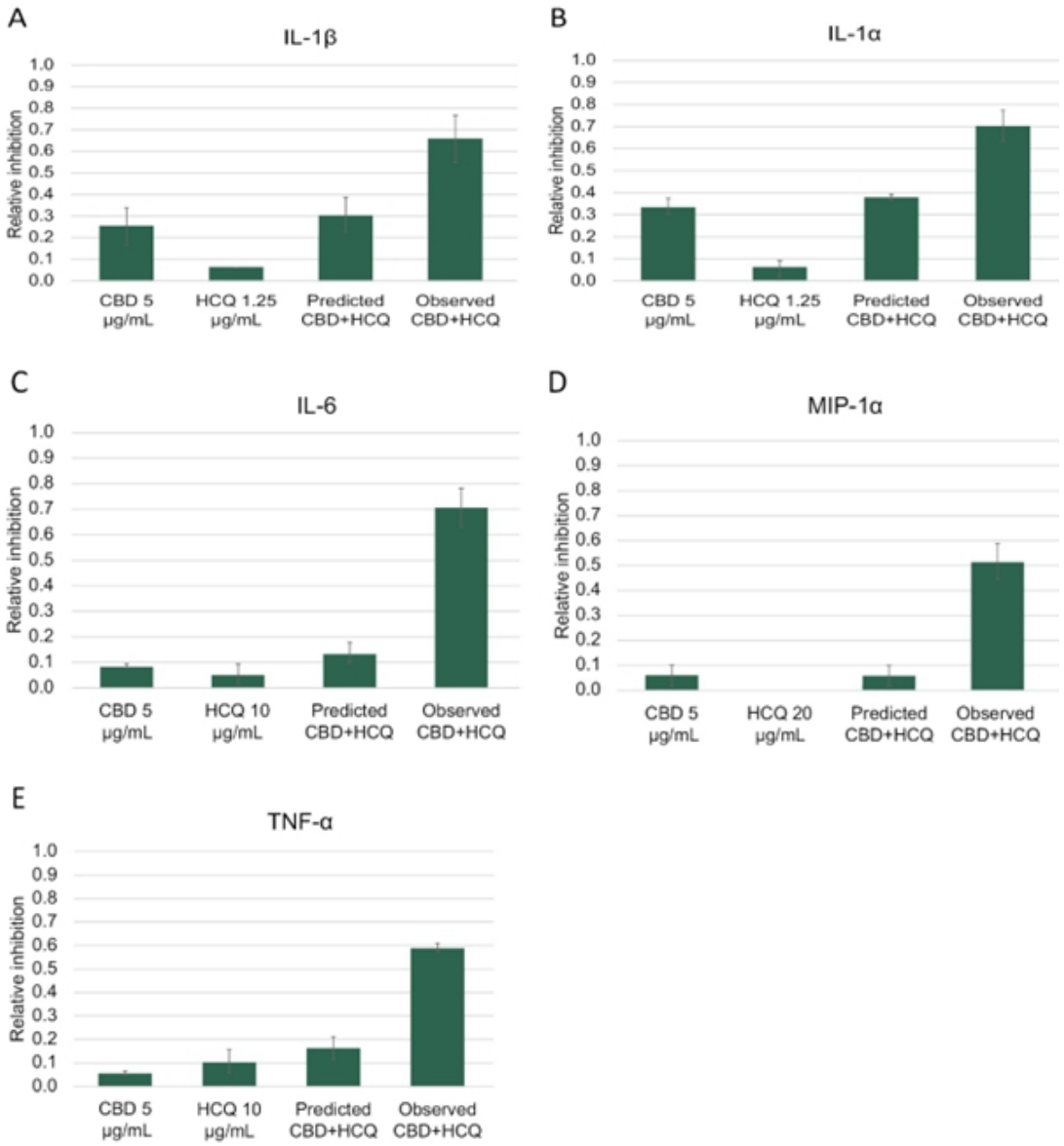
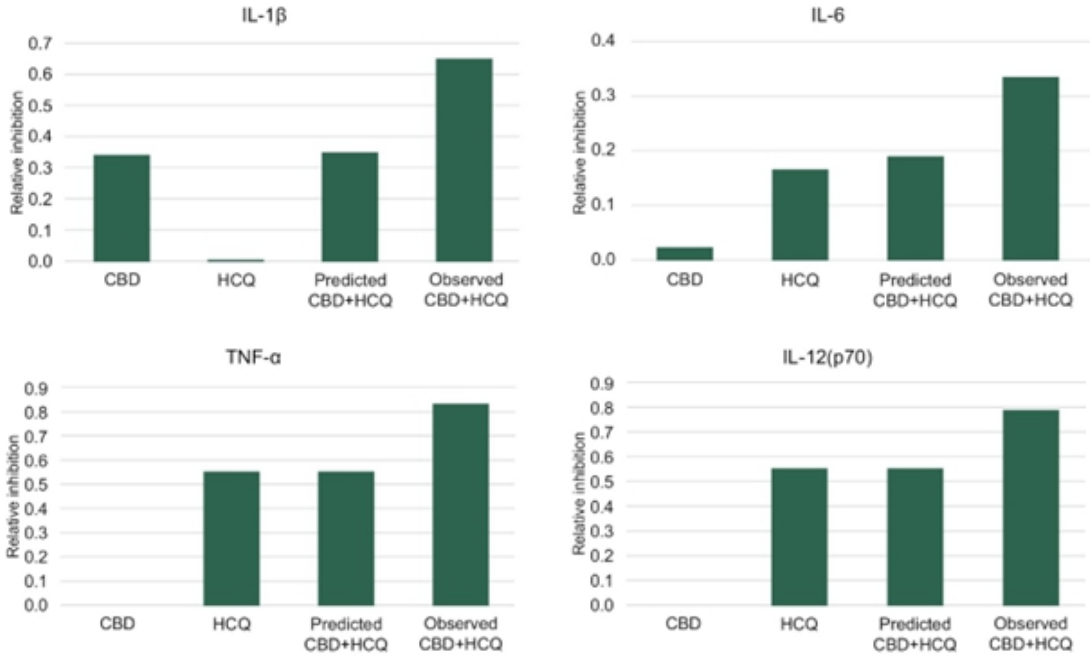


Figure 4. Inhibition of LPS-induced cytokine release from human PBMCs by CBD and HCQ. *Data is presented is the average relative inhibition for the PBMC donors. Predicted inhibition by CBD+HCQ was calculated using the formula* $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$. *Observed CBD+HCQ is the level of inhibition 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 $E_{pred\ A+B}=(E_A+E_B)-(E_AE_B)$. An EOB score of greater than 0 is indicative of synergy.

The results of the in vivo study are presented in Figure 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-1β, IL-6, TNF- α, IL12(p70), and IFN-γ in a mouse model of LPS induced sepsis. The average EOB scores ranged from 0.15-0.30. Levels of the five inflammatory cytokines were reduced compared to animals treated with vehicle to a greater extent in animals treated with IHL-675A than in those treated with CBD alone. Reduction in cytokine levels compared to vehicle treated group in the group treated with IHL-675A was 26% to 81% greater relative to the predicted effect of the CBD HCQ combination across the five analyzed cytokines after 2 hours.



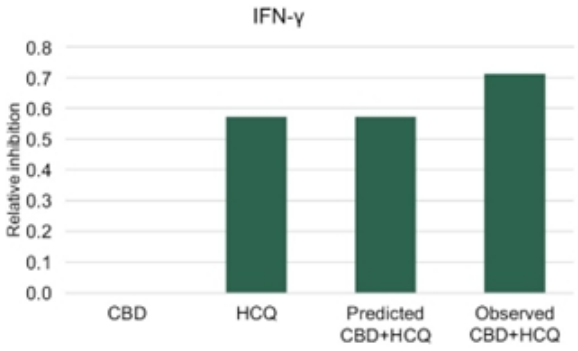


Figure 5. Synergistic anti-inflammatory activity of CBD and HCQ in a mouse sepsis model. *The anti-inflammatory activity of the combination of CBD and HCQ was greater than that predicted using the Excess over Bliss method. The CBD+HCQ combination was synergistic at inhibiting release of IL-1β, IL-6, TNF-α, IL12(p70), and IFN-γ.*

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

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

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

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

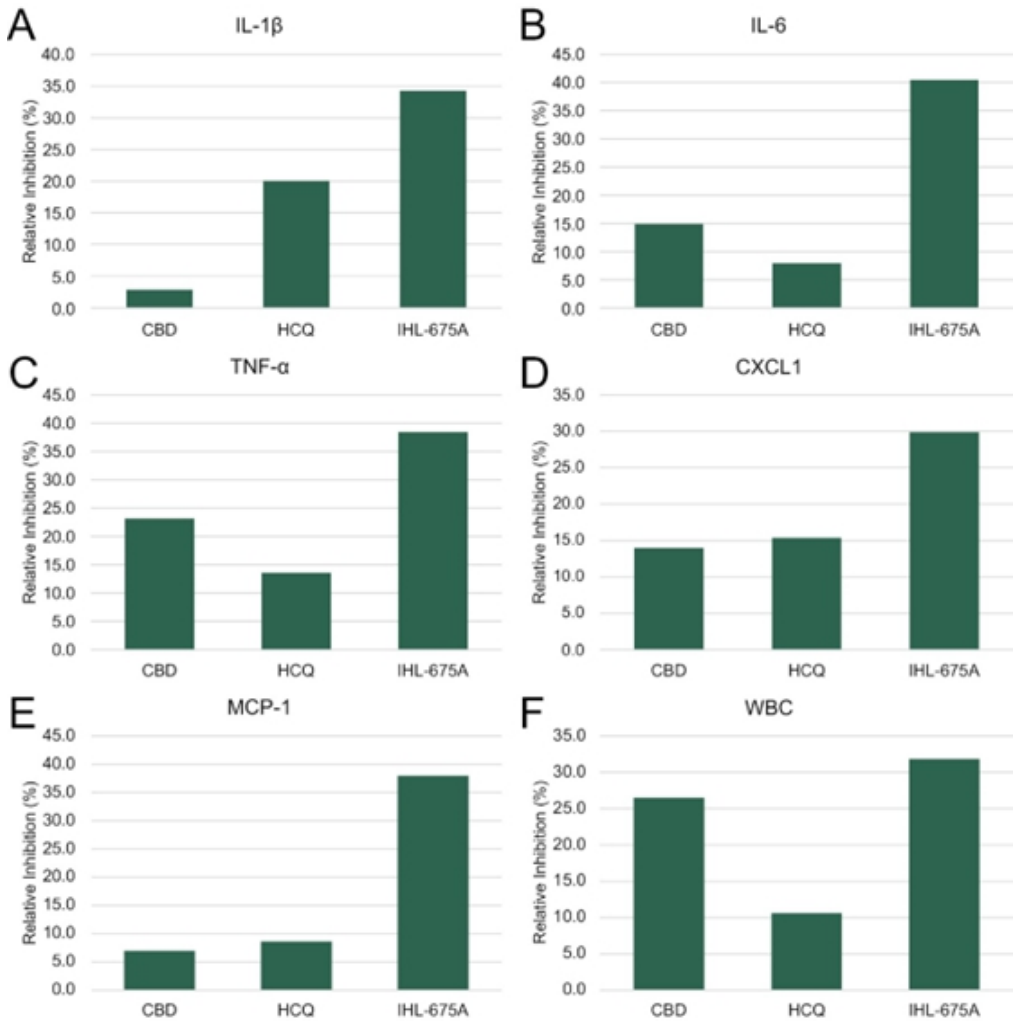


Figure 6. Reduction in cytokine levels and white blood cell count in BALF resulting from treatment with by IHL-675A, CBD or HCQ in a mouse model of pulmonary inflammation. *Mice were treated with CBD, HCQ or a combination of CBD and HCQ (IHL-675A) and then LPS was administered intratracheally. Twenty-four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

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

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

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

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

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

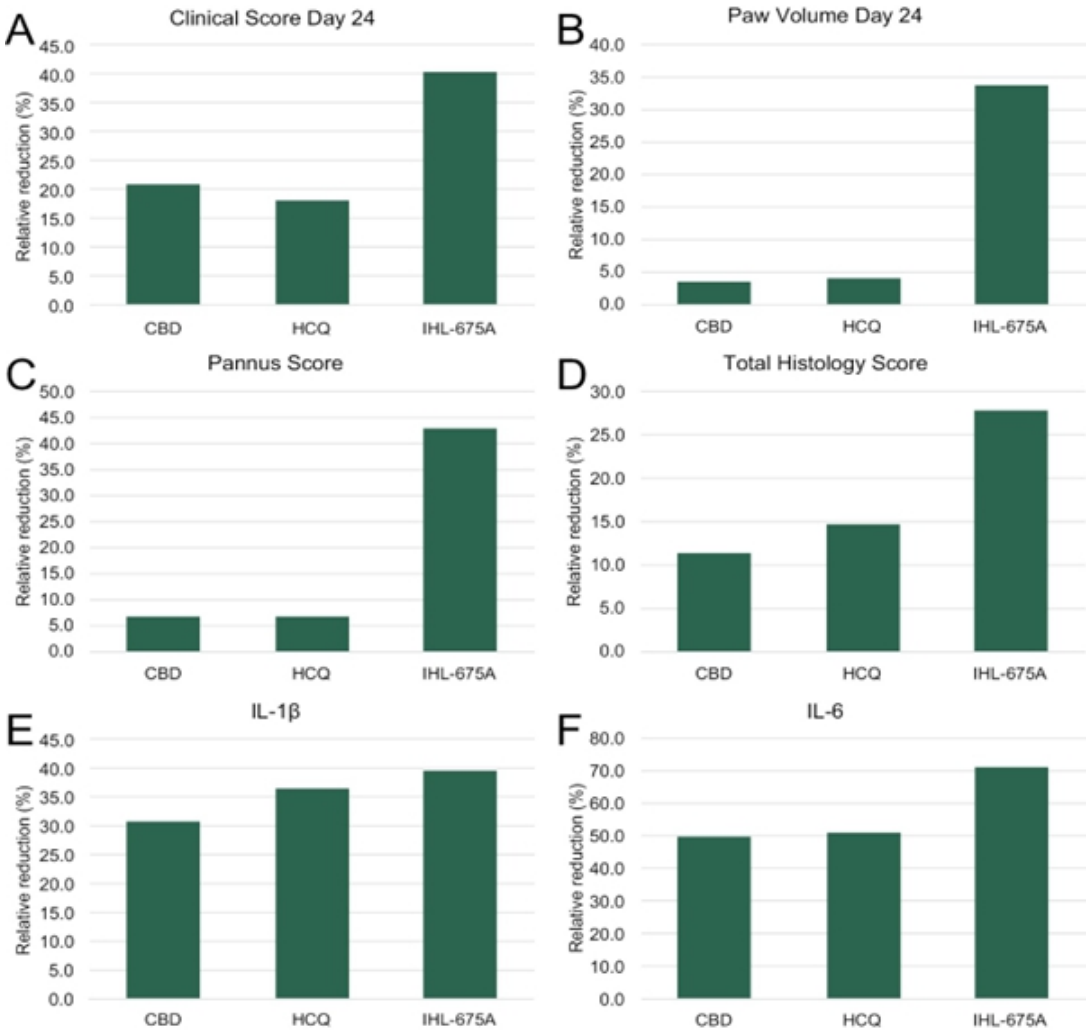


Figure 7. Comparison of IHL-675A to its component drugs CBD and HCQ in reduction of disease assessments in a rat model of rheumatoid arthritis. *Groups of rats that had undergone collagen-induced arthritis modelling were treated with IHL-675A, CBD or HCQ at equivalent doses (1 mg/kg CBD, 2.5 mg/kg HCQ). The reduction in arthritis disease severity in IHL-675A treated rats was greater than for either CBD or HCQ treated rats with respect to (A) clinical score at day 24, (B) paw volume at day 24, (C) pannus formation, (D) total histology score, (E) serum IL-1b levels and (F) serum IL-6 levels.*

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

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

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

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

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

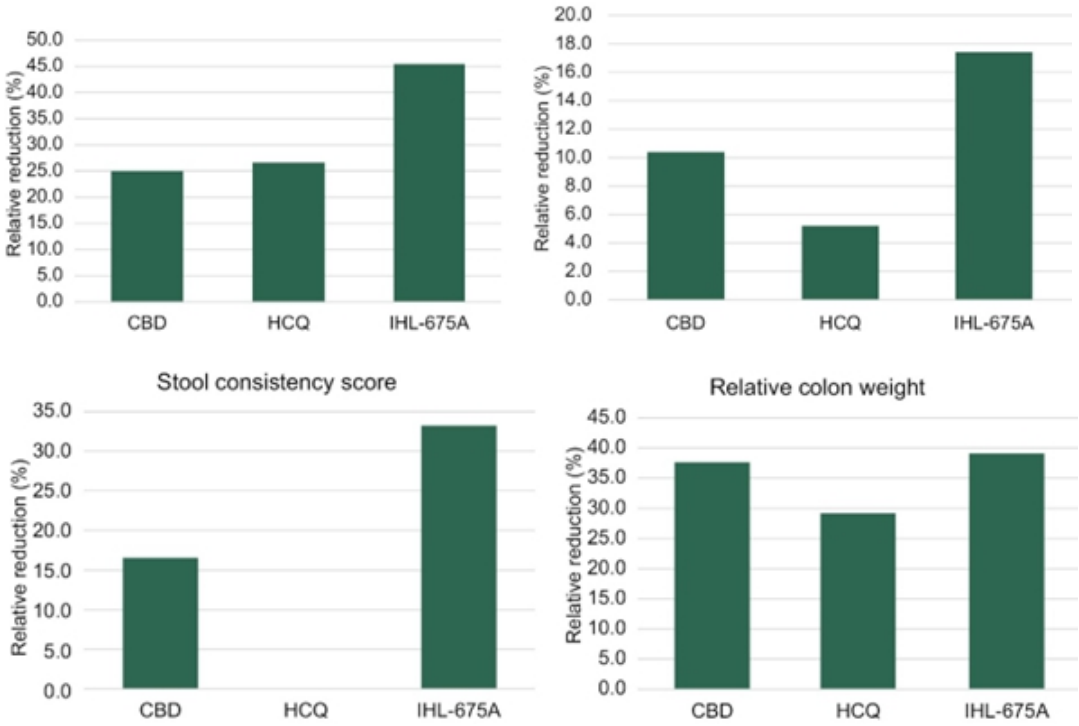


Figure 8. Reduction in colitis score assessments by CBD and HCQ (IHL-675A) in a mouse model of colitis. *Colitis was induced in mice by intracolonic installation of TNBS/ethanol and then treated with CBD, HCQ or CBD and HCQ (IHL-675A). After 4 days, mice were sacrifice and the colons extracted for macro 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.*

Phase 1 clinical trial for IHL-675A

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

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

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

Approval from the Human Research Ethics Committee to conduct the phase 1 study was received in July 2022. Participant recruitment commenced in August 2022 and dosing was completed in September 2022. Participants will continue to be monitored until the end of October 2022, after which blood samples collected during the study will be assessed for levels of CBD, HCQ and major metabolites to characterise the pharmacokinetics of each active pharmaceutical ingredient. The CSR will be available in Q1 2023. IHL-675A has been well tolerated, with no adverse events of concern reported to date. No serious adverse events have been reported.

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

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

Generalized Anxiety Disorder

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

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

Existing treatments

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

Psilocybin as a treatment for generalized anxiety disorder

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

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

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

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

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

- New York University, Ross et al 2016 (n=29): **Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial.** Psilocybin produced immediate, substantial, and sustained improvements in anxiety and depression, as well as decreases in cancer-related demoralization and hopelessness, improved spiritual wellbeing, and increased quality of life.

- Imperial College London, Carhart-Harris et al 2018 (n=20): **Psilocybin with psychological support for treatment-resistant depression: six-month follow-up.** Good tolerability, effect sizes large and symptom improvements appeared rapidly after just two psilocybin treatment sessions and remained significant six months post-treatment in a treatment-resistant cohort.

- University of California, Los Angeles, Grob et al 2011 (n=12): **Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer**. The State-Trait Anxiety Inventory trait anxiety subscale demonstrated a significant reduction in anxiety at one and three months after treatment. There were no clinically significant adverse events with psilocybin.

- John Hopkins University, Griffiths et al 2017 (n=51): **Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: a randomized double-blind trial.** Large and significant decreases in clinician-rated and self-rated measures of depression, anxiety or mood disturbance, and increase measures of quality of life, life meaning, death acceptance, and optimism.

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

Our investigational psilocybin therapy for Generalized Anxiety Disorder

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

Phase 2 exploratory clinical trial

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

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

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

FDA development plan and pre-IND meeting

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

Psilocybin therapy protocol

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

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

- Preliminary psychotherapy: conducted during the screening stage with key focus on clinical formulation, therapeutic alliance, psychedelic treatment psychoeducation and practical preparation for dosing.

- Preparation psychotherapy: conducted following full enrollment and prior to the first dosing session with a key focus on extending preliminary psychotherapy work, and covering more targeted and GAD-specific psychological and practical preparation for dosing.

- After dosing support: conducted within a week following the preparation session with key focus on trust, suitable mindset, conducive physical setting, and participant-led support. Dosing support is the psychotherapy session.

- Integration psychotherapy: conducted following the dosing sessions, including the day directly following each dosing session, with key focus on sustaining benefits through specific mindful, emotion and somatic-focused therapy, meaning-centered support, and facilitating contextual changes that support outcomes.

Monash University

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

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

Virtual Reality ("VR") Exposure Response Therapy ("ERP") and psychedelics

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

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

Clinical trial investigators

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

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

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

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

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).

Cannabinoid Chewing Gums and chewable tablets

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

Our subsidiary APIRx has multiple patents for cannabinoid-based drug candidates designed for treatment of addiction to different drug classes (including marijuana addiction, smoking addiction and opioid addiction) as well as sustaining pain (including for pain and spasticity in Multiple Sclerosis as well as nausea and vomiting in Chemotherapy).

MedChew Dronabinol for chemotherapy induced nausea and vomiting

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

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

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

Up to 84% of people suffering from MS also experience spasticity, which causes involuntary muscle stiffness and spasms. Pain is also a common symptom in MS, with up to two-thirds of people with MS reporting pain in worldwide studies. MedChew™ Rx is absorbed through the oral mucosal membrane and bypasses the liver, and first pass metabolism. MedChewTM Rx contains the same constituent formulation of CBD and THC as the product Sativex, which was initially approved in Canada in 2005 and is now available in 25 countries, including 18 in Europe, and Australia. MedChew Rx, however, facilitates extended dosing and reduces the need to readminister, which for Sativex is up to 12 times per day. It does not contain alcohol, which Sativex does, and will not exacerbate the dry mouth that is often associated with MS pharmacotherapy. MedChew Rx has underlying patent protection via granted patents related to chewing gums comprising cannabinoids. APIRx staff have completed regulatory meetings with Swiss-Medic (Switzerland) and CBG-MEG (Netherlands). There is potential to fast track to drug approval in Europe with a bioequivalence phase 1 study to bridge to Sativex CBD/THC oral spray safety and efficacy data.

Medicated Chewing Gum and Chewable Tablets for Treatment of Addiction

CheWell for Cannabis Dependence

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

We have data for CheWell as a high bioavailability product. A Phase 1 pharmacokinetic (PK) study demonstrated that the patented CheWell formulation led to >10x increase in CBD bioavailability compared to the standard CBD chewing gum delivery mechanisms. Data from 36 patient phase 2 proof of concept trial observed a 50% reduction in abdominal pain in CheWell treated Irritable bowel syndrome (IBS) patients, supporting a therapeutic effect in IBS. International regulatory analysis is being undertaken to identify what is required for commercial launch in different jurisdictions. Improved bioavailability means that even small doses of CBD within MCGTs could be highly effective even without a prescription from a doctor, thus meeting the TGA requirements for an OTC product. Increased bioavailability also reduces cost of goods, which increases margins. First marketing claim will be for IBS, however, the CheWell product could provide a therapeutic benefit for a range of indications where CBD may assist patients.

CanQuit for Smoking Cessation

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

CanQuit O for Opioid Addiction

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

CanChew Rx and SuppoCan for Inflammatory Bowel Disease

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

OraxiMax for Periodontal Disease and Gingivitis

Up to 50% of adults worldwide suffer from moderate to severe periodontitis and/or gingivitis. Periodontal disease treatment has been limited to professional dental cleaning and the use of systemic antibiotics. We are developing OraxiMax Toothpaste and Mouthwash contain CBD and Cannabigerol (CBG) which can prevent dental plaque formation, and thus gingivitis and periodontitis. Due to their proprietary formulations, the local availability of Active Pharmaceutical Ingredients ("APIs") are increased while systemic absorption is kept to minimum.

Benefits of CBD in dental protection include:

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

We have observed encouraging bioavailability data for OraxiMax products and intend to undertake a phase 2 study to demonstrate appropriate safety and efficacy to register the products with the FDA.

Topical cannabinoid development

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

Cannabinoids for Ophthalmic Conditions

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

Intellectual Property

We have implemented a patent filing strategy as we develop our products and therapies in conjunction with our medical advisory board. As of June 30, 2022, we own pending patent applications relating to our cannabinoid drug candidates. A summary of the number of patents, patent types and jurisdictions in listed in the table below. Once converted to the complete/PCT stage, the provisional patents will also be applicable to all PCT contracting states. International search reports and written opinions of the International Search Authority have confirmed that the key claims in our filed Patent Cooperation Treaty applications are novel and inventive and that the invention meets the requirements of industrial applicability. The preparation of the International Search Report (ISR) and International Search Opinion (ISO) for PCT applications is one of the main procedural steps of the international phase of the Patent Cooperation Treaty (PCT). The purpose of conducting the searches at the international phase is to identify the relevant prior art and for the International Searching Authority to establish a preliminary opinion as to whether the claims are novel, involve an inventive step and are industrially applicable. While the ISR and the ISO are non-binding, in the sense that national patent offices are not obliged to accept any finding of the International Searching Authority, these reports often represented a useful guide in relation to the patentability of the subject matter claimed in the PCT application.

In the context of the PCT applications that cover the cannabinoid drug candidates, IHL-216A, IHL-675A and IHL-42X, the International Searching Authority is the Australian Patent Office. Accordingly, the opinion expressed in the ISR / ISO for each of these PCT applications is based on searches that have been conducted by Australian Patent Examiners.

Product/technology	Number of applications	Type of patent protection	Applicable jurisdictions
IHL-42X/Compositions and methods for the treatment of obstructive sleep apnoea (OSA)	1	Complete/PCT	All 153 PCT contracting states[#]
IHL-675A/Compositions and methods for the treatment of an inflammatory conditions	2	Complete/PCT	All 153 PCT contracting states
IHL-216A/Compositions and methods for the treatment or prevention of traumatic brain injury (TBI)	2	Complete/PCT	All 153 PCT contracting states[#]

Standard/utility patents derived from the PCT application are intended to be pursued in key jurisdictions including Australia, US, Europe, Japan and Israel.

The cannabinoid drug candidate, IHL-675A, is a combination of CBD and hydroxychloroquine, which is specifically defined by claim 16 of International (PCT) Application No. PCT/AU2021/050226. The International Searching Authority considers claim 16 to be both novel and inventive.

The cannabinoid drug candidate, IHL-42X, is a combination of THC and acetazolamide for use in the treatment of obstructive sleep apnoea (OSA), which is specifically defined by claim 3 of International (PCT) Application No. PCT/AU2021/050734. The International Searching Authority considers claim 3 to be both novel and inventive.

The cannabinoid drug candidate, IHL-216A, is a combination of CBD and isoflurane, which is specifically defined by claim 23 of International (PCT) Application No. PCT/AU2020/051056. The International Searching Authority considers claim 23 to be both novel and inventive.

In addition to pursing patent protection for all of our assets, we rely on unpatented trade secrets, know-how and other confidential information as well as proprietary technological innovation and expertise that are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants.

Patent matters in biotechnology are highly uncertain and involve complex legal and factual questions. The availability and breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. Statutory differences in patentable subject matter may limit the scope of protection we can obtain on some or all of our licensed inventions or prevent us from obtaining patent protection either of which could harm our business, financial condition and results of operations. Since patent applications are not published until at least 18 months from their first filing date and the publication of discoveries in the scientific literature often lags behind actual discoveries, we cannot be certain that we, or any of our licensors, were the first creator of inventions covered by pending patent applications, or that we or our licensors, were the first to file patent applications for such inventions. Additionally, the grant and enforceability of a patent is dependent on a number of factors that may vary between jurisdictions. These factors may include the novelty of the invention, the requirement that the invention not be obvious in the light of prior art (including prior use or publication of the invention), the utility of the invention and the extent to which the patent clearly describes the best method of working the invention. In short, this means that claims granted in various territories may vary and thereby influence commercial outcomes.

While we have applied for and will continue to file for protection as appropriate for our therapeutic products and technologies, we cannot be certain that any future patent applications we file, or licensed to us, will be granted, or that we will develop additional proprietary products or processes that are patentable or that we will be able to license any other patentable products or processes. We cannot be certain that others will not independently develop similar products or processes, duplicate any of the products or processes developed or being developed by the company or licensed to us, or design around the patents owned or licensed by us, or that any patents owned or licensed by us will provide us with competitive advantages.

Furthermore, we cannot be certain that patents held by third parties will not prevent the commercialization of products incorporating the technology developed by us or licensed to us, or that third parties will not challenge or seek to narrow, invalidate or circumvent any of the issued, pending or future patents owned or licensed by us.

Our commercial success will also depend, in part, on our ability to avoid infringement of patents issued to others. If a court determines that we were infringing any third-party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. We cannot be certain that the licenses required under patents held by third parties would be made available on terms acceptable to us or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, export, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents, and any of these circumstances could have a material adverse effect on our business, financial condition and results of operations. We may have to resort to litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third-party proprietary rights. Such litigation could result in substantial costs and diversion of effort by us. We may have to participate in opposition proceedings before the Australian Patent and Trademark Office or another foreign patent office, or in interference proceedings declared by the United States Patent and Trademark Office, to determine the priority of invention for patent applications filed by competitors. Any such litigation interference or opposition proceeding, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could prevent us from developing, manufacturing or commercializing our products and could have a material adverse effect on our business, financial condition and results of operations.

As of June 30, 2022, the Company also owns trademark registrations in Australia, United States, Europe, China and Japan.

Patent Portfolio

The following table presents our portfolio of patents and patent applications filed by Incannex, including their status (as at June 30, 2022) and title.

Patent Family	Title	Status	Expires
PCT/AU2020/051056	Compositions for the treatment or prevention of traumatic brain injury	Pending	02/10/2040*
PCT/AU2021/050226	Methods and compositions for treating or preventing an inflammatory condition	Pending	15/03/2041*
PCT/AU2021/050734	Compositions and methods for the treatment of obstructive sleep apnoea (OSA)	Pending	09/07/2041*
AU 2021902170	A composition and uses thereof	Pending (PCT submitted)	14/07/2042^*
AU 2021902426	A method of treatment	Pending (PCT submitted)	04/08/2042^*

* Expiry date may be subject to any patent term extensions or adjustments that may be available.
^ Estimated expiry date of complete application claiming priority from the pending provisional application

The acquisition of APIRx added 19 granted patents and 23 pending patent applications to the Incannex patent portfolio. These patents cover all aspects of cannabinoid drug development including extraction, API modification, formulation and methods of use.

Competition

We are targeting indications that have no registered, limited or costly pharmacological solutions. Thus, competitor drugs for the indications we are assessing with our drug candidates either do not exist or are limited in efficacy or have unpleasant side effect profiles for certain cohorts of patients. The table below outlines existing drugs and therapies used to treat the illnesses we aim to treat with our drug candidates and their associated pitfalls for patients.

IHL Drug Candidate	Indication	Existing Products	Existing Product Pitfalls
IHL-42X	Obstructive Sleep Apnoea	− CPAP device	− Noisy mechanical device worn during sleep; − potential poor patient compliance due to discomfort.
IHL-216A	Traumatic Brain Injury/Concussion	None	N/A
IHL-675A	Lung Inflammation	− Corticosteroids − Ventilator	− Corticosteroids reduce immune system activity; − ventilators are associated with a high rate of mortality.
IHL-675A	Rheumatoid Arthritis	− Corticosteroids − DMARDS − Biologic agents	− High expense, significant side effect profiles; − lack of efficacy or tolerability in certain patient cohorts.
IHL-675A	Inflammatory Bowel Disease	− Corticosteroids − Immune system suppressors (ISSs) − Biologic agents	− Corticosteroids can reduce immune system activity; − ISSs can damage the digestive tract lining;
PSI-GAD	Generalized Anxiety Disorder	− Antidepressants (SSRI/SNRI classes)	− Non-curative, poor side effect profile; − some patients become treatment resistant.

Regulatory Authorities

The ongoing research and development, clinical, regulatory, commercial and manufacturing activities of our drug candidates are subject to extensive regulation by numerous governmental authorities, including (i) in Australia, principally the Therapeutics Goods Administration, or TGA; (ii) in the United States, principally the Food and Drug Administration, or FDA, as well as the Drug Enforcement Agency (DEA); and (iii) in Europe, principally the European Medicines Agency, or EMA and local competent authorities, ethics committees (ECs), institutional research boards (IRBs) and other regulatory authorities at federal, state or local levels. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval and post-approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our drug candidates.

United States

FDA process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Regulations that govern the pharmaceutical quality, safety, efficacy, labeling, storage, record keeping, advertising and promotion of such products under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and their implementing regulations. In particular, controlled substances, like synthetic cannabidiol and THC, are regulated by the U.S. Drug Enforcement Administration, or DEA.

The process of obtaining FDA approval and achieving and maintaining compliance with applicable laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with applicable FDA or other requirements may result in refusal to approve pending applications, a clinical hold, warning letters, civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market. FDA approval is required before any new drug or biologic, including a new use of a previously approved drug, can be marketed in the United States. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical quality, packaging, labeling and quality control.

Government oversight of the pharmaceutical industry is usually classified into pre-approval and post-approval categories. Most of the therapeutically significant innovative products marketed today are the subject of New Drug Applications, or NDAs, or Biologics License Applications, or BLAs. Pre-approval activities are used to assure the product is safe and effective before marketing.

Drug Approval Process — FDA

None of our drug candidates may be marketed in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's GLP and GMP regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- receive approval from the DEA prior to commencement of any clinical trials in the United States that involve the use of Schedule I controlled substances.
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA/BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs; and
- FDA review and approval of the NDA/BLA and DEA scheduling (for a controlled substance) prior to any commercial marketing or sale of the drug in the United States.

The manufacturing and quality, as well as preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot guarantee approval of our drug candidates will be granted on a timely basis, if at all. Notably, the FDA may reach different conclusions than we have after analyzing the same data, or there may difference of opinion amongst members of FDA's review team.

The FDA may inspect and audit domestic and foreign development facilities, planned production facilities, clinical trial sites and laboratory facilities. There is a pre-approval inspection after submission to market a new product, routine inspection of a regulated facility and a "for-cause" inspection to investigate a specific problem that has come to FDA's attention. After the product is approved and marketed, the FDA uses different mechanisms for assuring that firms adhere to the terms and conditions of approval described in the application and that the product is manufactured in a consistent and controlled manner. This is done by periodic unannounced inspections of production and quality control facilities by FDA's field investigators and analysts.

Preclinical tests include laboratory evaluation of toxicity in animals and in vitro (laboratory tests). The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND application is based on the results of initial testing done on animals for pharmacology and toxicity, which is used to develop a plan for testing the drug on humans. Only after preclinical testing, FDA determines whether the drug should be tested in people.

Further, an independent institutional review board, or IRB, covering each medical center proposing to conduct clinical trials must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations, which include requirements that all research subjects provide informed consent and that all clinical studies be conducted under the supervision of one or more qualified investigators.

Clinical trials (under an IND) involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an Institutional Review Board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of ongoing clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse reactions in case of an open IND. For purposes of an NDA or BLA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase I: Trials are initially conducted in a limited population of healthy human (in oncology Phase I trials are often conducted in patients) subjects or patients to test the drug candidate for safety and dose tolerance. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase II: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase III: The investigational product is administered to an expanded patient population in adequate and well-controlled studies to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the investigational product and to provide an adequate basis for product approval.

- Phase IV: In some cases, the FDA may condition approval of an NDA or BLA on the sponsor's agreement to conduct additional clinical trials to further assess the drug candidate's safety, purity and potency after NDA or BLA approval. Such post-approval trials are typically referred to as Phase IV clinical trials.

Concurrent with clinical studies, sponsors usually complete additional animal studies and must also develop additional information about the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop and validate methods for testing the identity, strength, quality and purity of the final product. Moreover, appropriate packaging must be selected and tested and stability studies must be conducted to assure product integrity and demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical trials, along with the aforementioned manufacturing information, are submitted to the FDA as part of a BLA/NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific goals for NDA/BLA review time. The testing and approval process requires substantial time, effort and financial resources. The FDA will review the BLA/NDA and may deem it to be inadequate to support approval, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

The FDA may deny approval of a BLA/NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the NDA/BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor does. Once issued, product approval may be withdrawn by the FDA if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs which may include pediatric assessment, and potentially studies required for an application for a new indication, new dosage form, a new dosing regimen, a new route of administration or a new active ingredient. Products may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, approval of a new or supplemental BLA may be required, which may involve conducting additional preclinical studies and clinical trials.

Expedited Review and Approval

The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, which are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. In particular, if accelerated approval is granted for any particular drug candidate, the FDA can subsequently revoke the marketing authorization for such product if post-market clinical trial results are unsuccessful. Generally, drugs that may be eligible for these programs are those for serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments.

Other U.S. Regulatory Requirements

After approval, products are subject to extensive continuing regulation by the FDA, which include company obligations to manufacture products in accordance with GMP, maintain and provide to the FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain FDA approval of certain manufacturing or labelling changes and comply with FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the BLA holder — all of which may become public. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or application holder.

We, and any manufacturers of our drug candidates, are required to comply with applicable FDA manufacturing requirements contained in the FDA's GMP regulations. GMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our drug candidates must meet GMP requirements. We, and any third-party manufacturers, are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our drug candidates to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting products for uses or in patient populations that are not described in the product's approved labelling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labelling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase IV testing, risk mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Controlled Substances

The CSA and its implementing regulations establish a "closed system" of distribution for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, labeling, importation, exportation, disposal and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements to prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substances utilized. For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV, or V — with varying qualifications for listing in each schedule. Scheduling determination by the DEA are dependent on approval of a substance or a specific formulation of a substance. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in treatment in the United States and lack accepted safety for use under medical supervision. They may be used only in federally-approved research programs and may not be marketed or sold for dispensing to patients in the United States. Pharmaceutical products having a currently accepted medical use may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III-V substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, and cannot be refilled. Marijuana and THC are Schedule I controlled substances under the CSA. Products approved for medical use in the United States that contain marijuana, THC or marijuana/THC extracts, must be placed in Schedules II-V, since approval by the FDA satisfies the "acceptable medical use" requirement. While marijuana and THC are controlled substances, the Agricultural Improvement Act of 2018 amended the CSA to exclude Cannabis meeting the statutory definition of hemp from the definition of marijuana. As a result, Cannabis that contains 0.3 percent or less of delta-9 THC on a dry weight basis is no longer considered a controlled substance. By extension, Cannabis-derived cannabidiol that satisfies the same limitation concerning delta-9 THC is also excluded from CSA regulatory controls. Because the definition of hemp does not expressly include synthetic equivalents of Cannabis or its derivatives, however, there is a lack of clarity about the CSA control status of pharmaceutically manufactured cannabidiol. Absent guidance to the contrary from the DEA, Cannabis and those products which contain Cannabis, that do not meet the definition of hemp remain in Schedule I of the CSA for purposes of development and research activities.

The DEA inspects all manufacturing facilities to review security, record keeping, reporting and compliance with other DEA regulatory requirements prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer (not a dosage form manufacturer or a repacker/relabeler) for a Schedule I or II substance must be published in the Federal Register and is open for 30 days to permit interested persons to submit comments, objections, or requests for a hearing. A copy of the notice of the Federal Register publication is forwarded by the DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses and must adhere to certain requirements to dispose of controlled substances. As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance, Schedule III, IV and V narcotic, specially designated Schedule III non-narcotics, or Schedule IV or V narcotic controlled in Schedule I or II by the Convention on Psychotropic Substances and submit import or export declarations for Schedule III, IV and V non-narcotics.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. This limited aggregate amount of Cannabis that the DEA allows to be produced in the United States each year is allocated among individual companies, which, in turn, must annually apply to the DEA for individual manufacturing and procurement quotas. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

We will not be subject to the DEA approval to conduct our clinical trials for the foreseeable future because we have conducted and plan to continue to conduct clinical trials for each clinical drug program in Australia. We may also decide to develop, manufacture or commercialize our drug candidates in additional countries. As a result, we will be subject to controlled substance laws and regulations from the TGA in Australia, Health Canada's Office of Controlled Substances in Canada, the Drugs & Firearms Unit (Home Office) of the National Drug Control System in the United Kingdom, and from other regulatory agencies in other countries where we develop, manufacture or commercialize each drug asset in the future.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our drug candidates. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials vary greatly from country to country.

European Union and United Kingdom

In the European Economic Area, or EEA, which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA by the EMA. Under European Union regulatory systems, we must submit and obtain authorization for a clinical trial application in each member state in which we intend to conduct a clinical trial. When conducting clinical trials in the European Union, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In April 2014, the European Union passed the Clinical Trials Regulation (Regulation 536/2014), which will replace the current Clinical Trials Directive. To ensure that the rules for clinical trials are identical throughout the European Union, the EU Clinical Trials Regulation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the Clinical Trials Regulation becomes applicable. According to the current plans of the EMA, the Clinical Trials Regulation is expected to become applicable.

After we have completed our clinical trials, we must obtain marketing authorization before we can market our product. We may submit applications for marketing authorizations under a centralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states.

The European Medicines Agency, or EMA, is a body of the European Union located in Amsterdam. The EMA is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. The EMA is involved in the scientific evaluation of medicines that fall within the scope of the centralized procedure. Like the FDA there is a harmonization between regulators and the EMA may inspect and audit the development facilities, planned production facilities, clinical trial sites and laboratory facilities. Additionally, after the product is approved and marketed, the EMA uses different mechanisms for assuring that firms adhere to the terms and conditions of approval described in the application and that the product is manufactured in a consistent and controlled manner. This is done by periodic unannounced inspections of production and quality control facilities.

If any of our drug candidates receive marketing approval in the EEA, we expect they will benefit from 8 years of data protection and 10 years of market protection. The periods run in parallel so effectively 8 years of data protection plus 2 years of market protection is granted. This means that a biosimilar application referencing our safety and efficacy data held on file at the EMA cannot be filed until the end of the data protection period of 8 years, and the biosimilar cannot be placed on the market until after a further 2 years have elapsed (8 + 2). Furthermore, an additional 1 year of market protection is available (8 + 2 + 1) where we obtain approval of a second indication having a significant clinical benefit in the initial 8-year period.

Similarly, since the Biologics Price Competition and Innovation Act (BPCIA) came into force in 2010, the United States provides 4 years of data exclusivity and 12 years of marketing exclusivity for a new biologic. The periods of exclusivity run in parallel, meaning that the FDA will not accept a biosimilar filing for 4 years and will not approve the biosimilar for a further 8 years (4 + 8).

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States, although the approval of a medicinal product in the United States is no guarantee of approval of the same product in the European Union, either at all or within the same timescale as approval may be granted in the United States. It entails satisfactory completion of pharmaceutical development, non-clinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union or its member states (as well as Iceland, Norway and Liechtenstein). If we fail to comply with applicable requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the national competent authority, or NCA, of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee, or EC, has issued a favorable opinion in relation to the clinical trial. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which will be directly applicable in all EU member states (meaning that no national implementing legislation in each European Union member state is required), aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. The new Clinical Trials Regulation became effective on January 31, 2022.

Marketing Authorization

To obtain a marketing authorization for a product in the European Economic Area (comprised of the EU member states plus Norway, Iceland and Liechtenstein), or EEA, an applicant must submit a MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EEA member states (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, our investigational COMP360 psilocybin therapy, as a new active substance indicated for the treatment of treatment-resistant depression, will have the option to be filed through the centralized procedure. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where either the product contains a new active substance indicated for the treatment of diseases other than those on the mandatory list, or where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation, or for which a centralized process is in the interest of public health.

Under the centralized procedure, the Committee for Medicinal Products for Human use, or the CHMP, which is the EMA's committee that is responsible for human medicines, established at the EMA is responsible for conducting the assessment of whether a medicine meets the required quality, safety and efficacy requirements, and whether it has a positive risk/benefit/risk profile. Under the centralized procedure, the maximum timeframe for the evaluation of a MAA is 210 days from the receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

PRIME Scheme

EMA now offers a scheme that is intended to reinforce early dialogue with, and regulatory support from, EMA in order to stimulate innovation, optimize development and enable accelerated assessment of PRIority MEdicines, or PRIME. It is intended to build upon the scientific advice scheme and accelerated assessment procedure offered by EMA. The scheme is voluntary and eligibility criteria must be met for a medicine to qualify for PRIME.

The PRIME scheme is open to medicines under development and for which the applicant intends to apply for an initial marketing authorization application through the centralized procedure. Eligible products must target conditions for which where is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods or therapy or improving existing ones. Applicants will typically be at the exploratory clinical trial phase of development and will have preliminary clinical evidence in patients to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need. In exceptional cases, applicants from the academic sector or SMEs (small and medium sized enterprises) may submit an eligibility request at an earlier stage of development if compelling non-clinical data in a relevant model provide early evidence of promising activity, and first in man studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.

If a medicine is selected for the PRIME scheme, EMA:

- appoints a rapporteur from the CHMP or from the Committee for Advanced Therapies (CAT) to provide continuous support and to build up knowledge of the medicine in advance of the filing of a marketing authorization application;
- issues guidance on the applicant's overall development plan and regulatory strategy;
- organizes a kick-off meeting with the rapporteur and experts from relevant EMA committees and working groups;
- provides a dedicated EMA contact person; and
- provides scientific advice at key development milestones, involving additional stakeholders, such as health technology assessment bodies and patients, as needed.

Medicines that are selected for the PRIME scheme are also expected to benefit from EMA's accelerated assessment procedure at the time of application for marketing authorization. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Pediatric Development

In the EEA, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Regulatory Data Protection in the European Union

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon grant of a marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No. 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents generic and biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a marketing authorization for a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity period. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EEA market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Controlled Drugs Classification

The position in the member states of the European Union is not harmonized. Member states have implemented the relevant UN Conventions (the Single Convention of Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971) into their national legislation, which has led to differences in how controlled substances are regulated in different countries of the European Union. It is therefore important to determine at a national level whether a substance is controlled and to comply with the applicable legal requirements.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product.

These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

In addition, all new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

Furthermore, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products, are strictly regulated in the European Union under Directive 2001/83/EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the European Union, or in the UK under the Human Medicines Regulations 2021. Although general requirements for advertising and promotion of medicinal products are established under EU Directive 2001/83/EC as amended, the details are governed by regulations in each European Union member state (as well as Iceland, Norway and Liechtenstein) and can differ from one country to another.

United Kingdom

The United Kingdom (UK) has left the European Union and will declare its independent processes to approve clinical research and marketing authorizations. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of drug candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for drug candidates and products in the UK in the long-term. The MHRA has published detailed guidance for industry and organizations to follow from January 1, 2021, which will be updated as the UK's regulatory position on medicinal products evolves over time. How precisely clinical research within the UK will be performed and how approval for drugs will be organized is subject to ongoing discussions

The UK will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Australia

In Australia, the relevant regulatory body responsible for the pharmaceutical industry is the Therapeutics Goods Administration, or TGA. As with the EMA and FDA there is a harmonization and collaboration between regulatory authorities. The TGA requires notification of all clinical trials via an electronic submission of a Clinical Trial Notification (CTN) prior to commencing the clinical trial.

Third-Party Payer Coverage and Reimbursement

Although our drug candidates have not been commercialized for any indication, if they are approved for marketing, commercial success of our drug candidates will depend, in part, upon the availability of coverage and reimbursement from third party payers at the federal, state and private levels.

In the United States and internationally, sales of any product that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third party payors, such as state and federal governments, managed care providers and private insurance plans.

Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of our drug candidates for formulary coverage and reimbursement. Even with such studies, our drug candidates may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our drug candidates, in whole or in part. In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our drug candidates that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted to potentially impact reimbursement rates for the drug candidates we are developing and may develop in the future and could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of drug candidates that, if successfully developed, we bring to market. Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business.

Similar political, economic and regulatory developments are occurring in the European Union and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In the future, there may continue to be additional proposals relating to the reform of the healthcare system in the United States and international healthcare systems. Future legislation, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which reimbursement for the costs of our drug candidates and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations. The adoption of certain proposals could limit the prices we are able to charge for our drug candidates, the amounts of reimbursement available for our drug candidates, and limit the acceptance and availability of our drug candidates. Therefore, substantial uncertainty exists as to the reimbursement status of newly approved health care products by third party payors.

Inflation and Seasonality

Management believes inflation has not had a material impact on our operations or financial condition. Management further believes that our operations are not currently subject to seasonal influences due to our current lack of marketed products. Moreover, the targets of our drug candidates, are not seasonal diseases. Accordingly, once we have marketed products, management does not expect that our business will be subject to seasonal influences.

Manufacturing and Raw Materials

We have no manufacturing capabilities and are dependent on third parties for cost effective manufacture and manufacturing process development of our drug candidates. Problems with third party manufacturers or the manufacturing process as such may delay or jeopardize clinical trials and commercialization of our drug candidates.

C. Organizational Structure

Below is a list of our significant subsidiaries, including our ownership percentage, its date of formation and its jurisdiction. These subsidiaries were established to allow us to conduct commercial and clinical operations in Europe and the United States and expand our operations in Australia.

Subsidiary	Ownership	Date of Formation/Acquisition	Jurisdiction
Incannex Pty Ltd	100%	November 30, 2018	Victoria, Australia
Psychennex Pty Ltd	100%	November 20, 2020	Victoria, Australia
APIRx Pharmaceutical USA, LLC	100%	August 5, 2022	Delaware

D. Property, Plants and Equipment

We own computer equipment, office furniture and laboratory equipment, which is primarily placed at our own offices and laboratories.

Office Location	Lease expiry date
Suite 15, Level 12, 401 Docklands Drive, Docklands 3008	April 2023
Suite 105, Level 8 Century Circuit, Norwest 2153, NSW Australia	July 2026
18 E. 50th Street, 5th Fl., Suite B, New York, New York USA 10022	-

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Overview

We are a development stage enterprise at an early stage in the development of our drug candidate. We have incurred net losses since inception and expect to incur substantial and increasing losses for the next several years as we expand our research and development activities ("R&D") and move our drug candidate into later stages of development. The process of carrying out the development of our drug candidates to later stages of development may require significant additional research and development expenditures, including pre-clinical testing and clinical trials, as well as for obtaining regulatory approval. To date, we have funded our operations primarily through the sale of equity securities, proceeds from the exercise of options, tax grants from R&D activities and interest income.

We receive tax incentives from the Australian government for R&D activities. Subject to certain exclusions, the Australian Government tax incentives provide benefits for eligible R&D activities. Entities are entitled to either (i) a 43.5% refundable tax offset for eligible companies with an aggregated turnover of less than A$20 million per annum or (ii) a non-refundable 38.5% tax offset for all other eligible companies. Our aggregated turnover is less than A$20 million and not be controlled by one or more income tax exempt entities, we anticipate being entitled to a claim of 43.5% refundable tax offset for costs relating to eligible R&D activities during the year.

A. Operating Results

Results of Operations

The following tables set forth our results of operations in Australian dollars for the years ended June 30, 2022, 2021 and 2020.

	Year ended June 30,		
	2022	2021	2020
	A$	A$	A$
Revenue	-	1,897,596	604,884
Other income	788,654	75,748	217,170
Product costs	(6,338)	(911,969)	(450,345)
Administration expense	(280,969)	(99,094)	(457,673)
Advertising and investor relations	(2,746,226)	(4,345,874)	(406,225)
Bad debt expense	(134,626)	-	-
Research and development costs	(5,371,821)	(4,749,514)	(2,110,639)
Compliance, legal and regulatory	(3,559,511)	(1,227,244)	(235,163)
Share based payments	(1,464,550)	(600,043)	(565,448)
Occupancy expenses	(112,341)	(115,836)	(2,085)
Salaries and employee benefit expense	(2,016,181)	(1,296,569)	(523,760)
Loss on discontinued operations, net of tax	-	-	(768,352)
Total comprehensive loss	(14,903,909)	(11,372,799)	(4,697,636)

Comparison of Fiscal Year Ended June 30, 2022 to June 30, 2021

Revenue

Revenue decreased from A$1,897,596 in fiscal 2021 to none in fiscal 2022. All our revenue in fiscal 2021 related to sales of cannabinoid products. In order to focus on the development of our drug candidates, we terminated our distribution agreement for the sale of cannabinoid products at the end of fiscal 2021 and, as a result, did not have any such sales in fiscal 2022.

Other Income

Other income increased from A$75,748 in fiscal 2021 to A$788,654 in fiscal 2022, due to an increase R&D tax refund for research and development activities from the Australian government in fiscal 2022.

Product costs

Production costs decreased from A$911,969 in fiscal 2021 to A$6,338 in fiscal 2022, due to primarily due to the cessation of sales of cannabinoid oil products at the end of fiscal 2021.

Administration expense

Administration expense increased from A$99,094 in fiscal 2021 to A$280,969 in fiscal 2022, due to an increase in general office expenses and expenses due to international payments impacted by foreign currency fluctuations.

Advertising and investor relations

Advertising and investor relations expense decreased 37% from A$4,345,874 in fiscal 2021 to A$2,746,226 in fiscal 2022, due to a decrease in share-based payments to our advisors.

Bad debt expense

Bad debt expense increased from none in fiscal 2021 to A$134,626 in fiscal 2022 due to an amount a third party owed us deemed irrecoverable at December 31, 2021.

Research and development costs

Research and development costs increased 13% from A$4,749,514 in fiscal 2021to A$5,371,821 in fiscal 2022, due to an increase in development costs related to our clinical trials, particularly with respect to IHL-675A, IHL-42X and IHL-216A.

Compliance, legal and regulatory

Compliance, legal and regulatory expense almost tripled from A$1,227,244 in fiscal 2021 to A$3,559,511 in fiscal 2022, due to an increase in expenses due to listing and compliance with the Nasdaq listing requirements while the regulatory costs required to conduct clinical trials and the costs to secure intellectual property positions in relation to our drug candidates remained stable.

Share based payments

Share-based payments expense more than doubled from A$600,043 in fiscal 2021 to A$1,464,550 in fiscal 2022, due to an increase in the costs associated with an increased number of share-based awards to employees and directors.

Occupancy expenses

Occupancy expenses decreased slightly from A$115,836 in fiscal 2021 to A$112,341 in fiscal 2022, due to a decrease in rental fees.

Salaries and employee benefit expense

Salaries and employee benefit expense increased from A$1,296,569 in fiscal 2021 to A$2,016,181 in fiscal 2022 due to an increase in headcount in the general administration department and an increase in our Chief Executive Officer's salary.

Total comprehensive loss

Total comprehensive loss increased 31% from A$11,372,799 in fiscal 2021 to A$14,903,909 in fiscal 2022, mostly due to higher legal and regulatory expenses, expenses for development of our clinical trials as well as higher salaries and employee benefits.

Comparison of Fiscal Year Ended June 30, 2021 to June 30, 2020

Revenue

Revenue increased to A$1,897,596 in fiscal year 2021 from A$604,884 in fiscal year 2020, due to an increase of sales of cannabinoid oil products in fiscal 2021. In order to focus on the development of our drug candidates, we terminated our distribution agreement for the sale of cannabinoid products at the end of fiscal 2021 and, as a result, will not have any future sales of such products.

Other Income

Other income decreased to A$75,748 in fiscal year 2021 from A$217,170 in fiscal year 2020, due to the discontinuation of the dental business.

Product costs

Production costs doubled to A$911,969 in fiscal year 2021 from A$450,345 in fiscal year 2020, due to higher costs involved in the production of the cannabinoid oil products as a result of higher sales.

Administration expense

Administration expense decreased to A$99,094 in fiscal year 2021 from A$457,673 in fiscal year 2020, due to discontinuation of our dental business.

Advertising and promotion

Advertising and promotion expense increased to A$4,345,874 in fiscal year 2021 from A$406,225 in fiscal year 2020, due to the costs of marketing of the cannabinoid oil products and the cost of investor relation activities.

Research and development costs

Research and development costs increased to A$4,749,514 in fiscal year 2021 from A$2,110,639 in fiscal year 2020, due to an increase in development costs related to our clinical trials, particularly with respect to IHL-675A, IHL-42X and IHL-216A.

Compliance, legal and regulatory

Compliance, legal and regulatory expense increased to A$1,227,244 in fiscal year 2021 from A$235,163 in fiscal year 2020, due to the regulatory costs required to conduct clinical trials and costs related to the sale of our cannabinoid oil products, and the cost to secure intellectual property positions in relation to our drug candidates and the cost of dual listing.

Share based payments

Share-based payments expense increased to A$600,043 in fiscal year 2021 from A$565,448 in fiscal year 2020, primarily due to the costs associated with an increased number of share-based awards to employees.

Occupancy expenses

Occupancy expenses increased to A$115,836 in fiscal year 2021 from A$2,085 in fiscal year 2020, due to the rental fees for our new Sydney office.

Salaries and employee benefit expense

Salaries and employee benefit expense more than doubled to A$1,296,569 in fiscal year 2021 from A$523,760 in fiscal year 2020, due to an increase in headcount.

Loss after tax from discontinuing operations

Loss after tax from discontinuing operations decreased to nil in fiscal year 2021 from A$768,352 in fiscal year 2020, due to the sale of the segment relating to the oral device business.

Total comprehensive loss

Total comprehensive loss increased to A$11,372,799 in fiscal year 2021 from A$3,929,284 in fiscal year 2020, primarily due to an increase in compliance, legal and regulatory expenses, expenses related to the development of our clinical trials and expenses associated with our salaries and employee benefits.

Off-Balance Sheet Arrangements

During fiscal years 2022, 2021 and 2020, we did not have any unconsolidated entities such as structured finance or special purpose entities that can be used to facilitate off-balance sheet arrangements.

Contractual obligations

Excluding accounts payable, we did not have any contractual obligations as of June 30, 2022 that were not reflected in the balance sheet. Lease obligations for office premises are reflected in our balance sheet.

We have contracted with Monash University to conduct research trials in relation to Psi-GAD-1 over a 3-year period. 50% of the contractual obligation was paid on commencement of the contract in November 2020 and A$618,070 remains due and payable up through November 2023.

Contingent liabilities

We did not have any material contingent liabilities outstanding as of June 30, 2022.

Capital commitments

We did not have any material capital expenditure commitments outstanding as of June 30, 2022.

B. **Liquidity and Capital Resources**

Since our inception, our operations have mainly been financed through the issuance of equity securities. Additional funding has come through interest earned from cash on term deposit.

As of June 30, 2022, we had cash of A$37,500,931. We anticipate that our current cash will be sufficient for the current fiscal year and to fund our operations until end of 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Due to our focus on research and development activities, we do not have ready access to credit facilities and, therefore, are not subject to externally imposed capital requirements. Our objective in relation to capital risk management is to balance our current working capital position against the requirements to meet research and development programs and corporate overheads.

We anticipate that we will require substantial additional funds in order to achieve our long-term goals and complete the research and development of our current drug candidates. We do not expect to generate significant revenue until we obtain regulatory approval to market and sell our drug candidate and sales of our drug candidate have commenced. We therefore expect to continue to incur substantial losses in the near future.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the scope, results and timing of preclinical studies and clinical trials;
- the costs and timing of regulatory approvals; and
- the costs of establishing sales, marketing and distribution capabilities.

Cash Flows

Comparison of cash flows for the fiscal year ended June 30, 2022, with June 30, 2021

The following table summarizes our cash flows for the periods presented:

	Year ended June 30,		
	2022	**2021**	**2020**
	A$	**A$**	**A$**
Net cash used in operating activities	(12,807,373)	(6,909,780)	(3,907,334)
Net cash provided by investing activities	-	29,277	13,000
Net cash provided by financing activities	41,184,687	12,400,730	7,404,392

Operating Activities

Net cash used in operating activities increased from A$6,909,780 in fiscal 2021 to A$12,807,373 in fiscal 2022, primarily due to the expansion of our clinical trials.

Investing Activities

Net cash provided by investing activities decreased from A$29,277 in fiscal 2021 to none in fiscal year 2022, due to no investment activities undertaken in fiscal 2022.

Financing Activities

Net cash provided by financing activities increased to A$41,184,687 in fiscal year 2022 from A$12,400,730 in fiscal year 2021, due to the exercise of options that raised net cash equal to A$40,274,243 in fiscal 2022.

Comparison of cash flows for the fiscal year ended June 30, 2021, with June 30, 2020

Operating Activities

Net cash used in operating activities increased to A$6,909,780 in fiscal year 2021 from A$3,907,334 in fiscal year 2020, primarily due to the expansion of our clinical trials.

Investing Activities

Net cash provided by investing activities increased to A$29,277 in fiscal year 2021 from A$13,000 in fiscal year 2020, primarily due to asset sales associated with the discontinuance of our dental devices business.

Financing Activities

Net cash provided by financing activities increased to A$12,400,730 in fiscal year 2021 from A$7,404,392 in fiscal year 2020, primarily due to the exercise of options that raised net cash equal to A$12,401,230 in 2021.

C. Research and Development, Patents and Licenses

For a description of our research and development programs and activities, see "Item 4. Information on the Company—B—. Business" Overview.

For year ended June 30, 2022, our expenditures for our each of our clinical trials were:

- PYX - GAD - A$765,312;
- IHL-675A - SAARDS Sepsis Associated Acute Respiratory Distress Syndrome - A$1,116,072;
- IHL-42X - OSA Obstructive Sleep Apnea - A$2,325,540;
- IHL-216A - Traumatic Brain Injury - A$985,866; and
- IHL-675A - Rheumatoid arthritis - A$4,745;

We anticipate being entitled to a claim of 43.5% refundable tax offset for costs relating to eligible R&D activities for each fiscal year from the Australian government.

D. Trend Information

We are a clinical stage pharmaceutical development company and it is not possible for us to predict with any degree of accuracy the outcome of our research or commercialization efforts.

Our primary expenditure involves research and development costs. Increases or decreases in research and development expenditure are attributable to the level of clinical trial activity and the amount of expenditure on those trials.

Since our acquisition of APIRx, we are exposed to foreign currency risk via trade and other payables we hold. We are required to make certain payments in U.S. dollars and other currencies.

E. Critical Accounting Estimates

See note 2 to our audited financial statements for the fiscal year ending June 30, 2022.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth our directors and senior management and the positions. There are no family relationships among any of the members of our board of directors and our senior management.

Name	Position
Joel Latham	Chief Executive Officer and Managing Director
Troy Valentine[(1)]	Chairman
Peter Widdows[(2)]	Director
Dr. George Anastassov	Director
Robert Clark	Director
Lekhram Changoer	Chief Technology Officer
Madhukar Bhalla	Chief Financial Officer and Company Secretary

(1) Member of the Audit Committee.
(2) Chair of Audit Committee.

Joel Latham. 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. 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 joining 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.

Troy Valentine. 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 Hartleys Limited) in 1994 before moving to Patersons Securities (now Canaccord Genuity) in 2000 where he 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 also a director of Australian boutique corporate advisory firm Alignment Capital Pty Ltd, which he co-founded in 2014.

Peter Widdows. Peter Widdows has been a Director since 2018. He is a Fellow Chartered Accountant with experience across various functions of business. He has extensive experience in Australian and international consumer goods markets and has worked as a senior executive in numerous geographies, including Europe, the United States and Asia Pacific. In particular, Mr. Widdows served as the Regional Chief Executive Officer — Australasia and Greater China at the H. J. Heinz Company from 2008 to 2010 and as the Chief Executive Officer and Managing Director — Australia at the H. J. Heinz Company from 2002 to 2008 and as the General Manager Strategy & Planning at Starkist Foods Inc. in Cincinnati from 1998 to 2000. Since September 2018, Mr. Widdows has been Chairman of Sunny Queen Australia Ltd, Australia's largest shell egg and egg-based meal producer and is also a Non-Executive Director of Youi Insurance Holdings Ltd, an Australian general insurance company.

Dr. George Anastassov. Dr. George Anastassov has been a Director since June 2022. Dr Anastassov has developed substantial experience regarding liaising and negotiating with FDA and the EMA, due to the fact that he has presented numerous regulatory submissions, including IND meeting packages and IND applications, to regulatory agencies over many years. Dr Anastassov is one of the developers of the first-in-the world cannabinoid-containing chewing gum-based delivery system. Prior to his appointment as a Director, Dr. Anastassov had been the founding managing director of APIRx Pharmaceuticals LLC since 2017 to 2022. whilst also being a key member of the medical and scientific advisory team, assisting with the development of the Combination Compounds. Previously, Dr Anastassov had been CEO and co-founder of AXIM Biotechnologies, which achieved an all-time-high market capitalization of approximately US$1.2 billion, since 2014 to 2018.

Robert Clark. Robert Clark has been a Director since August 2022. Mr. Clark is a senior-level strategic regulatory affairs expert with over 38 years of U.S. and international regulatory experience, including more than 20 years with Pfizer Inc. and more than 10 years with Novo Nordisk A/S. He is an expert on FDA and EMA matters, U.S. pharmaceutical advertising practices and regulatory aspects related to healthcare professionals and sales force activities. Since May 2012, Mr. Clark has been Vice President, U.S. Regulatory Affairs for Novo Nordisk, where he provides strategic leadership to a team of more than 50 regulatory staff and scientists in the development of new medicines. Prior to his appointment as a Director, Mr. Clark had been Vice President of Worldwide Regulatory Strategy and U.S. Regulatory Affairs at Pfizer from 1992 to 2021, where he led a team of up to 150 regional regulatory professionals supporting the drug development and approval processes.

Lekhram Changoer. Mr. Changoer has been Chief Technology Officer of Incannex since June 2022. He is responsible for the development and implementation of science and technical strategies for clinical and commercial manufacturing of pharmacotherapies. Prior to joining Incannex, Mr. Changoer was Director at APIRx. Previously, Mr. Changoer was CTO and Co-founder of AXIM Biotechnologies since 2014 to 2018.

Madhukar Bhalla. Madhukar Bhalla has been Chief Financial Officer and Company Secretary of Incannex since June 2021. Since July 2018, he has been acting as Company Secretary and Corporate Administrator at Classic Minerals Limited, an ASX-listed Australian company. Between November 2017 and July 2018, Mr. Bhalla acted as Corporate Governance and HR Manager at Role Models and Leaders Australia and, from 2016 to 2018, he acted as the Company Secretary for FairStar Resources Limited.

B. Compensation

Remuneration Principles

Remuneration of all executive and non-executive directors and officers is determined by the board of directors.

We are committed to remunerating senior executives and executive directors in a manner that is market-competitive and consistent with "Best Practice" including the interests of shareholders. Remuneration packages are based on fixed and variable components, determined by the executives' position, experience and performance, and may be satisfied via cash or equity.

Non-executive directors are remunerated out of the aggregate amount approved by shareholders and at a level that is consistent with industry standards. Non-executive directors do not receive performance-based bonuses and prior shareholder approval is required to participate in any issue of equity. No retirement benefits are payable other than statutory superannuation, if applicable.

Our remuneration policy is not directly based on our financial performance, rather on industry practice, given we operate in the biotechnology sector and our primary focus is research activities with a long-term objective of developing and commercializing the research and development results.

We envisage our performance in terms of earnings will remain negative while we continue in the research and development phase.

The purpose of a performance bonus is to reward individual performance in line with our objectives. Consequently, performance-based remuneration is paid to an individual where the individual's performance clearly contributes to a successful outcome. This is regularly measured in respect of performance against key performance indicators.

We use a variety of key performance indicators to determine achievement, depending on the role of the executive being assessed. These include:

- successful contract negotiations;

- achievement of research project milestones within scheduled time and/or budget; and
- our share price reaching a targeted level on the ASX over a period of time.

Executive Compensation

The following table sets forth all of the compensation awarded to, earned by or paid to each individual who served as directors and executive officers in fiscal 2022.

	Short-term Benefits			Post Employment Benefits	Long-term (share based payments)	Total
	Cash salary and fees A$	Cash bonus A$	Other A$	Super-annuation A$	Performance Rights, Shares and Options A$	A$
Directors						
Joel Latham	533,500	245,000	—	24,998	716,096	1,519,594
Troy Valentine	92,750	—	240,000	9,275	312,538	654,563
Dr. Sud Agarwal[1]	48,000	—	90,000	4,800	—	142,800
Peter Widdows	84,742	—	—	8,474	—	93,216
Dr. George Anastassov[2]	—	—	—	—	—	—
Robert Clark[3]	—	—	—	—	—	—
Other Key Management Personnel						
Madhukar Bhalla	60,000	—	—	—	—	60,000
Lekhram Changoer[4]	—	—	—	—	—	—
	818,992	**245,000**	**330,000**	**47,547**	**1,028,634**	**2,410,773**

(1) Dr. Sud Agarwal resigned on June 28, 2022.
(2) Dr. George Anastassov was appointed on June 28, 2022.
(3) Robert Clark was appointed on August 17, 2022.
(4) Lekhram Changoer was appointed on June 28, 2022

Service Agreements

The following members of key personnel have service agreements as at June 30, 2022 as follows:

Joel Latham	**Managing Director and Chief Executive Officer**
Agreement commenced:	July 1, 2020
Details	This employment agreement has no fixed term. Each party can terminate at will by giving three months' notice. However, if the termination is for cause, no notice is required.
Base salary including superannuation	A$460,000 per year, including a vehicle allowance. In addition, A$A30,000 as fees for role as director.
Madhukar Bhalla	**Chief Financial Officer and Company Secretary**
Agreement commenced:	June 28, 2021
Details	This service agreement has no fixed term. This service agreement can be terminated by either party at will by giving 1-month notice.
Base salary including superannuation	A$60,000 per year for services as Chief Financial Officer and Company Secretary.

Employee Share Option Plan and Performance Rights Plan

The Company does not currently have any Employee Share Option Plan or Performance Rights Plan. In the event that the directors determined that such plans were necessary, the Company would seek shareholder approval for any such plan prior to their use.

Over the past three years, the Company has issued options or performance rights to directors or management as part of their remuneration or as performance incentives. No performance rights were granted to directors and officers during fiscal year 2022. All of these issues have been approved by shareholders prior to their issuance.

Ordinary Share holdings

As at June 30, 2022, the numbers of shares held by our directors and officers were as follows.

	Balance at start of the year	Received on conversion of performance rights upon achievement of milestones	Received during the year on the exercise of options	Other changes during the year	Balance at end of the year
Ordinary shares					
Joel Latham	17,948,414	—	200,000	5,600,000	23,748,413
Troy Valentine	26,734,248	—	7,116,950	2,800,000	36,651,198
Dr. Sud Agarwal[1]	66,303,593	—	8,999,500	—	75,303,093
Peter Widdows	15,915,790	—	657,895	—	16,573,685
Dr. George Anastassov[2]	—	—	—	—	—
Robert Clark[3]	—	—	—	—	—
Lekhram Changoer[4]	—	—	—	—	—
Madhukar Bhalla	—	—	—	—	—
Total ordinary shares	126,902,045	—	16,974,345	8,400,000	152,276,389

(1) Dr. Sud Agarwal resigned on June 28, 2022.
(2) Dr. George Anastassov was appointed on June 28, 2022.
(3) Robert Clark was appointed on August 17, 2022.
(4) Lekhram Changoer was appointed on June 28, 2022

Options holdings

As at June 30, 2022, the numbers of options held by our directors and officers were as follows. Each option grants the right to receive one fully paid ordinary share in Incannex.

	Balance at start of the year	Exercise Price	Expiration date	Changes during the year	Balance at end of the year
Options					
Joel Latham	750,000	0.05	June 30, 2025	750,000	750,000
Joel Latham	750,000	0.05	June 30, 2026	750,000	750,000
Joel Latham	750,000	0.05	June 30, 2027	750,000	750,000
Joel Latham	200,000	0.08	September 30, 2021	(200,000)	—
Joel Latham	—	0.05	June 30, 2025	750,000	750,000
Joel Latham	—	0.05	June 30, 2026	750,000	750,000
Joel Latham	—	0.05	June 30, 2027	750,000	750,000
Joel Latham	—	0.26	July 1, 2025	933,333	933,333
Joel Latham	—	0.31	July 1, 2026	933,333	933,333
Joel Latham	—	0.35	July 1, 2027	933,334	933,334
Joel Latham	—	0.26	July 1, 2026	933,333	933,333
Joel Latham	—	0.31	July 1, 2027	933,333	933,333
Joel Latham	—	0.35	July 1, 2028	933,334	933,334
Troy Valentine	7,116,950	0.08	September 30, 2021	(7,116,950)	—
Troy Valentine	—	0.26	July 1, 2025	466,666	466,666
Troy Valentine	—	0.31	July 1, 2026	466,666	466,666
Troy Valentine	—	0.35	July 1, 2027	466,668	466,668
Troy Valentine	—	0.26	July 1, 2026	466,666	466,666
Troy Valentine	—	0.31	July 1, 2027	466,666	466,666
Troy Valentine	—	0.35	July 1, 2028	466,668	466,668
Dr. Sud Agarwal[1]	200,000,000	0.20	September 30, 2021	(200,000,000)	—
Peter Widdows[3]	657,895	0.08	September 30, 2021	(657,895)	—
Madhukar Bhalla	—	—	—	—	—
Total options	210,242,845			(195,074,845)	12,900,000

(1) Dr. Sud Agarwal resigned on June 28, 2022.

Performance rights

As at June 30, 2022, no performance rights were outstanding. Each performance right grants the right to receive one fully paid ordinary share in the Company.

C. Board Practices

Introduction

Our Board of Directors is elected by and accountable to our shareholders. It currently consists of five directors, including four non-executive directors, of which one is the non-executive Chairman of our Board of Directors. The Chairman of our Board of Directors is responsible for the management of the Board of Directors and its functions.

Election of Directors

Directors are elected at our annual general meeting of shareholders. Under our Constitution, a director, other than a managing director, must not hold office for more than three years or beyond the third annual general meeting following his appointment (whichever is the longer period) without submitting himself for re-election. Our Board of Directors has the power to appoint any person to be a director, either to fill a vacancy or as an additional director (provided that the total number of directors does not exceed the maximum allowed by law), and any director so appointed may hold office only until the next annual general meeting ("AGM") when he or she shall be eligible for election.

The appointment and expiration dates of each director in office on June 30, 2022, is as follows:

Name	Position	Year first appointed	Current term expires
Joel Latham	Managing Director and CEO	2018	__(1)
Troy Valentine	Chairman	2017	2022(2)
Peter Widdows	Director	2018	2023(2)
Dr. George Anastassov(3)	Director	2022	2024
Robert Clark(4)	Director	2022	2024

(1) According to our Constitution, a Managing Director's appointment is not subject to expiration.
(2) Term expires on the date of the AGM for that year.
(3) Dr. George Anastassov was appointed on June 28, 2022.
(4) Robert Clark was appointed on August 17, 2022.

Corporate Governance

ASX Corporate Governance Principles

In Australia, there are no defined corporate governance structures and practices that must be observed by a company listed on the ASX, except that entities of a certain size are required to have audit and remuneration committees and, in some instances, trading policies for key management personnel. Instead, the ASX Corporate Governance Council has published the Corporate Governance Principles and Recommendations, which contains what are called the Recommendations which articulate eight core principles which are intended to provide a reference point for companies about their corporate governance structures and practices. Under ASX Listing Rule 4.10.3, companies are required to attach a copy of the Company's corporate governance statement (which has been approved by the Board) and provide a statement in their annual report to shareholders disclosing the extent to which they have followed the Recommendations in the reporting period and where they have not followed all the Recommendations, identify the Recommendations that have not been followed, and the reasons for not following them and what (if any) alternative governance practices it adopted in lieu of the recommendations during that period. It is not mandatory to follow the Recommendations. As compliance with the Recommendations would entail excessive costs to us, and in light of our current size, we do not follow the Recommendations because the costs of doing so would outweigh the benefits.

Non-Executive and Independent Directors

Australian law does not require a company to appoint a certain number of independent directors to its board of directors or audit committee. However, under the Corporate Governance Principles and Recommendations, the ASX recommends, but does not require, that an ASX-listed company have a majority of independent directors on its board of directors. Our Board of Directors has determined that each of Troy Valentine and Peter Widdows qualifies as an independent director under the requirements of the ASX.

Our Board of Directors does not have regularly scheduled meetings at which only independent directors are present. The Board of Directors does meet regularly and independent directors are expected to attend all such meetings.

Committees of the Board of Directors

Audit Committee. Nasdaq Marketplace Rules require us to establish an audit committee comprised of at least three members, each of whom is financially literate and satisfies the respective "independence" requirements of the SEC and Nasdaq and one of whom has accounting or related financial management expertise at senior levels within a company.

Our Audit Committee assists our Board of Directors in overseeing the accounting and financial reporting processes of our company and audits of our financial statements, including the integrity of our financial statements, compliance with legal and regulatory requirements, our independent public accountants' qualifications and independence, and independent public accountants, and such other duties as may be directed by our Board of Directors. The Audit Committee is also required to assess risk management.

Our Audit Committee currently consists of two board members, Peter Widdows and Troy Valentine. Each of Troy Valentine and Peter Widdows satisfies the "independence" requirements of the U.S. Securities and Exchange Commission and Nasdaq Marketplace Rules. As permitted by Nasdaq Marketplace Rules, we will appoint a third independent board member to the audit committee within 1 year of listing on Nasdaq. The audit committee meets at least two times per year.

Corporate Governance Requirements under Nasdaq listing rules.

Incannex is allowed to follow Australian "home country" corporate governance practices in lieu of the otherwise applicable Nasdaq corporate governance standards as long as we disclose each requirement of Nasdaq Rule 5600 that we do not follow and describe the home country practice we follow in lieu of the relevant Nasdaq corporate governance standards. We follow Australian corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Marketplace Rules in respect of:

- Nasdaq requirement under Rule 5605(d) that a compensation committee be constituted — The ASX Listing Rules do not have an express requirement that each issuer listed on ASX have a compensation committee. We rely on an exemption from the requirement to constitute a compensation committee under the Nasdaq listing rules and we seek to claim such exemption.

- Nasdaq requirement under Rule 5605(e) that a nominations committee be constituted — The ASX Listing Rules do not have an express requirement that each issuer listed on ASX have a nominations committee. We rely on an exemption from the requirement to constitute a nominations committee under the Nasdaq listing rules and we seek to claim such exemption.

- Nasdaq requirement under Rule 5620(c) that a quorum consist of holders of 33 1/3% of the outstanding ordinary shares — The ASX Listing Rules do not have an express requirement that each issuer listed on ASX have a quorum of any particular number of the outstanding ordinary shares, but instead allow a listed issuer to establish its own quorum requirements. Our quorum is currently two persons who are entitled to vote. We believe this quorum requirement is consistent with the requirements of the ASX and is appropriate and typical of generally accepted business practices in Australia.

- Nasdaq requirements under Rules 5605(b)(1) and (2) relating to director independence, including the requirements that a majority of the board of directors must be comprised of independent directors and that independent directors must have regularly scheduled meetings at which only independent directors are present — The Nasdaq and ASX definitions of what constitute an independent director are not identical and the requirements relating to the roles and obligations of independent directors are not identical. The ASX, unlike Nasdaq, permits an issuer to establish its own materiality threshold for determining whether a transaction between a director and an issuer affects the director's status as independent and it does not require that a majority of the issuer's board of directors be independent, as long as the issuer publicly discloses this fact. In addition, the ASX does not require that the independent directors have regularly scheduled meeting at which only independent directors are present. We believe that our Board composition is consistent with the requirements of the ASX and that it is appropriate and typical of generally accepted business practices in Australia.

- The requirement that our independent directors meet regularly in executive sessions under Nasdaq Listing Rules. The ASX Listing Rules and the Corporations Act do not require the independent directors of an Australian company to have such executive sessions and we claim an exemption from this Nasdaq rule.

- The Nasdaq requirements under Rules 5605(d) that compensation of an issuer's officers must be determined, or recommended to the Board for determination, either by a majority of the independent directors, or a compensation committee comprised solely of independent directors, and that director nominees must either be selected, or recommended for the Board's selection, either by a majority of the independent directors, or a nominations committee comprised solely of independent directors. The Nasdaq compensation committee requirements are not identical to the ASX remuneration and nomination committee requirements. Issuers listed on the ASX are recommended under applicable listing standards to establish a remuneration committee consisting of a majority of independent directors and an independent chairperson, or publicly disclose that it has not done so. We do not have a compensation committee and therefore claim an exemption from this Nasdaq rule.

- The requirement prescribed by Nasdaq Listing Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, private placements of securities, or the establishment or amendment of certain share option, purchase or other compensation plans. Applicable Australian law and the ASX Listing Rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% (or 25% under certain circumstances) of our issued share capital in any 12-month period (but, in determining the 15% limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties (as defined in the ASX Listing Rules) and (iii) issuances of securities to directors or their associates under an employee incentive plan. We claim an exemption from this Nasdaq rule

Indemnification of Directors and Officers

Our Constitution provides that, we may indemnify a person who is, or has been, a director or an officer of our company, to the full extent permissible by law, out of our property against any liability incurred by such person as a director or an officer in defending proceedings, whether civil or criminal, and whatever their outcome.

In addition, our Constitution provides that to the extent permitted by law, we may pay, or agree to pay, a premium in respect of a contract insuring a person who is or has been a director or an officer of our company or one of our subsidiaries against any liability:

- incurred by the person in his or her capacity as a director or an officer of our company or a subsidiary of our company, and

- for costs and expenses incurred by that person in defending proceedings relating to that person acting as a director or an officer of Incannex, whether civil or criminal, and whatever their outcome.

We maintain a directors' and officers' liability insurance policy. We have established a policy for the indemnification of our directors and officers against certain liabilities incurred as a director or officer, including costs and expenses associated in successfully defending legal proceedings.

D. Employees

As of June 30, 2022, we had 5 employees. Of these employees, 3 were employed in research and development and 2 were employed in general management and administration. As at the end of fiscal year 2021, we had 4 employees.

Each of our full-time employees has entered into an agreement with an unlimited term. We may only terminate the employment of any of our employees in accordance with the relevant employee's contract of employment.

Our standard contract of employment for full time employees provides that we can terminate the employment of an employee without notice for serious misconduct or with between one to six months' notice without cause (as set out in the relevant employee's contract of employment).

E. Share Ownership

For a description of arrangements involving the employees in the capital of the company, including any arrangement that involves the issue or grant of options or shares or securities of the company, see "Item 6. Directors, Senior Management and Employees—B. Compensation—"Employee Share Option Plan" and "Performance Rights Plan."

Ownership of Senior Management and Directors

The following table sets forth certain information as of September 30, 2022, regarding the ownership of our ordinary shares by each of our directors and senior management and by all of our directors and senior management as a group. The percentages shown are based on 1,523,593,695 ordinary shares issued and outstanding as of September 30, 2022.

Name	Number of Ordinary Shares Owned	Percentage of Ownership
Joel Latham	23,748,413	1.56%
Troy Valentine[2]	36,651,198	2.41%
Dr. Sud Agarwal[1]	75,303,093	4.94%
Peter Widdows	16,573,685	1.09%
Dr. George Anastassov[3]	66,972,077	4.40%
Robert Clark[4]	—	—
Lekhram Changoer[5]	63,954,841	4.20%
Madhukar Bhalla	—	—
All directors and executive officers as a group (8 persons) –	283,203,307	10.09%

(1) Dr. Sud Agarwal owns approximately 30% of the ordinary shares in Cannvalate, which owns 32,000,000 ordinary shares of Incannex. Dr. Sud Agarwal, as major shareholder and director of Cannvalate, may be deemed to have voting and dispositive power with respect to the ordinary shares in Incannex held by Cannvalate. Please see "Principal Shareholders" to see beneficial interest including Cannvalate's interest in Incannex. Dr. Sud Agarwal resigned on June 28, 2022.

(2) Troy Valentine is a director, and owns a 50% equity interest in, Alignment Capital Pty Ltd, which owns 13,194,248 ordinary shares of Incannex. Troy Valentine is a director of Tranaj Nominees Pty Ltd, which owns 10,216,950 ordinary shares in Incannex. Troy Valentine is a director of Valplan Pty Ltd, which owns 3,000,000 ordinary shares in Incannex. Troy Valentine is a director and the sole shareholder of Cityside Pty Ltd, which owns 4,440,000 ordinary shares of Incannex. Troy Valentine is the beneficiary of the GFCR Investments Trust managed by Ekirtson Nominees Pty Ltd as trustee, which owns 2,875,000 ordinary shares in Incannex. Thus, Troy Valentine is deemed to beneficially own 33,726,198 ordinary shares in Incannex.

(3) Dr. George Anastassov was appointed on June 28, 2022.

(4) Robert Clark was appointed on August 17, 2022.

(5) Lekhram Changoer was appointed on June 28, 2022.

Code of Conduct

We have adopted a Code of Conduct applicable to all of our directors, officers and employees. Our Code of Conduct is available on our website at *www.incannex.com.au*. We post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the Code of Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of, this Annual Report.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table presents the beneficial ownership of our ordinary shares based on 1,523,593,695 ordinary shares outstanding at September 30, 2022, by each person known by us to be the beneficial owner of more than 5% of our ordinary shares.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own.

In computing the number of shares beneficially owned by a person or entity and the percentage ownership of such person or entity, we deemed to be outstanding all shares subject to options and warrants held by the person or entity that are currently exercisable, or exercisable within 60 days of September 30, 2022. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person or entity.

	Ordinary Shares Beneficially Owned	
Shareholder	**Number**	**Percentage**
Dr. Sud Agarwal[(1)]	107,303,093	7.04%

(1) Includes (i) 75,303,093 ordinary shares owned by Dr. Sud Agarwal and (ii) 32,000,000 ordinary shares owned by Cannvalate, in which Dr. Sud Agarwal owns approximately 30% and is Chairman and, as such, may be deemed to have voting and dispositive power with respect to the ordinary shares in Incannex held by Cannvalate.

As of September 30, 2022, there were 12,413 holders of record of our ordinary shares, of which 2 had registered addresses in the United States. As of September 30, 2022, there were 681,302 ADSs outstanding, representing 17,032,550 ordinary shares (or 1.12% of the then outstanding ordinary shares). As of September 30, 2022, there were 681,302 registered holders of ADSs. These numbers are not representative of the number of beneficial holders of our shares nor are they representative of where such beneficial holders reside, as many of these ordinary shares were held of record by brokers or other nominees.

To our knowledge, we are not directly or indirectly controlled by another corporation, by any foreign government or by any other natural or legal person severally or jointly. There are no agreements known to us, the operation of which may at a subsequent date result in a change in control of Incannex. All shareholders have the same voting rights.

B. Related Party Transactions

The following is a description of our related party transactions since July 1, 2019 and we note that all of them were negotiated at arm's length.

In fiscal years 2022, 2021 and 2020, respectively, the Company paid A$407,824, A$97,976 and A$145,200 in fees to Alignment Capital Pty Ltd ("Alignment"), an entity controlled by our Chairman Troy Valentine, as consideration for its services as lead manager with respect to the exercise of our ASX-listed options program.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Our audited consolidated financial statements for the fiscal years ending June 30, 2022, 2021 and 2020 are included in Item 18 of this Annual Report on Form 20-F, which is found immediately following the text of this Annual Report on Form 20-F.

The audit report of PKF Brisbane Audit ("PKF") as of and for the year ended June 30, 2022, is included therein immediately preceding the financial statements. The audit report of WithumSmith+Brown, PC ("Withum"), as of June 30, 2021 and for the years ended June 30, 2021 and 2020, is included therein immediately preceding the financial statements.

Legal Proceedings

We are not involved in any legal or arbitration proceedings that could have a material adverse impact on our financial position or profitability. We are not involved in any governmental proceedings.

Dividend Distribution Policy

We have never paid cash dividends to our shareholders. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Any future dividend policy will be determined by the Board of Directors and will be based upon various factors, including our results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as the Board of Directors may deem relevant. There is no assurance that dividends will ever be paid. See "Special Note Regarding Forward Looking Statements".

B. Significant Changes

No significant changes occurred since the date of the annual financial statements.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares have traded on the ASX under the symbol "IHL" since November 2016.

Our ADSs have traded on the Nasdaq Stock Market LLC under the symbol "IXHL" since February 2022.

For a description of the rights of our ADSs, see "Item 12. Description of Securities Other Than Equity Securities—D. American Depositary Shares."

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed and traded on the ASX, under the symbol "IHL".

We have listed our ordinary shares as represented by ADSs, each ADS representing 25 of our ordinary shares, on the Nasdaq Stock Market LLC under the symbol "IXHL". Deutsche Bank Trust Company Americas act as depositary.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable

B. Memorandum and Articles of Association

General

Our constituent document is a Constitution. The Constitution is subject to the terms of the Listing Rules of ASX Limited and the Corporations Act 2001. The Constitution may be amended or repealed and replaced by special resolution of shareholders, which is a resolution of which notice has been given and that has been passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution.

Purposes and Objects

As a public company we have all the rights, powers and privileges of a natural person. Our Constitution does not provide for or prescribe any specific objects or purposes.

The Powers of the Directors

Under the provision of our Constitution our directors may exercise all the powers of our company except any powers that the Corporations Act or the constitution attributes to Incannex.

Interested Directors

According to our constitution, if a Director discloses his or her in accordance with the Corporations Act, the director may (i) contract or make an arrangement with the Company, or a related body corporate of the Company or a body corporate in which the Company is interested, in any matter in any capacity, (ii) be counted in a quorum for a meeting of Directors considering the contract or arrangement, (iii) vote on whether the Company enters into the contract or arrangement, and on any matter that relates to the contract or arrangement, (iv) sign on behalf of the Company, or witness the affixing of the common seal of the Company to, any document in respect of the contract or arrangement, (v) retain the benefits under the contract or arrangement.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests or conflicts of interests and prohibits directors from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of related party benefits to our directors.

Directors' compensation

Our non-executive directors are paid remuneration for their services as directors which is determined in a general meeting of shareholders. The aggregate, fixed sum for directors' remuneration is to be divided among the directors in such proportion as the directors themselves agree and in accordance with our Constitution. Our executive directors are paid remuneration for their services as directors which is determined by all directors.

Fees payable to our non-executive directors must be by way of a fixed sum and not by way of a commission on or a percentage of profits or operating revenue. Remuneration paid to our executive directors must also not include a commission or percentage of operating revenue.

Pursuant to our Constitution, any director who performs services that in the opinion of our board of directors, are outside the scope of the ordinary duties of a director may be paid extra remuneration, which is determined by our board of directors.

In addition to other remuneration provided in our Constitution, all of our directors are entitled to be paid by us for reasonable travel accommodation and other expenses incurred by the directors in attending general meetings, board meetings, committee meetings or otherwise in connection with our business.

In addition, in accordance with our Constitution, a director may be paid a retirement benefit as determined by our board of directors subject to the limits set out in the Corporations Act and the ASX Listing Rules which broadly restrict our ability to pay our officers a termination benefit in the event of a change of control of the Company or our subsidiaries as well as impose requirements for shareholder approval to be obtained to pay certain retirement benefits to our officers.

Borrowing powers exercisable by Directors

Pursuant to our Constitution, the management and control of our business affairs are vested in our board of directors. Thus, our board of directors has the power to raise or borrow money, and charge any of our property or business or any uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, in each case, in the manner and on terms it deems fit.

Retirement of Directors

Pursuant to our Constitution and the ASX Listing Rules, each director, other than the managing director, must not hold office for more than three years or beyond the third annual general meeting following his or her appointment (whichever is longer). Further, at least one director is required to retire by rotation at each annual general meeting (such director being the director who has been longest in office since their last election). Directors who retire by rotation are eligible for a re-election to the board of directors unless disqualified from acting as a director under the Corporations Act or our Constitution.

Rights Attached to Our Ordinary Shares

The concept of authorized share capital no longer exists in Australia and as a result, our authorized share capital is unlimited. All our outstanding ordinary shares are validly issued, fully paid and non-assessable. The rights attached to our ordinary shares are as follows:

Dividend Rights.

The directors may declare that a dividend be paid to the members according to the shareholders' pro rata shareholdings and the directors may fix the amount, the time for payment and the method of payment. No dividend is payable except in accordance with the Corporations Act as amended from time to time and no dividend carries interest as against the Company.

Voting Rights.

Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Such voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future.

The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person, or by proxy, attorney or representative appointed pursuant to our Constitution. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place. At the reconvened meeting, the required quorum consists of any two members present in person, or by proxy, attorney or representative appointed pursuant to our Constitution. The meeting is dissolved if a quorum is not present within 30 minutes from the time appointed for the meeting.

An ordinary resolution, such as a resolution for the declaration of dividends, requires approval by the holders of a majority of the voting rights represented at the meeting, in person, by proxy, or by written ballot and voting thereon. Under our Constitution, the Corporations Act and the ASX Listing Rules, certain matters must be passed by way of a special resolution. A special resolution must be passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution and who vote at the meeting in person. Matters which are not required to be passed by special resolution are required to be passed by ordinary resolution.

Rights in Our Profits.

Our shareholders have the right to share in our profits distributed as a dividend and any other permitted distribution.

Rights in the Event of Liquidation.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the capital at the commencement of the liquidation paid up or which ought to have been paid up on the shares held by them respectively. This right may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights, such as the right in winding up to payment in cash of the amount then paid up on the share, and any arrears of dividend in respect of that share, in priority to any other class of shares.

Directors may make calls

Our Constitution provides that subject to the terms on which the shares have been issued directors may make calls on a shareholder for amounts unpaid on shares held by that shareholder, other than monies payable at fixed times under the conditions of allotment.

Changing Rights Attached to Shares

According to our Constitution, the rights attached to any class of shares, unless otherwise provided by the terms of the class, may be varied with either the written consent of the holders of not less than 75% of the issued shares of that class or the sanction of a special resolution passed at a separate general meeting of the shares of that class.

Annual and Extraordinary Meetings

Our directors must convene an annual meeting of shareholders at least once every calendar year. Notice of at least 28 days prior to the date of the meeting is required. A general meeting may be convened by any director, or shareholders in compliance with the Corporations Act.

Limitations on the Rights to Own Securities in Our Company

Subject to certain limitations on the percentage of shares a person may hold in our company, neither our Constitution nor the laws of the Commonwealth of Australia restrict in any way the ownership or voting of shares in our company.

Changes in Our Capital

Pursuant to the Listing Rules, our directors may in their discretion issue securities to persons who are not related parties of our company, without the approval of shareholders, if such issue, when aggregated with securities issued by our company during the previous 12-month period would be an amount that would not exceed 15% of our issued capital at the commencement of the 12 month period. Other allotments of securities require approval by an ordinary resolution of shareholders

C. Material Contracts

Share Sale and Purchase Agreement between Incannex and the sellers of APIRx Pharmaceutical USA, LLC

In May 2022, we entered into a Share Sale and Purchase Agreement to acquire 100% equity interests in APIRx. As consideration, we issued 218,169,506 ordinary shares in Incannex to the sellers of APIRx, at A$0.57 per share. Under the terms of the agreement, we acquired all assets and intellectual property rights of APIRx. We completed the acquisition in August 2022.

Clinical Trial Research Agreement with Alfred Health, dated June 22, 2021

On June 22, 2021, we entered into a Clinical Trial Research Agreement with Alfred Health. Under the terms of the agreement, Alfred Health is to conduct and manage an open label extension on the examination of the combination of dronabinol and acetazolamide for treatment of OSA. The open label extension is to be conducted on a maximum of 12 study participants. Incannex will provide all the information required to conduct the study and will pay market-standard fees to Alfred Health as consideration for its role. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement, and by Incannex at will upon written notice delivered to Alfred Health thirty days prior to the termination date.

Clinical Trial Research Agreement with Alfred Health, dated September 24, 2020

On September 24, 2020, we entered into a Clinical Trial Research Agreement with Alfred Health. Under the terms of the agreement, Alfred Health is to conduct and manage a dose finding crossover trial investigating the effect of dronabinol combined with acetazolamide on AHI in adults with OSA. The dose finding crossover trial is to be conducted on a maximum of 12 trial participants. Incannex will provide all the information required to conduct the study and will pay market-standard fees to Alfred Health as consideration for its role. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement, and by Incannex at will upon written notice delivered to Alfred Health thirty days prior to the termination date.

Clinical Trial Research Agreement with University of Western Australia

On April 6, 2021, we entered into a Clinical Trial Research Agreement with University of Western Australia. Under the terms of the agreement, the University of Western Australia is to conduct and manage a dose finding crossover trial investigating the effect of dronabinol combined with acetazolamide on AHI in adults with OSA. The dose finding crossover trial is to be conducted on a maximum of 12 trial participants. Incannex will provide all the information required to conduct the study and will pay market-standard fees to the University of Western Australia as consideration for its role. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement, and by Incannex at will upon written notice delivered to the University of Western Australia thirty days prior to the termination date.

Master Consultancy Agreement with Clinical Network Services (CNS) Pty Ltd

On June 29, 2020, we entered into a Master Consultancy Agreement with Clinical Network Services (CNS) Pty Ltd ("Clinical Network"). Under the terms of the agreement, Clinical Network is to act as Australian and New Zealand consultant to product development and management of clinical research programs. Incannex will pay market-standard fees to Clinical Network. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement.

Research Services Agreement with Monash University, dated November 27, 2020

On November 27, 2020, we entered into a Research Services Agreement with Monash University. Under the terms of the agreement, Monash University is to conduct research services with respect to Psi-GAD. Research activities are to be conducted with respect to a phase 2A randomized double-blind active-placebo-controlled trial to assess the safety and efficacy of Psi-GAD. Incannex will provide all the information required to conduct the study and will pay market-standard fees to Monash University. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement.

Research Services Agreement between Monash University, dated March 10, 2021

On March 10, 2021, we entered into a Research Services Agreement with Monash University. Under the terms of the agreement, Monash University is to conduct research services with respect to TBI. Research activities are to be conducted with respect to the neuroprotective effect of the combination of CBD and isoflurane in a rodent model of mild traumatic brain injury. Incannex will provide all the information required to conduct the study and will pay market-standard fees to Monash University. The agreement may be terminated by either party for cause, for the reasons set forth in the agreement.

Master Service Agreement between Avance Clinical Pty Limited

On July 12, 2021, we entered into a Master Service Agreement with Avance Clinical Pty Limited ("Avance"). Under the terms of the agreement, Avance will perform services to support Incannex's clinical trials and studies, as requested by Incannex. the agreement has an initial term of five years. Each party may terminate the agreement by delivering a written notice three months prior to the expiration of the term of the contract.

Appendix No. 2 to the Master Consultancy Agreement with Novotech Australia Pty Limited

On February 2, 2021, we entered into Appendix No. 2 to the Master Consultancy Agreement with Novotech Australia Pty Limited ("Novotech"), an affiliate of Clinical Network. Under the terms of the agreement, Novotech is to conduct an open label extension on the examination of the combination of dronabinol and acetazolamide for treatment of OSA. The terms of this agreement are governed by the terms of the Master Consultancy Agreement entered into with Clinical Network.

D. Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Cash Transaction Reports Agency, which monitors such transaction, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

The Foreign Acquisitions and Takeovers Act 1975

Under Australian law, in certain circumstances foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without approval from the Australian Treasurer. These limitations are set forth in the Australian *Foreign Acquisitions and Takeovers Act 1975* (Cth) ("FATA"), associated legislation and regulations. These limitations are in addition to the more general overarching Takeovers Prohibition of an acquisition of more than a 20% interest in a public company (in the absence of an applicable exception) under the takeover provisions of Australia's Corporations Act by any person whether foreign or otherwise.

If an investment is subject to foreign investment approval, it may have compulsory prior notification requirements, being a "notifiable action" or "notifiable national security action" or voluntary prior notification requirements being a "significant action" or "reviewable national security action". If an investment falls in this voluntary application category, the seeking of approval will extinguish certain future rights the Australian Treasurer has to review and approve the investment. Not applying for approval where the voluntary notification provisions apply will not be a breach of the FATA.

The Australian foreign investment regime applies differently to 'foreign government investors' and private foreign persons. Broadly, entities are considered as foreign persons if (i) a foreign holder (together with its associates) holds a direct or indirect interest of 20% or more in the entity or (ii) multiple foreign holders hold an aggregate interest (direct or indirect) of at least 40%. An entity will be a 'foreign government investor' if (i) a foreign government or foreign government owned entity, or a number of foreign government owned entities from the same country own a direct or indirect interest of 20% or (ii) or multiple foreign governments or foreign government owned entities from any country own a direct or indirect interest of 40%.

Under the FATA, foreign persons are required to notify and obtain prior approval from the Foreign Investment Review Board for a range of acquisitions of an interest in an Australian entity on a mandatory basis, including:

- acquisitions of a direct interest (generally 10% or more) by a foreign government investor in an Australian entity, irrespective of value;
- acquisitions by any foreign person of:
  - a 'substantial interest' (generally 20% or more) in an Australian entity valued above the relevant monetary threshold. This is generally A$289 million (indexed annually) or A$1,250 million in case of U.S. investors where the investment is being made directly by a U.S investor, in each case calculated by the higher of the total asset value and the total value of the issued securities of the Australian entity; or

- a direct interest in a 'national security business' or entity that carries on a national security business, or holds 'national security land', irrespective of value; and

- acquisitions of interests in Australian entities operating in sensitive industries (such as media, telecommunications, and encryption and security technologies), land-rich Australian entities or agribusiness Australian entities.

Each foreign person seeking to acquire holdings in excess of the above caps (including their associates) would need to complete an application form setting out the proposal and relevant particulars of the acquisition/shareholding and pay the relevant application fees. The Australian Treasurer then has 30 days to consider the application and make a decision and a further 10 days to notify the applicant. However, the Australian Treasurer has broad powers to extend this time period, including extending the period by up to a further 90 days by publishing an interim order. Most commonly, the Australian Treasurer will request an applicant agree to an extension to avoid needing to publish the interim order, such agreement is usually in the best interest of the applicant as interim orders are made public and by agreeing to an extension the application process is kept confidential. Otherwise applications are strictly confidential and not released to the public.

The Australian Foreign Investment Review Board, an Australian advisory board to the Australian Treasurer has provided a guideline titled *Australia's Foreign Investment Policy,* which provides an outline of the policy. As for the risk associated with seeking approval, the policy provides, among other things, that the Treasurer will reject an application if it is contrary to the national interest.

If an application is made to the Australian Treasurer (whether voluntary or compulsory), the Australian Treasurer may either issue a non-objection notice, a non-objection notice with conditions or a rejection notice.

If the necessary approvals are not obtained, the Treasurer has a range of enforcement powers, including the power to make an order requiring the acquirer to dispose of the shares it has acquired within a specified period of time. Once a foreign person (together with any associate) holds a direct interest or a substantial interest in an entity, any further acquisition of interests, including in the course of trading in the secondary market, would require a new FIRB approval unless an exemption applies.

Once granted, a FIRB approval is valid for a 12 month period, meaning the proposed acquisition which was the subject of an application can occur any time during that 12 month period.

E. Taxation

The following is a discussion of Australian and United States tax consequences material to our shareholders. To the extent that the discussion is based on tax legislation which has not been subject to judicial or administrative interpretation, the views expressed in the discussion might not be accepted by the tax authorities in question or by court. The discussion is not intended, and should not be construed, as legal or professional tax advice and does not exhaust all possible tax considerations.

Holders of our ADSs should consult their own tax advisors as to the United States, Australian or other tax consequences of the purchase, ownership and disposition of ADSs, including, in particular, the effect of any foreign, state or local taxes.

U.S. Taxation

The following is a summary of material U.S. federal income tax consequences that generally apply to U.S. Holders (as defined below) who hold ADSs as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"). This summary is based on the Code, its legislative history, final, temporary and proposed United States Treasury regulations promulgated thereunder, published rulings and court decisions, and the bilateral income tax convention between Australia and the United States (the "Treaty"), all as in effect on the date hereof and all of which are subject to change, or changes in interpretation, either prospectively or retroactively. This discussion does not address all of the tax consequences relating to the purchase, ownership, and disposition of ADSs and does not take into account U.S. Holders who may be subject to special rules, including: financial institutions, insurance companies, , tax-exempt organizations, real estate investment trusts, regulated investment companies, grantor trusts, non-resident aliens of the United States or taxpayers whose functional currency is not the U.S. dollar, persons who hold the ADSs through partnerships or other pass-through entities, persons who acquired their ADSs through the exercise or cancellation of any employee share options or otherwise as compensation for their services, investors that actually or constructively own 10% or more of our shares, dealers or traders in securities or currencies, certain former citizens or long-term residents of the United States, dual resident corporations, persons that generally mark their securities to market for United States federal income tax purposes, persons who are residents of Australia for Australian income tax purposes, and investors holding ADSs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction. This summary does not address the Medicare tax imposed on certain investment income, any state, local and foreign tax considerations or any U.S. federal estate, gift or alternative minimum tax considerations relevant to the purchase, ownership and disposition of our ADSs. In addition, this discussion is based in part upon representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreements will be performed according to its terms.

If a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes owns ADSs, the U.S. federal income tax treatment of its partners will generally depend upon the status of the partner and the activities of the partnership. A partnership should consult its tax advisors regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of ADSs.

For purposes of this summary, the term "U.S. Holder" means a beneficial owner of ADSs that is for U.S. federal income tax purposes: an individual who is a citizen or resident of the United States; a corporation that is created or organized in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to U.S. federal income tax regardless of its source; or a trust if (a) a court within the United States is able to exercise primary supervision over administration of the trust, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (b) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

Distributions

For U.S. federal income tax purposes, a U.S. Holder of ADSs will be treated as owning the ordinary shares underlying the ADSs. Subject to the passive foreign investment company rules discussed below, the gross amount of any distribution received by a U.S. Holder with respect to our ordinary shares or ADSs, including the amount of any Australian taxes withheld therefrom, will be included in gross income as a dividend to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our earnings and profits will be treated first as a non-taxable return of capital to the extent of a U.S. Holder's tax basis in the ADSs and thereafter will be treated as gain from the sale or exchange of the ADSs. We have not maintained and do not plan to maintain calculations of earnings and profits for U.S. federal income tax purposes. As a result, a U.S. Holder may need to include the entire amount of any such distribution in income as a dividend. Dividends will not, however, be eligible for the "dividends received deduction" generally allowed to corporate shareholders with respect to dividends received from U.S. corporations.

The U.S. dollar value of any distribution on the ADSs made in Australian dollars generally should be calculated by reference to the spot exchange rate between the U.S. dollar and the Australian dollar in effect on the date the distribution is actually or constructively received by the U.S. Holder regardless of whether the Australian dollars so received are in fact converted into U.S. dollars. A U.S. Holder who receives payment in Australian dollars and converts those Australian dollars into U.S. dollars at an exchange rate other than the rate in effect on such day may have a foreign currency exchange gain or loss, which would generally be treated as ordinary income or loss from sources within the United States for U.S. foreign tax credit purposes.

Subject to complex limitations and certain holding period requirements, a U.S. Holder may elect to claim a credit for Australian tax withheld from distributions against its U.S. federal income tax liability. The limitations set out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the U.S. federal income taxes otherwise payable with respect to each such class of income. Dividends generally will be treated as foreign-source passive category income for U.S. foreign tax credit purposes or in the case of certain U.S. Holders as foreign source "general category" income. A U.S. Holder that does not elect to claim a U.S. foreign tax credit may instead claim a deduction for Australian tax withheld.

Subject to certain limitations, dividends received by a non-corporate U.S. Holder are subject to tax at a reduced maximum tax rate of 20 percent if the dividends are "qualified dividends". Dividends are qualified dividends if: (a)(i) the issuer is entitled to benefits under the Treaty or (ii) the shares are readily tradable on an established securities market in the United States and (b) certain other requirements are met. We believe that we are entitled to benefits under the Treaty and that the ADSs currently are readily tradable on an established securities market in the United States. However, no assurance can be given that the ADSs will remain readily tradable. Further, the reduced rate does not apply to dividends if we are a PFIC in the year prior to or the year in which the dividend is paid.

The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the claiming of foreign tax credits for U.S. Holders of ADSs. Such actions would also be inconsistent with the claiming of the reduced rate of tax, described above, applicable to dividends received by certain non-corporate holders. Accordingly, the analysis of the creditability of Australian taxes and the availability of the reduced tax rate for dividends received by certain non-corporate holders, each described above, could be affected by actions taken by intermediaries in the chain of ownership between the holder of an ADS and our Company.

Disposition of ADSs

If you sell or otherwise dispose of ADSs, you will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the U.S. dollar value of the amount realized on the sale or other disposition and your adjusted tax basis in the ADSs. Subject to the passive foreign investment company rules discussed below, such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if you have held the ADSs for more than one year at the time of the sale or other disposition. In general, any gain that you recognize on the sale or other disposition of ADSs will be gain from U.S. sources for purposes of the foreign tax credit limitation; losses will generally be allocated against U.S. source income. The deduction of capital losses is subject to certain limitations under the Code.

In the case of a cash-basis U.S. Holder who receives Australian dollars in connection with the sale or other disposition of ADSs, the amount realized will be calculated based on the U.S. dollar value of the Australian dollars received as determined by reference to the spot rate in effect on the settlement date of such exchange. A U.S. Holder who receives payment in Australian dollars and converts Australian dollars into U.S. dollars at a conversion rate other than the rate in effect on the settlement date may have foreign currency exchange gain or loss that would be treated as ordinary income or loss from sources within the United States for U.S. foreign tax credit purposes.

An accrual-basis U.S. Holder may elect the same treatment required of cash-basis taxpayers with respect to a sale or disposition of ADSs, provided that the election is applied consistently from year to year. Such election may not be changed without the consent of the Internal Revenue Service ("IRS"). In the event that an accrual-basis U.S. Holder does not elect to be treated as a cash-basis taxpayer (pursuant to the Treasury regulations applicable to foreign currency transactions), such U.S. Holder may have foreign currency gain or loss for U.S. federal income tax purposes because of differences between the U.S. dollar value of the currency received prevailing on the trade date and the settlement date. Any such currency gain or loss would be treated as ordinary income or loss from sources within the United States for U.S. foreign tax credit purposes. However, if foreign currency is converted into U.S. dollars on the date received by the U.S. Holder, a cash-basis or electing accrual-basis U.S. Holder should not recognize any gain or loss on such conversion.

Passive Foreign Investment Company rules

There is a risk that we may be a PFIC, for U.S. federal income tax purposes. Our treatment as a PFIC could result in a reduction in the after-tax return to the U.S. Holders of our ADSs and may cause a reduction in the value of such securities.

For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, cash is considered to be an asset which produces passive income. Passive income for these purposes generally includes dividends, interest, royalties, rents, annuities and the excess of gains over losses from the disposition of assets which produce passive income. In making a PFIC determination, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% or more (by value) of the share capital.

Based on the composition of our assets and income, we believe that Incannex was not a PFIC for U.S. federal income tax purposes with respect to fiscal 2022. However, the determination of PFIC status is a factual determination that must be made annually at the close of each taxable year and, therefore, there can be no certainty as to our status in this regard until the close of the current or any future taxable year. Changes in the nature of our income or assets or a decrease in the trading price of our ADSs may cause us to be considered a PFIC in the current or any subsequent year. If we were a PFIC in any year during a U.S. Holder's holding period for our ADSs, we would ordinarily continue to be treated as a PFIC for each subsequent year during which the U.S. Holder owned the ADSs.

Under the default PFIC "excess distribution" regime, if we are a PFIC in any taxable year during which a U.S. Holder owns ADSs, such U.S. Holder could be liable for additional taxes and interest charges upon (i) certain distributions by us (generally any distribution paid during a taxable year that is greater than 125 percent of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the ADSs), and (ii) any gain realized on a sale, exchange or other disposition, including a pledge, of the ADSs, whether or not we continue to be a PFIC for the year of the disposition. In these circumstances, the tax will generally be determined by allocating such distributions or gain ratably over the U.S. Holder's holding period for the ADSs. The amount allocated to the current taxable year and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income (rather than capital gain) earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest applicable marginal rates for the year and an interest charge at the rate applicable to underpayments of tax will also be imposed on the amount of taxes allocated to such other taxable years.

An indirect shareholder may be taxed on a distribution paid to the direct owner of a PFIC and on a disposition of the share indirectly owned. Indirect shareholders are strongly urged to consult their tax advisors regarding the application of these rules.

If we are a PFIC and subsequently cease to be a PFIC in a future year, a U.S. Holder may avoid the continued application of the tax treatment described above by electing to be treated as if it sold its ADSs on the last day of the last taxable year in which we were a PFIC. Any gain would generally be recognized and subject to tax under the excess distribution regime described above. Loss would not be recognized. A U.S. Holder's basis in its ADSs would be increased by the amount of gain, if any, recognized on the deemed sale. A U.S. Holder would be required to treat its holding period for its ADSs as beginning on the day following the last day of the last taxable year in which we were a PFIC.

If the ADSs are considered "marketable stock" and if a U.S. Holder properly elects to "mark-to-market" its ADSs in a timely fashion, the U.S. Holder would not be subject to tax under the excess distribution regime described above. Instead, the U.S. Holder would generally include in income any excess of the fair market value of the ADSs at the close of each tax year over the adjusted tax basis of the ADSs. If the fair market value of the ADSs had depreciated below the adjusted basis at the close of the tax year, the U.S. Holder would be entitled to deduct the excess of the adjusted basis of the ADSs over their fair market value at that time. However, such deductions generally would be limited to the net mark-to-market gains, if any, the U.S. Holder included in income with respect to such ADSs in prior years. Income recognized and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of ADSs with respect to which the mark-to-market election is made, is treated as ordinary income or loss (except that loss is treated as capital loss to the extent the loss exceeds the net mark-to-market gains, if any, that a U.S. Holder included in income with respect to such ordinary shares in prior years). However, gain or loss from the disposition of ADSs (as to which a "mark-to-market" election was properly made) in a year in which we are no longer a PFIC, will be capital gain or loss. Our ordinary shares or ADSs will be "marketable" stock as long as they remain regularly traded on a national securities exchange, such as the Nasdaq, or a foreign securities exchange regulated by a governmental authority of the country in which the market is located and which meets certain requirements, including that the rules of the exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter, but no assurances can be given in this regard. Our ordinary shares are traded on the ASX, which may qualify as an eligible foreign securities exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including shares in any of our subsidiaries that are treated as PFICs.

A U.S. Holder of ADSs should not be able to avoid the tax consequences described above by electing to treat us as a qualified electing fund. In general, a qualified electing fund is, with respect to a U.S. person, a PFIC if the U.S. person has elected to include its proportionate share of a company's ordinary earnings and net capital gains in U.S. income on an annual basis. A qualified electing fund election can only be made with respect to us if we provide U.S. Holders with certain information on an annual basis and we do not intend to prepare the information that U.S. Holders would need to make the qualified electing fund election.

Backup Withholding and Information Reporting

Payments in respect of ADSs may be subject to information reporting to the IRS and to U.S. backup withholding tax (at a rate of 24% under current law). Backup withholding will not apply, however, if a U.S. Holder (i) is a corporation, (ii) satisfies an applicable exemption, or (iii) furnishes correct taxpayer identification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder's U.S. tax liability, and a U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS.

Australian Taxation

In this section we discuss the material Australian tax considerations that apply to non-Australian tax residents with respect to the acquisition, ownership and disposal of the absolute beneficial ownership of ADSs, which are evidenced by ADSs. This discussion is based upon existing Australian tax law as of the date of this Annual Report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian income tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty. Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the purchase, ownership and disposition of the ADSs or shares.

Nature of ADSs for Australian Taxation Purposes

Holders of our ADSs should be treated as the owners of the underlying ordinary shares for Australian income tax and capital gains tax purposes. Therefore, dividends paid on the underlying ordinary shares will be treated for Australian tax purposes as if they were paid directly to the owners of ADSs, and the disposal of ADSs will be treated for Australian tax purposes as the disposal of the underlying ordinary shares. In the following analysis we discuss the application of the Australian income tax and capital gains tax rules to holders of ADSs which are not residents of Australia for tax purpose.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent they are paid out of company profits that have been subject to income tax. Fully franked dividends are not subject to dividend withholding tax. Dividends that are not franked or are partly franked and are paid to non-Australian resident shareholders are subject to dividend withholding tax when paid to non-Australian resident shareholders.

Unfranked (or partially franked) dividends paid to a non-resident shareholder will be subject to withholding tax at a rate of 30%, unless the shareholder is a resident of a country with which Australia has a double taxation agreement.

In accordance with the provisions of the Double Taxation Convention between Australia and the United States, the maximum rate of Australian tax on any unfranked portion of a dividend to which a resident of the United States is beneficially entitled is reduced to 15%, where the U.S. resident holds less than 10% of the voting rights in our company, or 5% where the U.S. resident holds 10% or more of the voting rights in our company. Special rules apply to Regulated Investment Companies and Real Estate Investment Trusts that hold shares and receive dividends. The Double Taxation Convention between Australia and the United States does not apply to limit the tax rate on dividends where the ADSs are effectively connected to a permanent establishment or a fixed base carried on by the owner of the ADSs in Australia through which the shareholder carries on business or provides independent personal services, respectively.

Tax on Sales or other Dispositions of Shares — Capital Gains Tax

Australian capital gains derived by non-Australian residents in respect of the disposal of capital assets that are not taxable Australian property will be disregarded. Non-Australian resident shareholders will not be subject to Australian capital gains tax on the capital gain made on a disposal of our shares, unless they, together with associates, hold 10% or more of our issued capital, tested either at the time of disposal or over any continuous 12- month period in the 24 months prior to disposal, and the value of our shares at the time of disposal is principally attributable to Australian real property assets.

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rate but for certain shareholders a discount capital gain may apply if the shares have been held for 12 months or more and the shareholder was a resident of Australia for some or all of the ownership period. For individuals, this discount is 50%. Net capital gains are calculated after reduction for capital losses (including certain prior year capital losses), which may only be offset against capital gains.

Some non-Australian resident shareholders may hold shares on revenue rather than on capital account, for example, share traders. These shareholders may have the gains made on the sale or other disposal of the shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian resident shareholders assessable under these provisions in respect of gains made on shares held on revenue account would be assessed on such gains at the Australian tax rates applicable to non-Australian residents, which start at a marginal rate of 32.5% for non-Australian resident individuals. Some relief from the Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the United States and Australia, for example, because the shareholder does not have a permanent establishment in Australia.

To the extent an amount would be included in a non-Australian resident shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

Dual Residency

If a shareholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax applicable would be limited by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

No Australian death duty (estate tax)

Australia does not have estate or death duties. No capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries, may, however, give rise to a capital gains tax liability.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the reporting requirements of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act. As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations are not subject to the disclosure and procedural requirements of regulation 14A under the Exchange Act, transactions in our equity securities by our officers and directors are exempt from reporting and the "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we file with the U.S. Securities and Exchange Commission an annual report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm, and we submit reports to the U.S. Securities and Exchange Commission on Form 6-K containing (among other things) press releases and unaudited financial information for the first six months of each fiscal year. We post our annual and half-year reports on our website promptly following their filing with the U.S. Securities and Exchange Commission. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this Annual Report on Form 20-F, and the reference to our website in this Annual Report on Form 20-F is an inactive textual reference only.

This document and the exhibits thereto and any other document we file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the U.S. Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington D.C. 20549. You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the U.S. Securities and Exchange Commission at 1-800-SEC-0330.

The U.S. Securities and Exchange Commission maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants that make electronic filings with the U.S. Securities and Exchange Commission using its EDGAR (Electronic Data Gathering, Analysis, and Retrieval) system.

The documents concerning our company which are referred to in this document may also be inspected at our office located at Suite 105, 8 Century Circuit, Norwest 2153, NSW Australia.

I. Subsidiary Information

See Item 4C "Organizational Structure" for further information.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash consist entirely of cash held in interest-bearing accounts with banks in Australia. Thus, our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of Australian interest rates. However, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. See note "16. Financial Instruments" to our notes to the financial statements for a further discussion of market risk and sensitivity analysis.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

American Depositary Shares

Deutsche Bank Trust Company Americas, as depositary, will register and deliver the ADSs. Each ADS will represent ownership of 25 ordinary shares, deposited with National Nominees Limited, as custodian for the depositary. Each ADS will also represent ownership of any other securities, cash or other property which may be held by the depositary. The depositary's corporate trust office at which the ADSs will be administered is located at 60 Wall Street, New York, NY 10005, USA. The principal executive office of the depositary is located at 60 Wall Street, New York, NY 10005, USA.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, or DTC, pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depositary to the ADS holders entitled thereto.

We will not treat ADS holders as our shareholders and accordingly, you, as an ADS holder, will not have shareholder rights. Australian law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your ADSs. As a holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and you, as an ADS holder, and the beneficial owners of ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. The laws of the State of New York govern the deposit agreement and the ADSs. See "— Jurisdiction and Arbitration."

Fees and Expenses

As an ADS holder, you will be required to pay the following service fees to the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs):

Service	Fees
To any person to which ADSs are issued or to any person to which a distribution is made in respect of ADS distributions pursuant to stock dividends or other free distributions of stock, bonus distributions, stock splits or other distributions (except where converted to cash)	Up to US$0.05 per ADS issued
Cancellation of ADSs, including the case of termination of the deposit agreement	Up to US$0.05 per ADS cancelled
Distribution of cash dividends	Up to US$0.05 per ADS held
Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements	Up to US$0.05 per ADS held
Distribution of ADSs pursuant to exercise of rights.	Up to US$0.05 per ADS held
Depositary services	Up to US$0.04 per ADS held on the applicable record date(s) established by the depositary bank

As an ADS holder, you will also be responsible for paying certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs) such as:

- Taxes (including applicable interest and penalties) and other governmental charges;
- Fees for the transfer and registration of ordinary shares charged by the registrar and transfer agent for the ordinary shares in the Australian (i.e., upon deposit and withdrawal of ordinary shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.

- Taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when ordinary shares are deposited or withdrawn from deposit).

- Fees and expenses incurred in connection with the delivery or servicing of ordinary shares on deposit.

- Fees and expenses incurred in connection with complying with exchange control regulations and other regulatory requirements applicable to ordinary shares, deposited securities, ADSs and ADRs.

- Any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (i.e., share dividends, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

The depositary may make payments to us or reimburse us for certain costs and expenses, by making available a portion of the ADS fees collected in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable, or which become payable, on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register or transfer your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any net proceeds, or send to you any property, remaining after it has paid the taxes. You agree to indemnify us, the depositary, the custodian and each of our and their respective agents, directors, employees and affiliates for, and hold each of them harmless from, any claims with respect to taxes (including applicable interest and penalties thereon) arising from any refund of taxes, reduced rate of withholding at source or other tax benefit obtained for you. Your obligations under this paragraph shall survive any transfer of ADRs, any surrender of ADRs and withdrawal of deposited securities or the termination of the deposit agreement.

See Exhibit 2.3: "Description of Securities" for additional information on the ADSs.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of June 30, 2022, as required by Rule 13a-15(b) under the Exchange Act. Based on that evaluation, our management has concluded that, as of June 30, 2022, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2022, based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO 2013). Based on our evaluation under the criteria set forth in Internal Control — Integrated Framework, our management concluded that our internal control over financial reporting was effective as of June 30, 2022.

This Annual Report does not include an attestation report of the Company's registered public accounting firm as we are an emerging growth company.

Inherent Limitations on Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) for the fiscal year ended June 30, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

Not applicable.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Peter Widdows is a member of our board of directors and serves on our audit committee as Chairman. Our board has determined that Peter Widdows is an audit committee financial expert and satisfies the "independence" requirements of the U.S. Securities and Exchange Commission, the Nasdaq Rules and ASX Rules.

ITEM 16B. CODE OF ETHICS

We have adopted a code of conduct that applies to our directors, chief executive officer and all senior financial officers of our company, including the chief financial officer, chief accounting officer or controller, or persons performing similar functions. Our Code of Conduct is available on our website at *www.incannex.com.au*.

Written copies are available upon request. If we make any substantive amendment to the code of conduct or grant any waivers, including any implicit waiver, from a provision of the code of conduct, we will disclose the nature of such amendment or waiver on our website.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

We retained PKF as our independent registered public accounting firm for fiscal year 2022 and Withum for fiscal year 2021. Set forth below is a summary of the fees paid to PKF and Withum for services provided, respectively in fiscal years 2022 and 2021.

	Fiscal 2022 A$	Fiscal 2021 A$
Audit Fees[1]	442,208	287,975[2]
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total remuneration	**442,208**	**287,975**

(1) The total remuneration includes A$357,208 paid to Withum in relation to audit fees regarding fiscal years 2021, 2020 and 2019 incurred by Incannex in connection with its listing on Nasdaq Stock Market LLC. Incannex paid A$85,000 to PKF regarding the auditing of its fiscal year 2022. The total remuneration does not include A$37,785 and A$23,138 paid to HLB Mann Judd, for fiscal 2021 and 2022, respectively, in connection with audit services performed under the rules of the Australian Accounting Standards Board.

(2) The total remuneration paid to Withum does not concern the auditing of fiscal year 2021, rather the auditing of historical financial statements related to fiscal year 2020 and 2019 that was needed to file the initial registration statement with the SEC.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted policies and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm. Pre-approval of an audit or non-audit service may be given as a general pre-approval, as part of the audit committee's approval of the scope of the engagement of our independent registered public accounting firm, or on an individual basis. Any proposed services exceeding general pre-approved levels also requires specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the Securities and Exchange Commission, and also requires the audit committee to consider whether proposed services are compatible with the independence of the registered public accounting firm.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

The Company announced that on July 7, 2022, we dismissed Withum as our independent registered public accounting firm. On July 7, 2022, we appointed PKF as our independent registered public accounting firm. This change in our independent registered public accounting firm was approved by the Board of Directors on July 7, 2022.

Withum's reports on the financial statements for the year ended June 30, 2021, did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or auditing principles.

During the period of Withum's engagement there were (i) no disagreements between us and Withum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Withum, would have caused it to make a reference to the subject matter of the disagreements in connection with its report; and (ii) no "reportable events" as defined in Item 16F(a)(1)(v) of Form 20-F. The Company has requested Withum to furnish it with a letter addressed to the Securities and Exchange Commission stating whether Withum agrees with the statements contained above. A copy of the letter from Withum, dated October 28, 2022, to the Securities and Exchange Commission is filed as an exhibit hereto.

During the two most recent fiscal years ended June 30, 2022 and 2021 neither the Company, nor someone on behalf of the Company, has consulted PKF regarding either (a) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Company's consolidated financial statements, and neither a written report was provided to the Company nor oral advice was provided that PKF concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (b) any matter that was the subject of a disagreement as defined in Item 16F(a)(1)(iv) of Form 20-F and related instructions to Item 16F of Form 20-F, or any reportable events as described in Item 16F(a)(1)(v) of Form 20-F.

ITEM 16G. CORPORATE GOVERNANCE

Under Nasdaq Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the Nasdaq Rules. A foreign private issuer that elects to follow a home country practice instead of any such Nasdaq Rules must submit to Nasdaq, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. We submitted such a written statement to Nasdaq. See "Item 6. Directors, Senior Management and Employees—C. Board Practices— Corporate Governance Requirements under Nasdaq listing rules" for a summary of such differences.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to furnish financial statements and related information specified in Item 18.

ITEM 18. FINANCIAL STATEMENTS

The following financial statements are filed as part of this Annual Report on Form 20-F.

INCANNEX HEALTHCARE LIMITED

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

PKF Brisbane Audit

PKF

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Incannex Healthcare Ltd

Opinion on the Financial Statements

We have audited the accompanying consolidated statement of financial position of Incannex Healthcare Ltd (the "Consolidated Entity") as of 30 June 2022 and the related consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year ended 30 June 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Consolidated Entity as of 30 June 2022, and the results of its operations and its cash flows for the year then ended, in conformity with International Financial Reporting Standards ("IFRS") and Interpretations as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Consolidated Entity's management. Our responsibility is to express an opinion on the Consolidated Entity's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Consolidated Entity in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Consolidated Entity is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Consolidated Entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ PKF BRISBANE AUDIT
PCAOB ID No. 6622

BRISBANE, AUSTRALIA
October 28, 2022
We have served as the Consolidated Entity's auditor since July 14, 2022.

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

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the year ended 30 June 2022

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

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2022

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

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 30 June 2022

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

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CASH FLOWS

For the year ended 30 June 2022

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

The accompanying notes form part of these financial statements

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 30 June 2022

1. Significant accounting policies

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

Nature of Operations

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

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

New or amended Accounting Standards and Interpretations adopted

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

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

Historical cost convention

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

Critical accounting estimates

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

Comparatives

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

Statement of compliance

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

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

Parent entity information

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

Principles of consolidation

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

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

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

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

Operating segments

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

Foreign currency translation

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

Foreign currency transactions

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

Revenue recognition

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

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

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

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

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

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

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

Other income

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

Interest income

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

Income tax

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

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

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or

- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled, and it is probable that the temporary difference will not reverse in the foreseeable future.

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

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

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

Government grants

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

Current and non-current classification

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

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

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

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

Cash

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

Trade and other receivables

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

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

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

Other financial assets

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

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

Intangibles

Research and development

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

Trade and other payables

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

Provisions

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

Employee benefits

Short-term employee benefits

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

Other long-term employee benefits

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

Retirement benefit obligations

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

Share-based payments

Equity-settled compensation benefits are provided to employees.

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

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

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

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

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

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

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

Fair value measurement

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

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

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

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

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

Issued capital

Ordinary shares are classified as equity.

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

Dividends

Dividends are recognized when declared during the financial years.

Loss per share

Basic loss per share

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

Diluted loss per share

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

Goods and Services Tax (‘GST’) and other similar taxes

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

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

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

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

New Accounting Standards not yet adopted

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

2. Critical accounting judgements, estimates and assumptions

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

Coronavirus (COVID-19) pandemic

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

Share-based payment transactions

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

3. Revenue

	Consolidated	
	2022	**2021**
(a) Revenue (point in time)	$	**$**
Cannabinoid oils sales	-	1,897,596
	-	1,897,596
(b) Other income		
Income from other arrangements	-	35,569
Government grants	-	37,500
Interest	6,271	2,679
Refundable R&D tax offset	782,383	-
	788,654	**75,748**

4. Segment Information

Identification of reportable operating segments

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

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

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

1. Research and develop the use of psychedelic medicine and therapies for the treatment of mental health disorders. This activity commenced during the year. During the current year the operations consisted entirely of research and development activities, including clinical trials.

2. Research and develop the use of medicinal cannabinoid products. During the year the Group continued to research and develop its products and the range of its products, including further clinical trials.

3. Corporate operations, consisting of management of the organisation, capital management and management of resources. Revenues consist of finance income and other income.

The Group has only one geographical segment, namely Australia.

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

30 June 2022	**Psychedelic products**	**Cannabinoid Products**	**Corporate**	**Consolidated**
	$	**$**	**$**	**$**
Revenue from external customers	-	-	-	-
Interest revenue	-	96	6,175	6,271
Other revenue	-	782,383	-	782,383
Other expenses	(883,708)	(4,642,796)	(10,166,059)	(15,692,563)
Segment loss after income tax	**(883,708)**	**(3,860,317)**	**(10,159,884)**	**(14,903,909)**
Segment assets	**56,058**	**263,731**	**37,559,819**	**37,879,608**
Segment liabilities	**(354,310)**	**(577,819)**	**(1,078,404)**	**(2,010,533)**

30 June 2021	**Psychedelic products**	**Cannabinoid Products**	**Corporate**	**Consolidated**
	$	**$**	**$**	**$**
Revenue from external customers	-	1,897,596[1]	-	1,897,596
Interest revenue	-	6	2,673	2,679
Other revenue	-	-	73,069	73,069
Other expenses	(768,316)	(5,202,371)	(7,375,456)	(13,346,143)
Segment loss after income tax	**(768,316)**	**(3,304,769)**	**(7,299,714)**	**(11,372,799)**
Segment assets	**2,000**	**104,267**	**9,222,528**	**9,328,795**
Segment liabilities	**-**	**(86,522)**	**(668,527)**	**(755,049)**

[1] *Of the total revenue from pharmaceuticals in each year, 100% was through Cannvalate Pty Ltd's distribution network.*

5. Income tax

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

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

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

The benefit will only be realised if:

a) the Company derives future assessable income of a nature and of an amount sufficient to enable the benefit to be realised.
b) the Company complies with the conditions for deductibility imposed by the law; and
c) no changes in tax legislation adversely affect the Company in realising the benefit.

6. Loss per share

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

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

7. Dividends

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

8. Cash and cash equivalents

	Consolidated	
	2022	**2021**
	$	**$**
Cash at bank and on hand	37,500,931	9,123,617
	37,500,931	**9,123,617**
Cash at bank earns interest at floating rates based on daily bank deposit rates.		
Reconciliation of loss for the year to net cash flows from operating activities:		
Loss after income tax	(14,903,909)	(11,372,799)
Non-cash based expenses:		
Share-based payments	1,464,550	600,043
Depreciation and amortisation	-	-
Non-cash expense for investor relation services	-	3,781,344
Release of Gameday reserve of sales refund	-	(15,484)
Other non-cash expenses	(594,394)	91,354
Changes in net assets and liabilities:		
(Increase)/Decrease in receivables	(92,320)	214,903
(Increase)/Decrease in inventory	-	183,159
Decrease in other current assets	53,447	172
Increase/(Decrease) in trade payables and accrued expenses	1,111,080	(291,311)
Increase/(Decrease) in other liabilities	154,173	(101,161)
Cash flows used in operations	**(12,807,373)**	**(6,909,780)**

9. Trade and other receivables (Current)

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

Expected credit losses

The Group applies the AASB 9 (IFRS 9) simplified model of 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.

10. Other assets (current)

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

11. Trade and other payables (current)

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

12. Issued capital

	Consolidated	
	2022	**2021**
	$	**$**
	86,586,794	45,852,107

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

1 *The fair value of shares issued to employees and Directors expensed during the period has been recorded through the share base payment equity reserve refer to note 13 for further details.* Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of shares held. On a show of hands, every shareholder present at a meeting is entitled to one vote and upon a poll each share is entitled to one vote. Ordinary shares have no par value, and the Company does not have a limited amount of authorised capital.

13. Reserves

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

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

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

14. Share based payments

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

Fair value of shares issued

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

Options

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

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

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

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

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

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

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

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

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

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

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

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

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

Performance Rights

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

Security Description	**$0.$0.08 Options**	**Balance at start of year**	**Granted by the Company**	**Converted or Expired**	**Balance at end of year**
30 June 2022	30-Sep-21	-	-	-	-
30 June 2021	30-Sep-21	41,553,593	-	(41,553,593)	-

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

15. Remuneration of auditors

	Consolidated 2022 $	Consolidated 2021 $
Audit or review of the financial reports of the company		
Amounts received & receivable by the auditor:		
Audit services – PKF Brisbane Audit	85,000	-
Audit services – HLB Mann Judd	23,138	37,785
Audit services – Withum Smith & Brown (US auditor)	357,208	287,975
Other services – Withum Smith & Brown (US auditor)	-	-
	465,346	325,760

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

16. Financial Instruments

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

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

(a) Interest rate risk

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

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

(b) Sensitivity analysis

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

(c) Net fair values

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

(d) Commodity price risk

The Group's exposure to price risk is minimal.

(e) Credit risk

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

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

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

(f) Liquidity risk

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

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

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

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

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

(g) Capital Management

The Group's objectives when managing capital are to safeguard its ability to continue as a going concern, so that it may continue to provide returns for shareholders and benefits for other stakeholders. Due to the nature of the Group's 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.

17. Commitments and contingencies

Lease commitments

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

Other commitments

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

18. Key Management Personnel compensation and related party disclosure

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

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

Key management personnel compensation

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

Transactions with related entities

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

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

19. Details of the controlled 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 is incorporated in Australia and IHL owns 100% of the issued ordinary shares in IXPL (2021: 100%). PXPL is incorporated in Australia and IHL owns 100% of the issued ordinary shares in PXPL (2021: 100%).

20. Events Subsequent to Reporting Date

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

On 5 August 2022, the Company completed the acquisition on APIRx Pharmaceuticals via the issuance of 218,169,497 IHL ordinary shares to the stakeholders of APIRx in an all–scrip transaction. As substantially all of the fair value of the assets acquired in the transaction relates to intangible assets (e.g., patents, trademarks, active clinical and pre-clinical research and development projects), the transaction has been determined to be an asset acquisition and not a business combination. On 5 August 2022, the Company issued shares and options to Ryba LLC post year end pursuant to the mandate executed between the companies in November 2021. As the transaction between the Company and APIRx was deemed complete on 05 August 2022 the shares and options were issued.

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

21. Parent entity disclosures

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

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

Contingencies of the Parent Entity

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

Guarantees of the Parent Entity

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
of Incannex Healthcare Limited:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Incannex Healthcare Limited (the "Company") as of 30 June 2021 and 2020, the related consolidated statements of comprehensive income/(loss), changes in equity and cash flows, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of 30 June 2021 and 2020, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

New York, New York
November 3, 2021

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)
For the years ended 30 June 2021 and 2020

	Notes	Year Ended 30 June 2021	Year Ended 30 June 2020
Revenue	*3*	$ 1,897,596	$ 604,884
Other income	*3*	75,748	217,170
Total revenue and other income		1,973,344	822,054
Product costs	*1*	(911,969)	(450,345)
Administration expense	*1*	(99,094)	(457,673)
Advertising and promotion	*1*	(4,345,874)	(406,225)
Research and development costs	*1*	(4,749,514)	(2,110,639)
Compliance, legal and regulatory	*1*	(1,227,244)	(235,163)
Share based payments	*12*	(600,043)	(565,448)
Occupancy expenses	*1*	(115,836)	(2,085)
Salaries and employee benefit expense	*1*	(1,296,569)	(523,760)
Total expenses		(13,346,143)	(4,751,338)
Loss before tax from continuing operations		**(11,372,799)**	**(3,929,284)**
Income tax benefit	*5*	—	—
Loss after tax from continuing operations		**(11,372,799)**	**(3,929,284)**
Loss on discontinued operations, net of tax	*6*	—	(768,352)
Total comprehensive loss		**$ (11,372,799)**	**$ (4,697,636)**
Basic loss per share from continuing and discontinued operations (cents per share)	*7*	(1.16)	(0.69)
Basic loss per share from continuing operations (cents per share)	*7*	(1.16)	(0.57)

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
As of 30 June 2021 and 2020

	Notes	30 June 2021	30 June 2020
Assets			
Current assets			
Cash	***9***	$ 9,123,617	$ 3,603,390
Trade and other receivables	***10***	169,088	413,268
Other assets	***11***	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 attributable to owners of the parent			
Share capital	***16***	$ 45,852,107	$ 34,192,043
Reserves	***17***	6,612,641	1,490,588
Deficit		(43,891,002)	(32,518,203)
Net equity		**$ 8,573,746**	**$ 3,164,428**

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
For the years ended 30 June 2021 and 2020

	Notes	Share Capital		Reserves	Deficit	Total
		Shares	Amount			
Balance at 1 July 2019		**581,897,040**	**$ 26,951,744**	**$ 451,643**	**$ (27,820,567)**	**$ (417,180)**
Options exercised	***12***	34,427,321	1,077,093	—	—	1,077,093
Options issued to advisors	***12,17***	—	—	449,093	—	449,093
Share based payments	***12,17***	—	—	589,852	—	589,852
Shares issued	***16***	132,330,128	7,105,354	—	—	7,105,354
Shares issue costs		—	(942,148)	—	—	(942,148)
Comprehensive loss for the year		—	—	—	(4,697,636)	(4,697,636)
Balance at 30 June 2020		**748,654,489**	**$ 34,192,043**	**$ 1,490,588**	**$ (32,518,203)**	**$ 3,164,428**
Balance at 30 June 2020		**748,654,489**	**$ 34,192,043**	**$ 1,490,588**	**$ (32,518,203)**	**$ 3,164,428**
Options exercised	***12***	286,500,523	12,498,706	—	—	12,498,706
Options issued to advisors	***12,17***	—	—	3,781,344	—	3,781,344
Share based payments	***12,17***	—	—	600,043	—	600,043
Shares issued	***16***	33,256,212	—	—	—	—
Shares issue costs		—	(838,642)	740,666	—	(97,976)
Comprehensive loss for the year		—	—	—	(11,372,799)	(11,372,799)
Balance at 30 June 2021		**1,068,411,224**	**$ 45,852,107**	**$ 6,612,641**	**$ (43,891,002)**	**$ 8,573,746**

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended 30 June 2021 and 2020

	Notes	Year Ended 30 June 2021	Year Ended 30 June 2020
Cash flows from operating activities			
Receipts from customers		$ 1,974,010	$ 1,172,084
Receipts from other income		82,807	217,170
Payments to suppliers and employees		(8,969,276)	(5,299,667)
Interest received		2,679	3,079
Net cash used in operating activities	***9(i)***	(6,909,780)	(3,907,334)
Cash flows from investing activities			
Proceeds from sale of Gameday subsidiary		29,277	—
Proceeds from disposal of property, plant and equipment		—	13,000
Net cash provided by investing activities		29,277	13,000
Cash flows from financing activities			
Proceeds from shares issued (net of costs)		12,400,730	7,469,392
Debt repaid		—	(65,000)
Net cash provided by financing activities		12,400,730	7,404,392
Net increase in cash		$ 5,520,227	$ 3,510,058
Cash at beginning of the year		3,603,390	93,332
Cash at end of the year	***9***	**$ 9,123,617**	**$ 3,603,390**

The consolidated statement of cash flows above presents the total cash flows of the Company, inclusive of discontinued operations. The cash flows from discontinued operations for the years ended 30 June 2021 and 30 June 2020 are as follows:

- Cash flows used in operating activities: nil in 2021 and $636,857 in 2020;
- Cash flows from in investing activities: nil in 2021 and $13,000 in 2020;
- Cash flows used in financing activities: nil in 2021 and nil in 2020

Additional supplemental cash flow information (Note 9)

The accompanying notes are an integral part of these consolidated financial statements

1. Significant accounting policies

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

Nature of Operations

Incannex Healthcare Limited (the "Company") and its consolidated subsidiaries (collectively, the "Group") is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies. The Company's common shares trade on the Australian Securities Exchange ("ASX"). The Company's registered office is at Suite 105, 8 Century Circuit, Norwest 2153, NSW Australia.

For the fiscal year ended 30 June 2021, the Group incurred a total comprehensive loss after income tax of $11.4 million and had net cash outflows from operations of $6.9 million. The Group held total cash of $9.1 million as of 30 June 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 International Accounting Standards Board ('IASB') that are mandatory for the current reporting periods.

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

Historical cost convention

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

Critical accounting estimates

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

Comparatives

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

Statement of compliance

These consolidated financial statements were authorised for issue by the Board of Directors in October 2021.

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

Parent entity information

In accordance with IFRS 10 *Consolidated Financial Statements*, these consolidated financial statements present the results of the Group only. Supplementary information about the parent entity is disclosed in note 24.

Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of the Company as at 30 June 2021 and 2020 and the results of all subsidiaries for the years then ended. Incannex Healthcare Limited and its subsidiaries together are referred to in these consolidated financial statements as the 'Group'. Details of all controlled entities are set out in Note 22.

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

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

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

Operating segments

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

Foreign currency translation

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

Foreign currency transactions

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

Revenue recognition

The Company's revenues were generated from the sale of pharmaceutical Medicinal Cannabis products through the Special Access Scheme in Australia. Revenue comprises the fair value of the consideration received, or receivable and it is shown net of tax and discounts. The Company also earned revenue from the sale of dentist products through e-commerce website, however, the Company discontinued this segment on 30 June 2020.

The Company also earned revenue from the sale of the cannabinoid oil products through Cannvalate Pty Ltd under a distribution agreement ("Distribution Agreement") entered into with Cannvalate in March 2019 and terminated in June 2021. The Company recorded revenue from this contract on a gross basis in compliance with IFRS 15. In particular, IFRS 15-B35B states, "*When (or as) an entity that is a principal satisfies a performance obligation, the entity recognizes revenue in the gross amount of consideration to which it expects to be entitled in exchange for the specified good or service transferred."*

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

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

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

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

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

The Company disaggregates revenue from contracts with customers based on the categories that most closely depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. During the years ended 30 June 2021 and 2020, the Company recognized revenue from only one such category, being cannabinoid oils sales. As stated in Note 4 to these consolidated financial statements, the Company previously recognized revenue from oral and dental devices, although these operations have been discontinued. All sales are made within Australia and the Company has not disaggregated revenue based on geography.

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

Other income

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

Income tax

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

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

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

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

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

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

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.

Government grants

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

Current and non-current classification

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

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

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

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

Cash

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

Trade and other receivables

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

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

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

Inventory

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

Impairment of financial assets

The Group recognizes 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 recognized 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.

Impairment of non-financial assets

Non-financial assets are subject to impairment test whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. Where the carrying value of the non-financial asset exceeds its recoverable amount (i.e. the higher of value in use and fair value less costs to dispose), the asset is written down and impairment charge is recognized accordingly.

Where it is not possible to estimate the recoverable amount of an individual asset, the impairment test is carried out on the asset's cash-generating unit (i.e. the smallest group of assets to which the asset belongs that generates cash inflow that is largely independent of cash inflows from other assets).

An impairment loss allocated to an asset, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized.

Reversal of an impairment loss, as above, is limited to the lower of the carrying amount of the asset that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and the asset's recoverable amount. After an impairment of non-financial asset is recognized, the Company examines at each reporting date whether there are indications that the impairment which was recognized in the past no longer exists or should be reduced. The reversal of impairment loss of an asset is recognized in profit or loss.

Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items. In connection with the discontinued operations (Note 6), the Company's property, plant and equipment future value was deemed negligible and recorded a impairment expense for the carrying value during the financial year ended 30 June 2020. As such, value of property, plant and equipment was nil as of 30 June 2021 and 2020.

Depreciation is calculated on a straight-line basis to write off the net cost of each item of property, plant, and equipment (excluding land) over their expected useful lives as follows:

Buildings	40 years
Leasehold improvements	3 – 10 years
Plant and equipment	3 – 7 years

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

Leasehold improvements are depreciated over the unexpired period of the lease or the estimated useful life of the assets, whichever is shorter.

An item of property, plant and equipment is derecognized upon disposal or when there is no future economic benefit to the Group. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss.

Intangible assets

In connection with the discontinued operations (Note 6), the Company's intangible assets future value was deemed negligible and recorded a impairment expense for the carrying value during the financial year ended 30 June 2020. As such, value of intangible assets was nil as of 30 June 2021 and 2020.

Research and development

Research costs are expensed in the period in which they are incurred. Development costs are capitalised when it is probable that the project will be a success considering its commercial and technical feasibility; the Group is able to use or sell the asset; the Group has sufficient resources and intent to complete the development; and its costs can be measured reliably. Capitalised development costs are amortised on a straight-line basis over the period of their expected benefit, being their finite life of 10 years. The Company has no capitalised any development costs for the years ended June 30, 2021 and 2020.

Trade and other payables

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

Lease liabilities

A lease liability is recognized at the commencement date of a lease. The lease liability is initially recognized 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.

No lease liabilities are recognized for leases where the lease term is 12 months or less at the commencement date and for leases where the underlying value is deemed to be of low value. The costs of any such leases are recorded within expenses as incurred.

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

Employee benefits

Short-term employee benefits

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

Other long-term employee benefits

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

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

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

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

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

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

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

Fair value measurement

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

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

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

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

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

Issued capital

Ordinary shares are classified as equity.

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

Dividends

Dividends are recognized when declared during the financial years.

Loss per share

Basic loss per share

Basic loss per share is calculated by dividing the profit attributable to the owners of Incannex Healthcare Limited, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial years, adjusted for bonus elements in ordinary shares issued during the financial years. These values are set out in Note 7.

Diluted loss per share

Diluted loss per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares. These values are set out in Note 7.

Goods and Services Tax (‘GST’) and other similar taxes

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

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

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

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

New Accounting Standards not yet adopted

International Financial Reporting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the Group for the annual reporting periods ended 30 June 2021 and 2020. The Group's assessment of the impact of these new or amended Accounting Standards and Interpretations, most relevant to the Group, are set out below.

Amendments to IAS 1: Classification of Liabilities as Current or Non-current

The amendment clarifies the requirements relating to determining if a liability should be presented as current or non-current in the statement of financial position. Under the new requirement, the assessment of whether a liability is presented as current or non-current is based on the contractual arrangements in place as at the reporting date and does not impact the amount or timing of recognition. The amendment applies retrospectively for annual reporting periods beginning on or after January 1, 2022. The Company is currently evaluating the potential impact of these amendments on the Company's consolidated financial statements.

Amendments to IAS 37: Onerous Contracts and the cost of Fulfilling a Contract

The amendment specifies that 'cost of fulfilling' a contract comprises the 'costs that relate directly to the contract'. Costs that relate directly to a contract can either be incremental costs of fulfilling that contract or an allocation of other costs that relate directly to fulfilling contracts. The amendment is effective for annual periods beginning on or after January 1, 2022, with early application permitted. The Company is currently evaluating the potential impact of these amendments on the Company's consolidated financial statements.

IFRS 17 Insurance Contracts

IFRS 17 Insurance Contracts has been issued, but is not yet mandatorily required to be adopted by the Company. The Company will be required to adopt IFRS 17 during the financial year ending 30 June 2024. The Directors do not expect the adoption of IFRS 17 to have a material impact on the financial position or performance of the Company once adopted.

2. Critical accounting judgements, estimates and assumptions

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

Coronavirus (COVID-19) pandemic

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

Share-based payment transactions

The Group measures the cost of equity-settled transactions with employees and third parties by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using either the trinomial or Black-Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity. Refer to notes 12 and 17 for further information.

3. Revenue & expenses

	Consolidated	
	Year Ended 30 June 2021	**Year Ended 30 June 2020**
(a) Revenue (point in time)		
Cannabinoid oils sales	$ 1,897,596	$ 604,884
	$ 1,897,596	$ 604,884
(b) Other income		
Income from other arrangements[1]	$ 35,569	$ 123,125
Government grants[2]	37,500	89,500
Interest	2,679	4,545
	$ 75,748	$ 217,170
(c) Expenses		
Executive directors' remuneration	$ 600,043	$ 539,923

(1) Income from other arrangements

Income from other arrangements for the fiscal year ended 30 June 2021 relates to sales of Gameday Mouthguards, for orders fulfilled from sales prior to the Company selling the Gameday segment (Note 6). In addition, the Company also recognized other income for settlement of sales refunds in December 2020. Management did not deem the amounts to be material and therefore are not included in the discontinued operations during the fiscal year ended 30 June 2021.

Income from other arrangements for the fiscal year ended 30 June 2020 was a result of a transaction entered into with AXIM Biotechnologies, in consideration of the terms of the full understanding 6,800,000 IHL shares were issued in full consideration of the intended transaction.

AXIM was not able to fulfil their part of the transaction, and the contract was terminated. In lieu of returning the shares, the Company received cash. As this revenue is not derived from any normal trading transactions, it has been accounted for as a separate line item in the accounts. The return of these shares and the subsequent income is a one off income item for IHL and has not resulted in a change in equity per the consolidated statement of financial position.

(2) Notes for Government grants

Other income from government grants relates to assistance provided by the Australian Government in relation to the COVID-19 pandemic. The Company has reasonable assurance that it has complied with the conditions attaching to these grants. There were no unfulfilled conditions or other contingencies attaching to these grants as at 30 June 2021 and 2020.

4. Segment Information

Identification of reportable operating segments

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

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

Based on the quantitative thresholds included in IFRS 8, for the fiscal year ended 30 June 2020, the Group was organized into two operating segments based on differences in products and services provided (1) medicinal cannabis and (2) oral and dental devices. On 30 June 2020, the Company disposed of the oral and dental devices segment (refer note 6) to focus entirely on medicinal cannabis product sales and development. The Group was organized primarily into one operating segment for the fiscal year ended 30 June 2021, consisting of medicinal cannabis, with oral and dental devices recording other expenses related for the fiscal year ended 30 June 2021 in its respective operating segment.

The Group has only one geographical segment, namely Australia.

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

Segment results

	Oral and Dental Devices (discontinued)	Psychedelic	Medicinal Cannabis	Unallocated	Consolidated
For the year ended 30 June 2021					
Revenue from external customers	$ —	$ —	$ 1,897,596(1)	$ —	$ 1,897,596
Interest income	—	—	6	2,673	2,679
Other income	—	—	—	73,069	73,069
Depreciation	—	—	—	—	—
Amortisation	—	—	—	—	—
Other expenses	—	(768,316)	(5,202,371)	(7,375,456)	(13,346,143)
Segment loss after income tax	**$ —**	**$ (768,316)**	**$ (3,304,769)**	**$ (7,299,714)**	**$ (11,372,799)**
Segment assets	**$ —**	**$ 2,000**	**$ 104,267**	**$ 9,222,528**	**$ 9,328,795**
Segment liabilities	**$ —**		**$ (86,522)**	**$ (668,527)**	**$ (755,049)**
For the year ended 30 June 2020					
Revenue from external customers	$ 718,656	$ —	$ 604,884(1)	$ —	$ 1,323,540
Interest income	8	—	2	4,543	4,553
Other income	140,816	—	212,625	—	353,441
Depreciation	(14,854)	—	—	—	(14,854)
Amortisation	(21,688)	—	—	—	(21,688)
Other expenses	(1,591,290)	—	(2,899,761)	(1,851,577)	(6,342,628)
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)**

(1) Of the total revenue from medicinal cannabis in the fiscal year ended 30 June 2021 and 2020, 100% was through Cannvalate Pty Ltd's distribution network.

5. Income tax

The prima facie income tax (expense)/benefit on pre-tax accounting (loss)/profit from operations reconciles to the income tax benefit in the consolidated financial statements as follows:

	Consolidated	
	Year Ended 30 June 2021	Year Ended 30 June 2020
Accounting loss before tax	$ (11,372,799)	$ (4,697,636)
Income tax benefit at the applicable tax rate of 26% (2020: 27.5%)	$ 2,956,928	$ 1,291,850
Non-deductible expenses at the applicable tax rate of 26% (2020:27.5%)	(1,192,112)	(155,498)
Deferred tax assets not recognized	(1,764,816)	(1,136,352)
Income tax benefit	$ —	$ —
Deductible temporary differences for which no deferred tax asset has been recognized		
Unused tax losses at 26% (2020: 27.5%)	$ 5,425,637	$ 3,872,022
Net unrecognized tax benefit	$ 5,425,637	$ 3,872,022

The net unrecognized tax benefit has not been recognized as an asset in the consolidated financial statements because recovery of the asset is not considered probable in the context of IAS 12 Income Taxes.

The benefit will only be realised if:

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

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

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

6. 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 sale 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 sale of Gameday will allow the Group to pursue and focus entirely on its medicinal cannabis activities.

Financial performance information

	Consolidated	
	Year Ended 30 June 2021	**Year Ended 30 June 2020**
Revenue from external customers	$ —	$ 718,656
Interest income	—	8
Other income	—	140,816
Product costs	—	(589,570)
Administration expense	—	(38,985)
Advertising and promotion	—	(218,865)
Depreciation	—	(14,854)
Amortisation	—	(21,688)
Loss on disposal of property, plant and equipment	—	(13,654)
Impairment cost	—	(82,989)
Occupancy expenses	—	(81,493)
Salaries and employee benefit expense	—	(565,734)
Loss before income tax	**—**	**(768,352)**
Income tax benefit	—	—
Loss after income tax from discontinued operations	**$ —**	**$ (768,352)**
Carrying amounts of assets and liabilities disposed		
Cash	$ —	$ 17,970
Inventories	—	6,000
Other current assets	—	6,100
Trade and other payables	—	(793)
Total proceeds from sale	**$ —**	**$ 29,277**

Impairment cost

During the process of the sale of Gameday, various assets of Gameday that were unwanted by the acquirer were assessed to determine their future value or ability to be sold. Specifically, these assets included specialist or customised plant and equipment, capitalised intangible assets, and the recovery of receivables.

For each of these assets it was determined that the future value was negligible and for each the contribution to the total impairment cost recorded during the fiscal year ended 30 June 2020 is set out below:

(i) Plant and equipment

	Original Cost	**Accumulated Depreciation**	**Book value prior to impairment**	
	$ 76,136	$ (32,221)	$ 43,915	(A)

(ii) Intangible assets

	Original cost	**Accumulated Amortisation**	**Book value prior to impairment**	
	$ 116,731	$ (89,042)	$ 27,689	(B)

(iii) Receivables

	Original book value	Recoverable amount	Book value prior to impairment	
	$ 11,635	$ (250)	$ 11,385	(C)
Impairment cost (A+B+C)			**$ 82,989**	

7. Loss per share

	Year Ended 30 June 2021	Year Ended 30 June 2020
Basic loss per share– continuing and discontinued operations – cents per share	$ (1.16)	$ (0.69)
Basic loss per share– continuing operations – cents per share	$ (1.16)	$ (0.57)
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 ($)	$ (11,372,799)	$ (4,697,636)
– Loss from continuing operations ($)	$ (11,372,799)	$ (3,929,284)
– Weighted average number of ordinary shares (number)	976,931,338	684,035,399

8. Dividends

The Company has not declared a dividend for the years ended 30 June 2020 or 2021.

9. Cash

	Consolidated	
	30 June 2021	30 June 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.

i. Reconciliation of loss for the years to net cash flows from operating activities:

	Year Ended 30 June 2021	Year Ended 30 June 2020
Loss after income tax	$ (11,372,799)	$ (4,697,636)
Non-cash based expenses(income):		
Share based payments	600,043	565,448
Depreciation and amortisation	—	36,542
Non-cash expense for investor relation services	3,781,344	—
Release of Gameday reserve of sales refund	(15,484)	—
Non-cash expense for annual leave	91,354	97,221
Changes in net assets and liabilities:		
Decrease/(increase) in receivables	214,903	(315,484)
Decrease/(increase) in inventory	183,159	(30,355)
Decrease in other current assets	172	2,928
(Increase)/decrease in trade and other payables	(291,311)	464,223
Decrease in other liabilities	(101,161)	(30,221)
Cash flows used in operations	$ (6,909,780)	$ (3,907,334)

ii. Non-cash financing activities

The Company has recorded non-cash transactions in the form of share based payments as disclosed in Note 12 to these consolidated financial statements. The total value of share-based payments recorded during the year ended 2021 is $600,043 (2020: $565,448).

The Company has recorded $740,666 of non-cash transactions during the year ended 30 June 2021 in the form of 30,164,690 unlisted options issued on 2 October 2020 as consideration for broker support related to the exercise of 262 million IHLOB options series. The amount is recorded as issuance costs. Subsequent to the year ended 30 June 2021, these options were exercised (Note 23).

The Company recorded other current liabilities of $244,403 as at 30 June 2019, relating to option issues awaiting shareholder approval. During the year ended 30 June 2020, this liability was settled via the issue of options upon which time the liability balance of $244,403 was transferred to equity.

10. Trade and other receivables (Current)

	Consolidated	
	30 June 2021	30 June 2020
Current		
Trade receivables	$ —	$ 225,125
Other receivables	53,447	51,026
GST recoverable	115,641	137,117
	$ 169,088	$ 413,268

Opening receivables, contract assets and contract liabilities with customers:

There was no revenue recognized in the years ended 30 June 2021 and 2020 from performance obligations satisfied (or partially satisfied) in previous years.

Expected credit losses

The Group applies the IFRS 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.

11. Other assets (current)

	Consolidated	
	30 June 2021	30 June 2020
Prepayments	$ 29,784	$ 11,083
Office rental bond	—	25,179
Prepayment clinical trial insurance	$ 6,306	$ —
	$ 36,090	$ 36,262

12. 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 as compensation is determined using the closing price of shares on the grant date and expensed over the vesting period.

Options

The following table summarizes the Company's stock option activity for the years ended 30 June 2021 and 2020:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)
Outstanding as of 30 June 2019	262,960,728	$ 0.040	1.255
Granted	412,169,705	$ 0.139	
Exercised	(34,427,321)	$ 0.031	
Outstanding as of 30 June 2020	640,703,112	$ 0.104	0.748
Granted	72,414,690	$ 0.152	
Exercised	(286,500,523)	$ 0.044	
Expired or forfeited	(88,000,000)	$ 0.104	
Outstanding as of 30 June 2021	338,617,279	$ 0.166	0.568
Exercisable as of 30 June 2021	337,117,279	$ 0.167	

The exercise price of options outstanding as of 30 June 2021 and 2020 ranged between $0.05 and $0.25. The weighted average grant date fair value of options granted was $0.10 and $0.22 for the year ended 30 June 2021.

As of 30 June 2021, there was $116,680 of total unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of approximately one year.

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

	Number	Grant Date	Expiry Date	Exercise Price	Total fair value
Options granted to third parties					
Unlisted options	10,000,000	20-Nov-2020	20-Nov-2023	$ 0.15	$ 647,348
Unlisted options	10,000,000	20-Nov-2020	20-Nov-2023	$ 0.25	$ 527,766
Unlisted options	10,000,000	25-Feb-2021	20-Nov-2023	$ 0.20	$ 1,352,588
Unlisted options	10,000,000	25-Feb-2021	20-Nov-2023	$ 0.25	$ 1,253,140
Unlisted options	30,164,690	02-Oct-2020	30-Sep-2021	$ 0.08	$ 740,665
Total options granted to third parties	70,164,690				$ 4,521,507
Options granted to employees					
Unlisted options	750,000	01-Jul-2020	30-Jun-2025	$ 0.05	$ 25,432
Unlisted options	750,000	01-Jul-2020	30-Jun-2026	$ 0.05	$ 27,450
Unlisted options	750,000	01-Jul-2020	30-Jun-2027	$ 0.05	$ 29,040
Total options granted to employees	2,250,000				$ 81,922
Total options	**72,414,690**				$ 4,603,429

The following share options were issued to employees and consultants as share based payments during the year ended 30 June 2020:

	Number	Grant Date	Expiry Date	Exercise Price	Total fair value
Options granted to third parties					
Unlisted options	10,000,000	8-Aug-2019	01-Jan-2020	$ 0.02	$ 85,251
Unlisted options	10,000,000	8-Aug-2019	01-May-2020	$ 0.03	$ 51,531
Unlisted options	12,000,000	8-Aug-2019	01-May-2020	$ 0.04	$ 34,966
Unlisted options	14,000,000	19-Aug-2019	01-Dec-2020	$ 0.06	$ 30,297
Unlisted options	16,000,000	19-Aug-2019	01-Dec-2020	$ 0.08	$ 18,248
Unlisted options	18,000,000	19-Aug-2019	01-Dec-2020	$ 0.10	$ 11,606
Unlisted options	20,000,000	19-Aug-2019	01-Dec-2020	$ 0.12	$ 7,700
Unlisted options	20,000,000	19-Aug-2019	01-Dec-2020	$ 0.14	$ 4,804
Unlisted options	89,919,705	Various[(1)]	30-Sep-2021	$ 0.08	$ 449,067
Total options granted to third parties	209,919,705				$ 693,470
Options granted to employees					
Unlisted options	750,000	26-Jun-2020	30-Jun-2025	$ 0.05	$ 24,817
Unlisted options	750,000	26-Jun-2020	30-Jun-2026	$ 0.05	$ 26,424
Unlisted options	750,000	26-Jun-2020	30-Jun-2027	$ 0.05	$ 27,754
Unlisted options	200,000,000	26-Jun-2020	30-Sep-2021	$ 0.20	$ 306,299
Total options granted to employees	202,250,000				$ 385,294
Total options	**412,169,705**				$ 1,078,764

(1) 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.

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

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

	$0.08 Options 30-Sep-2021	$0.15 Options 20-Nov-2023	$0.25 Options 20-Nov-2023	$0.20 Options 20-Nov-2023	$0.25 Options 20-Nov-2023
Number	30,164,690	10,000,000	10,000,000	10,000,000	10,000,000
Dividend yield (%)	—%	—%	—%	—%	—%
Expected volatility (%)	86%	100%	100%	101%	101%
Risk-free interest rate (%)	0.17%	0.11%	0.11%	0.12%	0.12%
Expected life of option (years)	1	3	3	2.7	2.7
Exercise price (cents)	8	15	25	20	25
Grant date share price (cents)	7.7	11.5	11.5	22	22
Vesting date	2-Oct-2020	20-Nov-2020	20-Nov-2020	25-Feb-2021	25-Feb-2021

The fair value of the equity-settled share options granted is estimated as at the grant date using a Black-Scholes option model (for all $0.05 options) and a trinomial option model (for the $0.20 options) taking into account the terms and conditions upon which the options were granted, as follows for the year ended 30 June 2020:

	$0.05 Options 30-Jun-2025	$0.05 Options 30-Jun-2026	$0.05 Options 30-Jun-2027	$0.20 Options 30-Sep-2021
Number	750,000	750,000	750,000	2,000,000
Dividend yield (%)	—%	—%	—%	—%
Expected volatility (%)	92%	92%	92%	93%
Risk-free interest rate (%)	0.39%	0.48%	0.58%	0.25%
Expected life of option (years)	5	6	7	1.25
Exercise price (cents)	5.0	5.0	5	20
Grant date share price (cents)	4.8	4.8	4.8	4.8
Vesting date	30-Jun-2020	30-Jun-2021	30-Jun-2022	Refer (a) below

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

(a) The options vest upon the shares having a closing price of 20 cents per share or more for any 5 trading days at any time from the date of grant of the options until the expiry date of the options (30 September 2021).

Performance Rights

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

30 June 2021

Security Description	Balance at start of year	Granted by the Company	Converted or Expired	Balance at end of year
Performance Rights[(1)]	41,553,593	—	(41,553,593)	—

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

30 June 2020

Security Description	Balance at start of year	Granted by the Company	Converted or Expired	Balance at end of year
Performance Rights[1]	24,166,668	32,303,593	(14,916,668)	41,553,593
Performance Shares[2]	20,000,002	—	(20,000,002)	—

(1) 32,303,593 performance rights were issued as remuneration for the Company's Chief Medical Officer (Dr Sud Agarwal), after approval by shareholders on 26 June 2020. 11,916,668 performance rights converted into ordinary shares upon achievement of designated performance hurdles and 3,000,000 performance rights expired.

(2) Performance shares were issued to holders upon the Company's relisting in November 2016. Performance hurdles attaching to these shares related to sales targets within the now discontinued devices business. These targets were not achieved and the performance shares lapsed on 30 June 2020.

The value-based performance rights have milestones which are market-based. In arriving at the fair value of these rights the probability of achieving these milestones (related to various levels of market capitalisation) has been estimated using a trinomial option model, with major inputs for 30 June 2020 being grant date share price. of $0.048; risk-free rate of 0.25%; and volatility of 95%, for a total value of $469,324. Of the performance rights $280,253 and $189,071 was expensed in the years ended 30 June 2021 and 2020, respectively.

The milestone performance rights are valued at the share price at grant date ($0.048) taking into account management's estimate s of the likelihood of meeting the milestones.

13. Inventory

	Consolidated	
	30 June 2021	30 June 2020
Current		
Medicinal cannabis products in-transit	$ —	$ 183,159
Total inventory	$ —	$ 183,159

14. Trade and other payables (current)

	Consolidated	
	30 June 2021	30 June 2020
Trade payables	$ 233,117	$ 590,099
Accrued expenses	381,717	316,046
Employee leave entitlements	140,215	48,861
	$ 755,049	$ 955,006

Employee leave entitlements Reconciliation:

	Year Ended 30 June 2021
Carrying value as at 1 July 2020	$ 48,861
Leave accrued by employees during the year	91,354
Balance at 30 June 2021	$ 140,215

	Year Ended 30 June 2020
Carrying value as at 1 July 2019	$ 36,899
Leave accrued by employees during the year	11,962
Balance at 30 June 2020	$ 48,861

15. Other current liabilities

	Consolidated	
	30 June 2021	30 June 2020
Provision for sales refunds[(1)]	$ —	$ 116,645
	$ —	$ 116,645

(1) Under the terms of the sale agreement for the disposal of the devices business (refer to note 6) the Company is liable to pay to the buyer for any refunds related to devices sold that refunded after 30 June 2020. The Company recorded and estimated amount as of 30 June 2020. In the fiscal year ended 30 June 2021, the Company reached a settlement that they would no longer be liable for refunds given the historical lag associated with returns. After which, the Company recorded the remaining balance as other income.

Provision for sales refunds Reconciliation:

	Year Ended 30 June 2021
Carrying value as at 1 July 2020	$ 116,645
Repayments made	(101,161)
Settlement of liability recorded in other income	(15,484)
Balance at 30 June 2021	$ —

16. Issued capital

(a) Issued Capital

	Consolidated	
	30 June 2021	30 June 2020
Ordinary shares	$ 45,852,107	$ 34,192,043

(b) Ordinary shares — movements during years

	Year ended 30 June 2021 (No. of shares)	Year ended 30 June 2020 (No. of shares)
At beginning of year	748,654,489	581,897,040
Issues of new shares – placements	—	114,663,460
Issues 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	34,427,321
At end of year	**1,068,411,224**	**748,654,489**

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.

17. Reserves

Equity based premium reserve

	Consolidated	
	Year Ended 30 June 2021	Year Ended 30 June 2020
Balance at start of year	$ 1,490,588	$ 451,643
Options issued to advisors[(1)]	4,522,010	449,093
Options issued to Cannvalate Pty Ltd[(2)]	—	244,403
Equity instruments issued to management and directors	600,043	345,449
Balance at end of year	$ 6,612,641	$ 1,490,588

(1) During the year ended 30 June 2021, 40,000,000 options exercisable at $0.15, $0.20, and $.25 were issued to consultants for investor relation services. In addition, 30,164,690 options exercisable at $0.08 were issued as consideration for broker support of the exercise of the 262m listed IHLOB options series (see Note 12). During the year ended 30 June 2020, 33,000,000 options exercisable at $0.08 and expiring on 30 September 2021, were issued to brokers who supported the July 2019 capital raisings. These options have been valued using a Black-Scholes option model with inputs being grant date share price of $0.04 risk-free rate of 0.24% and volatility of 92%.

(2) On 9 August 2019, at a general meeting of shareholders, the issue of 120,000,000 options to Cannvalate Pty Ltd as remuneration for Cannvalate's management of the Company's clinical program was approved. This amount was initially recorded as a payable as at 30 June 2019 and transferred to the reserve in the year ended 30 June 2020. The options were valued using Black-Scholes option model with inputs being grant date share price of $0.02; risk-free rate of 1.07% and volatility of 59%.

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

18. Remuneration of auditors

	Consolidated	
	Year Ended 30 June 2021	Year Ended 30 June 2020
Audit or review of the financial reports of the Company		
Amounts received & receivable by the auditor:		
Audit services – HLB Mann Judd	$ 37,785	$ 37,000
Audit services – Withum Smith & Brown (US auditor)	287,975	—
Total	$ 325,760	$ 37,000

Withum Smith & Brown, PC were appointed auditors in the United States of America ("USA") in preparation for listing the Company's securities in the USA. During the year ended 30 June 2021 , the work carried out involved the audit of PCAOB standards and IFRS standards as issued by IASB compliant financial statements.

The above remuneration of auditors has been recorded within compliance, legal, and regulatory expense in the consolidated statement of comprehensive loss.

19. Financial Instruments

The Group's principal financial instruments comprise cash and short-term deposits and convertible notes.

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 years, 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 recognized, in respect of each class of financial asset, financial liability and equity instrument are disclosed in note 1 to the consolidated 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.

(b) Sensitivity analysis

During the years ended 30 June 2021 and 2020, 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 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, available-for-sale financial assets and certain derivative instruments, the Group's exposure to credit risk arises from default of the counter party, with a maximum exposure equal to the carrying amount of these instruments.

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

(f) Liquidity risk

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

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

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

The Group's contractual liabilities at 30 June 2020 were as follows:

Description	Less than 1 month	1 to 3 months	3 months to 1 year	1 to 5 years	Total
Consolidated					
Payables & accruals	$ 906,145	$ —	$ —	$ —	$ 906,145
	$ 906,145	$ —	$ —	$ —	$ 906,145

(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 a drug development business, 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 and corporate overheads. This is achieved by maintaining appropriate liquidity to meet anticipated operating requirements, with a view to initiating fund raisings as required.

20. Commitments and contingencies

Lease commitments

The Group holds two commercial leases for its office premises in Melbourne and Sydney, Australia. Both of these leases had terms of 12 months from the commencement date of the lease. Future minimum payments under these contracts as at 30 June are as follows:

	Consolidated	
	30 June 2021	30 June 2020
Within one year	$ 56,496	$ 9,697
One to three years	37,916	—
Total minimum contract payments	$ 94,412	$ 9,697

In transitioning to IFRS 16, these leases were not capitalised.

21. Key Management Personnel compensation and related party disclosure

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

Troy Valentine

Peter Widdows

Joel Latham

Sud Agarwal

Key management personnel compensation

	Consolidated	
	Year Ended 30 June 2021	**Year Ended 30 June 2020**
Short-term employee benefits	$ 761,231	$ 638,201
Share based payments[(1)]	672,699	565,448
Post-employment benefits	38,877	29,985
Total KMP compensation	$ 1,472,807	$ 1,233,634

(1) The Company notes the amounts do not agree to the Consolidated Statements of Changes in Equity for the year ended 30 June 2021. The Company notes there was a reversal of expense in the amount of $72,656 related to 88,000,000 share options issued to Cannvalate Pty Ltd due to the options being forfeited. These options had been issued during financial year ended June 30, 2020.

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 ended 30 June 2021, $97,976 (2020: $145,200) 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 act as lead manager in the various capital raisings conducted during the year.

Cannvalate Pty Ltd (Cannvalate) is an entity of which Dr Sud Agarwal is a significant shareholder, the CEO and a director. In March 2019, the Company entered into a distribution agreement with Cannvalate. As stated in Note 4, of the total revenue from medicinal cannabis in the fiscal year ended 30 June 2020, 100% was through Cannvalate's distribution network. This agreement is no longer effective and was terminated in June 2021.

As stated in Note 19, On 9 August 2019, at a general meeting of shareholders, the issue of 120,000,000 options to Cannvalate as remuneration for Cannvalate's management of the Company's clinical program was approved. This amount was initially recorded as a payable as at 30 June 2019 and transferred to reserves in the year ended 30 June 2020.

There $229,889 of amounts payable to related parties as of 30 June 2021, which are included in trade and other payables on the consolidated statements of financial position.

22. Details of the controlled entity

The consolidated financial statements include the financial statements of Incannex Healthcare Limited ('IHL') and its wholly owned subsidiary Incannex Pty Ltd ('IXPL'). IXPL is incorporated in Australia and IHL owns 100% of the issued ordinary shares in IXPL (2020: 100%).

On 30 June 2020, the Group disposed entirely of its 100% subsidiary — Gameday International Pty Ltd, ('Gameday').

23. Subsequent events

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

On 16 August 2021, the Company issued an additional 2,739,662 ordinary shares due to the exercise of "IHLAH" share options at an exercise price of $0.08 per share for proceeds of $219,173.

On 25 August 2021, the Company issued 9,201,186 ordinary shares due to the exercise of "IHLAH" share options at an exercise price of $0.08 per share on for proceeds of $736,095.

On 7 September 2021, the Company issued ordinary shares for total proceeds of $4,587,667 due to the exercise of "IHLAH" share options:

— 7,345,833 of ordinary shares at an exercise price of $0.08 per share

— 20,000,000 of ordinary shares at an exercise price of $0.20 per share

On 21 September 2021, the Company issued 61,311,557 ordinary shares due to the exercise of "IHLAH" share options at an exercise price of $0.08 per share on for proceeds of $4,904,925.

On 4 October 2021, The Company issued ordinary shares for total proceeds of $5,114,109 due to the exercise of "IHLAH" share options:

— 11,427,616 of ordinary shares at a exercise price of $0.08 per share

— 20,999,500 of ordinary shares at an exercise price of $0.20 per share

On 7 October 2021, the Company issued 6,852,322 ordinary shares due to the exercise of "IHLAH" share options at an exercise price of $0.08 per share on for proceeds of $548,186.

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

24. Parent entity disclosures

Incannex Healthcare Limited (ACN 096 635 246) is the parent entity which is registered and domiciled in Australia.

The registered address of the parent entity is Suite 105, 8 Century Circuit, Norwest 2153, NSW Australia.

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.

	30 June 2021	30 June 2020
Financial Position as at 30 June 2021 and 2020		
Current assets	$ 9,222,528	$ 3,573,665
Non-Current assets[(i)]	—	—
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	$ 3,069,437
Share capital	$ 45,852,107	$ 34,192,043
Reserves	6,612,641	1,490,588
Deficit	(43,910,747)	(32,613,194)
Shareholders' equity	$ 8,554,001	$ 3,069,437

(i) In the year ended 30 June 2020, the loan to the subsidiary company has been fully impaired.

Contingencies of the Parent Entity

There were no contingent liabilities involving the parent entity as at 30 June 2021 and 2020.

Guarantees of the Parent Entity

There were no guarantees involving the parent entity as at 30 June 2021 and 2020.

ITEM 19. EXHIBITS

The following exhibits are filed as part of this Annual Report on Form 20-F:

EXHIBIT INDEX

Exhibit	Description
1.1	Constitution of Incannex Healthcare Limited (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022).
2.1	Form of Deposit Agreement between Incannex Healthcare Limited and Deutsche Bank Trust Company Americas as Depositary (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)
2.3#	Description of Securities
4.1	Employment Agreement between Incannex Healthcare Limited and Joel Latham, dated July 1, 2020 (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.2	Service Agreement between Incannex Healthcare Limited and Madhukar Bhalla, dated June 28, 2021 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.3✓	Clinical Trial Research Agreement between Alfred Health and Incannex Healthcare Limited, dated June 22, 2021 (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.4✓	Clinical Trial Research Agreement between Alfred Health and Incannex Healthcare Limited, dated September 24, 2020 (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.5✓	Clinical Trial Research Agreement between University of Western Australia and Incannex Healthcare Limited, dated April 6, 2021(incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.6✓	Master Consultancy Agreement between Clinical Network Services (CNS) Pty Ltd (now Novotech Australia) Pty Limited) and Incannex Healthcare Limited, dated June 29, 2020 (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.7✓	Research Services Agreement between Monash University and Incannex Healthcare Limited, dated November 27, 2020 (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.8✓	Research Services Agreement between Monash University and Incannex Healthcare Limited, dated March 10, 2021 (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.9✓	Master Service Agreement between Avance Clinical Pty Limited and Incannex Healthcare Limited, dated July 12, 2021 (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.10✓	Appendix No. 2 to the Master Consultancy Agreement between Novotech Australia Pty Limited and Incannex Healthcare Limited, dated February 2, 2021 (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form 20-F filed with the SEC on January 25, 2022)
4.11#	Share Sale and Purchase Agreement between Incannex Healthcare Limited and the sellers of APIRx Pharmaceutical USA, LLC, dated May 12, 2022.
8.1#	List of subsidiaries of Registrant
12.1#	Certification of the Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
12.2#	Certification of the Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
13.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
13.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
15.1#	Letter to Securities and Exchange Commission from Withum Smith+Brown, PC dated October 28, 2022
101.INS#	Inline XBRL Instance Document.
101.SCH#	Inline XBRL Taxonomy Extension Schema Document.
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF#	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB#	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE#	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104#	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Filed herewith.

✓ Certain confidential information in this exhibit was omitted by means of marking such information with brackets ("[***]") because the identified confidential information is not material and is the type that the registrant treats as private or confidential.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Incannex Healthcare Limited

/s/ Joel Latham

By: Joel Latham
Title: Chief Executive Officer and Managing Director

Date: October 28, 2022

Exhibit 2.3

Description of Securities

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American Depositary Receipt. For directions on how to obtain copies of those documents, see "Where You Can Find Additional Information."

Holding the ADSs

How will you hold your ADSs?

You may hold ADSs either (i) directly (a) by having an American Depositary Receipt, or ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (b) by holding ADSs in DRS, or (ii) indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADS holder. This description assumes you hold your ADSs directly. ADSs will be issued through DRS, unless you specifically request certificated ADRs. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent as of the record date (which will be as close as practicable to the record date for our ordinary shares) set by the depositary with respect to the ADSs.

- ***Cash***. The depositary will convert or cause to be converted any cash dividend or other cash distribution we pay on the ordinary shares or any net proceeds from the sale of any ordinary shares, rights, securities or other entitlements under the terms of the deposit agreement into U.S. dollars if it can do so on a practicable basis and can transfer the U.S. dollars to the United States and will distribute promptly the amount thus received. If the depositary shall determine in its judgment that such conversions or transfers are not practical or lawful or if any government approval or license is needed and cannot be obtained at a reasonable cost within a reasonable period or otherwise sought, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold or cause the custodian to hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid and such funds will be held for the respective accounts of the ADS holders. It will not invest the foreign currency and it will not be liable for any interest for the respective accounts of the ADS holders. Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary, that must be paid, will be deducted. See "Taxation." It will distribute only whole U.S. dollars and cents and will round down fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

- ***Shares***. For any ordinary shares we distribute as a dividend or free distribution, either (1) the depositary will distribute additional ADSs representing such ordinary shares or (2) existing ADSs as of the applicable record date will represent rights and interests in the additional ordinary shares distributed, to the extent reasonably practicable and permissible under law, in either case, net of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary will only distribute whole ADSs. It will try to sell ordinary shares which would require it to deliver a fractional ADS and distribute the net proceeds in the same way as it does with cash. The depositary may sell a portion of the distributed ordinary shares sufficient to pay its fees and expenses, and any taxes and governmental charges, in connection with that distribution.

- ***Elective Distributions in Cash or Shares***. If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, the depositary, after consultation with us and having received timely notice as described in the deposit agreement of such elective distribution by us, has discretion to determine to what extent such elective distribution will be made available to you as a holder of the ADSs. We must timely first instruct the depositary to make such elective distribution available to you and furnish it with satisfactory evidence that it is legal to do so. The depositary could decide it is not legal or reasonably practicable to make such elective distribution available to you. In such case, the depositary shall, on the basis of the same determination as is made in respect of the ordinary shares for which no election is made, distribute either cash in the same way as it does in a cash distribution, or additional ADSs representing ordinary shares in the same way as it does in a share distribution. The depositary is not obligated to make available to you a method to receive the elective dividend in shares rather than in ADSs. There can be no assurance that you will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

- ***Rights to Purchase Additional Shares***. If we offer holders of our ordinary shares any rights to subscribe for additional shares, the depositary shall having received timely notice as described in the deposit agreement of such distribution by us, consult with us, and we must determine whether it is lawful and reasonably practicable to make these rights available to you. We must first instruct the depositary to make such rights available to you and furnish the depositary with satisfactory evidence that it is legal to do so. If the depositary decides it is not legal or reasonably practicable to make the rights available but that it is lawful and reasonably practicable to sell the rights, the depositary will endeavor to sell the rights and in a riskless principal capacity or otherwise, at such place and upon such terms (including public or private sale) as it may deem proper distribute the net proceeds in the same way as it does with cash.

  The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them.

  If the depositary makes rights available to you, it will establish procedures to distribute such rights and enable you to exercise the rights upon your payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The Depositary shall not be obliged to make available to you a method to exercise such rights to subscribe for ordinary shares (rather than ADSs).

  U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

  There can be no assurance that you will be given the opportunity to exercise rights on the same terms and conditions as the holders of ordinary shares or be able to exercise such rights.

- ***Other Distributions***. Subject to receipt of timely notice, as described in the deposit agreement, from us with the request to make any such distribution available to you, and provided the depositary has determined such distribution is lawful and reasonably practicable and feasible and in accordance with the terms of the deposit agreement, the depositary will distribute to you anything else we distribute on deposited securities by any means it may deem practicable, upon your payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. If any of the conditions above are not met, the depositary will endeavor to sell, or cause to be sold, what we distributed and distribute the net proceeds in the same way as it does with cash; or, if it is unable to sell such property, the depositary may dispose of such property in any way it deems reasonably practicable under the circumstances for nominal or no consideration, such that you may have no rights to or arising from such property.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if we and/or the depositary determines that it is illegal or not practicable for us or the depositary to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons entitled thereto.

No shares will be accepted for deposit prior to the date of effectiveness of this Annual Report.

How do ADS holders cancel an American Depositary Share?

You may turn in your ADSs at the depositary's corporate trust office or by providing appropriate instructions to your broker. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to you or a person you designate at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, to the extent permitted by law.

How do ADS holders interchange between Certificated ADSs and Uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send you a statement confirming that you are the owner of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to you an ADR evidencing those ADSs.

Voting Rights

How do you vote?

You may instruct the depositary to vote the ordinary shares or other deposited securities underlying your ADSs at any meeting at which you are entitled to vote pursuant to any applicable law, the provisions of our constitution, and the provisions of or governing the deposited securities. Otherwise, you could exercise your right to vote directly if you withdraw the ordinary shares. However, you may not know about the meeting sufficiently enough in advance to withdraw the ordinary shares.

If we ask for your instructions and upon timely notice from us by regular, ordinary mail delivery, or by electronic transmission, as described in the deposit agreement, the depositary will notify you of the upcoming meeting at which you are entitled to vote pursuant to any applicable law, the provisions of our constitution, and the provisions of or governing the deposited securities, and arrange to deliver our voting materials to you. The materials will include or reproduce (a) such notice of meeting or solicitation of consents or proxies; (b) a statement that the ADS holders at the close of business on the ADS record date will be entitled, subject to any applicable law, the provisions of our constitution, and the provisions of or governing the deposited securities, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the ordinary shares or other deposited securities represented by such holder's ADSs; and (c) a brief statement as to the manner in which such instructions may be given to the depositary. Voting instructions may be given only in respect of a number of ADSs representing an integral number of ordinary shares or other deposited securities. For instructions to be valid, the depositary must receive them in writing on or before the date specified. The depositary will try, as far as practical, subject to applicable law and the provisions of our constitution, to vote or to have its agents vote the ordinary shares or other deposited securities (in person or by proxy) as you instruct.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the ordinary shares underlying your ADSs. In addition, there can be no assurance that ADS holders and beneficial owners generally, or any holder or beneficial owner in particular, will be given the opportunity to vote or cause the custodian to vote on the same terms and conditions as the holders of our ordinary shares.

The depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote and you may have no recourse if the ordinary shares underlying your ADSs are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we will give the depositary notice of any such meeting and details concerning the matters to be voted at least 28 Business Days in advance of the meeting date.

Compliance with Regulations

Information Requests

Each ADS holder and beneficial owner shall (a) provide such information as we or the depositary may request pursuant to law, including, without limitation, relevant Australian law, any applicable law of the United States of America, our constitution, any resolutions of our Board of Directors adopted pursuant to such constitution, the requirements of any markets or exchanges upon which the ordinary shares, ADSs or ADRs are listed or traded, or to any requirements of any electronic book-entry system by which the ADSs or ADRs may be transferred, regarding the capacity in which they own or owned ADRs, the identity of any other persons then or previously interested in such ADRs and the nature of such interest, and any other applicable matters, and (b) be bound by and subject to applicable provisions of the laws of the Australia, our constitution, and the requirements of any markets or exchanges upon which the ADSs, ADRs or ordinary shares are listed or traded, or pursuant to any requirements of any electronic book-entry system by which the ADSs, ADRs or ordinary shares may be transferred, to the same extent as if such ADS holder or beneficial owner held ordinary shares directly, in each case irrespective of whether or not they are ADS holders or beneficial owners at the time such request is made.

Disclosure of Interests

Each ADS holder and beneficial owner shall comply with our requests pursuant to Australian law, the rules and requirements of the Nasdaq and any other stock exchange on which the ordinary shares are, or will be, registered, traded or listed or our constitution, which requests are made to provide information, inter alia, as to the capacity in which such ADS holder or beneficial owner owns ADS and regarding the identity of any other person interested in such ADS and the nature of such interest and various other matters, whether or not they are ADS holders or beneficial owners at the time of such requests.

Reclassifications, Recapitalizations and Mergers

If we:	Then:
Change the nominal or par value of our ordinary shares	The shares or other securities received by the depositary will become deposited securities.
Reclassify, split up or consolidate any of the deposited securities	Each ADS will automatically represent its equal share of the new deposited securities.
Distribute securities on the ordinary shares that are not distributed to you, or recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action	The depositary may distribute some or all of the cash, shares or other securities it received. It may also deliver new ADSs or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the form of ADR without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, including expenses incurred in connection with foreign exchange control regulations and other charges specifically payable by ADS holders under the deposit agreement, or materially prejudices a substantial existing right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended. If any new laws are adopted which would require the deposit agreement to be amended in order to comply therewith, we and the depositary may amend the deposit agreement in accordance with such laws and such amendment may become effective before notice thereof is given to ADS holders.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement if we ask it to do so, in which case the depositary will give notice to you at least 90 days prior to termination. The depositary may also terminate the deposit agreement if the depositary has told us that it would like to resign, or if we have removed the depositary, and in either case we have not appointed a new depositary within 90 days. In either such case, the depositary must notify you at least 30 days before termination.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property and deliver ordinary shares and other deposited securities upon cancellation of ADSs after payment of any fees, charges, taxes or other governmental charges. Six months or more after the date of termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. After such sale, the depositary's only obligations will be to account for the money and other cash. After termination, we shall be discharged from all obligations under the deposit agreement except for our obligations to the depositary thereunder.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the Company, the ADRs and the deposit agreement.

The depositary will maintain facilities in the Borough of Manhattan, The City of New York to record and process the issuance, cancellation, combination, split-up and transfer of ADRs.

These facilities may be closed at any time or from time to time when such action is deemed necessary or advisable by the depositary in connection with the performance of its duties under the deposit agreement or at our reasonable written request.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary and the Custodian; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary and the custodian. It also limits our liability and the liability of the depositary. The depositary and the custodian:

- are only obligated to take the actions specifically set forth in the deposit agreement without gross negligence or willful misconduct;
- are not liable if any of us or our respective controlling persons or agents are prevented or forbidden from, or subjected to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement and any ADR, by reason of any provision of any present or future law or regulation of the United States or any state thereof, the Commonwealth of Australia or any other country, or of any other governmental authority or regulatory authority or stock exchange, or on account of the possible criminal or civil penalties or restraint, or by reason of any provision, present or future, of our memorandum and articles of association or any provision of or governing any deposited securities, or by reason of any act of God or war or other circumstances beyond its control (including, without limitation, nationalization, expropriation, currency restrictions, work stoppage, strikes, civil unrest, revolutions, rebellions, explosions and computer failure);
- are not liable by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our memorandum and articles of association or provisions of or governing deposited securities;
- are not liable for any action or inaction of the depositary, the custodian or us or their or our respective controlling persons or agents in reliance upon the advice of or information from legal counsel, any person presenting ordinary shares for deposit or any other person believed by it in good faith to be competent to give such advice or information;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement;
- are not liable for any special, consequential, indirect or punitive damages for any breach of the terms of the deposit agreement, or otherwise;
- may rely upon any documents we believe in good faith to be genuine and to have been signed or presented by the proper party;
- disclaim any liability for any action or inaction or inaction of any of us or our respective controlling persons or agents in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, holders and beneficial owners (or authorized representatives) of ADSs, or any person believed in good faith to be competent to give such advice or information; and
- disclaim any liability for inability of any holder to benefit from any distribution, offering, right or other benefit made available to holders of deposited securities but not made available to holders of ADS.

The depositary and any of its agents also disclaim any liability (i) for any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the deposit agreement, (ii) the failure or timeliness of any notice from us, the content of any information submitted to it by us for distribution to you or for any inaccuracy of any translation thereof, (iii) any investment risk associated with the acquisition of an interest in the deposited securities, the validity or worth of the deposited securities, the credit-worthiness of any third party, (iv) for any tax consequences that may result from ownership of ADSs, ordinary shares or deposited securities, or (v) for any acts or omissions made by a successor depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without gross negligence or wilful misconduct while it acted as depositary.

In the deposit agreement, we agree to indemnify the depositary under certain circumstances.

Jurisdiction and Arbitration

The laws of the State of New York govern the deposit agreement and the ADSs and we have agreed with the depositary that the federal or state courts in the City of New York shall have exclusive jurisdiction to hear and determine any dispute arising from or in connection with the deposit agreement and that the depositary will have the right to refer any claim or dispute arising from the relationship created by the deposit agreement to arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The arbitration provisions of the deposit agreement do not preclude you from pursuing claims under the Securities Act or the Exchange Act in federal or state courts.

Jury Trial Waiver

The deposit agreement provides that each party to the deposit agreement (including each holder, beneficial owner and holder of interests in the ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any lawsuit or proceeding against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable law.

Requirements for Depositary Actions

Before the depositary will issue, deliver or register a transfer of an ADS, split-up, subdivide or combine ADSs, make a distribution on an ADS, or permit withdrawal of ordinary shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities and payment of the applicable fees, expenses and charges of the depositary;

- satisfactory proof of the identity and genuineness of any signature or any other matters contemplated in the deposit agreement; and

- compliance with (A) any laws or governmental regulations relating to the execution and delivery of ADRs or ADSs or to the withdrawal or delivery of deposited securities and (B) such reasonable regulations and procedures as the depositary may establish, from time to time, consistent with the deposit agreement and applicable laws, including presentation of transfer documents.

The depositary may refuse to issue and deliver ADSs or register transfers of ADSs generally when the register of the depositary or our transfer books are closed or at any time if the depositary or we determine that it is necessary or advisable to do so.

Your Right to Receive the Shares Underlying Your ADSs

You have the right to cancel your ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depositary has closed its transfer books or we have closed our transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting; or (3) we are paying a dividend on our ordinary shares;

- when you owe money to pay fees, taxes and similar charges;

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities, or other circumstances specifically contemplated by Section I.A.(l) of the General Instructions to Form F-6 (as such General Instructions may be amended from time to time); or

- for any other reason if the depositary or we determine, in good faith, that it is necessary or advisable to prohibit withdrawals.

The depositary shall not knowingly accept for deposit under the deposit agreement any ordinary shares or other deposited securities required to be registered under the provisions of the Securities Act, unless a registration statement is in effect as to such ordinary shares.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depositary to the ADS holders entitled thereto. Profile is a required feature of DRS which allows a DTC participant, claiming to act on behalf of an ADS holder, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register such transfer.

THOMSON GEER
LAWYERS

Share Sale and Purchase Agreement

between

Each of the Parties listed in Schedule 1
(each a **Seller** and together, the **Sellers**)

and

Lekhram Changoer, George Anastassov and Eric Kim
(each a **Restrained Individual** and together, the **Restrained Individuals**)

and

Incannex Healthcare Limited
ACN 096 635 246
(**Buyer**)

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This Agreement is made on the **2022**

between **Each of the Parties listed in Schedule 1** (each a **Seller** and together, the **Sellers**)

and **Incannex Healthcare Limited** ACN 096 635 246 (**Buyer**)

and **George Anastassov** (**George**) **Lekhram Changoer** (**Lekhram**), **Eric Kim**. (**Eric**)

(each a **Restrained Individual** and together, the **Restrained Individuals**)

Recitals

A The Sellers own all legal and beneficial interests in the Sale Shares.

B The Sellers have agreed to sell all legal and beneficial interests in the Sale Shares to the Buyer and the Buyer has agreed to buy all legal and beneficial interests in the Sale Shares from the Sellers on the basis set out in this Agreement.

C The Restrained Individuals have agreed to be subject to certain restraints on the basis set out in this Agreement.

Now it is agreed as follows:

1 Definitions and interpretation

1.1 Definitions

In this Agreement, unless the context requires otherwise

Accounts Date means 31 December 2021.

Accounts means the consolidated balance sheet of the Company Group as at the Accounts Date and the consolidated profit and loss statement of the Company Group as at the Accounts Date for the 12 months ending on the Accounts Date as Fairly Disclosed to the Buyer.

Agreed Form means in a form agreed on or around the date of this Agreement between the parties to the relevant document and initialled by each of them for the purposes of identification.

Agreement means this share sale and purchase agreement.

ASIC means the Australian Securities and Investments Commission.

ASX means, as the context requires, ASX Limited ACN 008 624 691 or the financial market operated by it.

ASX Listing Rules means the official listing rules of ASX.

ATO means the Australian Taxation Office.

Authorisation means any licence, consent, approval, permit, registration or other authorisation given or issued by any Governmental Agency or any other person.

Business Day means a day on which the banks are open for business in Melbourne, Victoria, other than a Saturday, Sunday or public holiday in Melbourne, Victoria.

Business means the business of innovative biotechnology focused on research, development, and production of prescription pharmaceutical cannabinoid medicines, carried on by the Company Group as at the date of this Agreement.

Buyer Group means the Buyer and each Related Body Corporate of the Buyer, and after Completion includes the Company Group.

Buyer Warranties means the warranties given by the Buyer as set out in Schedule 6.

cGMP means current good manufacturing practice.

Claim means any allegation, claim, Demand, cause of action, proceeding, litigation judgment, damage, Loss, cost, expense or liability in respect of this Agreement or the transactions contemplated under this Agreement, however arising, whether present, unascertained, immediate, future or contingent, whether based in contract, tort or statute and whether involving a Third Party or a Party.

Company means APIRx Pharmaceutical USA, LLC, details of which are set out in Part 1 of Schedule 2.

Company Group means the Company and the Subsidiaries, and each is a **Company Group Entity**.

Completion means completion of the sale and purchase of all legal and beneficial interest in the Sale Shares in accordance with clause 6 and the allotment and issue of the Subscription Shares in accordance with clause 4.3.

Completion Date means the date on which Completion occurs.

Completion Steps means the steps to be taken on Completion as set out in Schedule 4.

Conditions means the conditions precedent set out in Schedule 3.

Contractors means all contractors or consultants engaged by the Company Group in the conduct of the Business at the Completion Date.

Controller has the meaning given in the Corporations Act.

Corporations Act means the *Corporations Act 2001* (Cth).

Demand means a written notice of, or a demand for, an amount payable, or for any other action.

Due Diligence Investigation means the due diligence investigation of the Company Group undertaken by and on behalf of the Buyer prior to the date of this Agreement.

Duty means any stamp, transaction or registration duty, or similar charge, imposed by any Governmental Agency, and includes but is not limited to, any interest, fine, penalty, charge or other amount imposed in respect of the above, but excludes any Tax.

Employees means all the persons employed by the Company Group in the conduct of the Business at the Completion Date.

Encumbrance means an interest or power:

(a) reserved in or over an interest in any asset including, but not limited to, any retention of title or preferential right; or

(b) created or otherwise arising in or over any interest in any asset under any form of security whatsoever including a bill of sale, contract or set-off, mortgage, charge, lien, pledge, trust, power or security interest (within the meaning of PPSA),

whether registered or unregistered and including any agreement to grant or create any of the above.

Entity has the meaning given to that term in section 64A of the Corporations Act.

Escrow Deed means an escrow deed in the form agreed between the Parties.

Fairly Disclosed means disclosure in sufficient detail and context to enable a reasonable person in the position of the Buyer to fairly identify the nature and scope of the relevant fact, matter, event or circumstance.

Governmental Agency means any government or governmental, semi-governmental, administrative, monetary, fiscal or judicial body, department, commission, authority, tribunal, agency or entity and includes a Tax Authority and drug administration bodies.

GST means goods and services tax or similar value added tax levied or imposed in Australia under the GST Law or otherwise on a supply.

GST Act means *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

GST Law has the same meaning as in the GST Act, and also includes any applicable legislative determinations and Australian Taxation Office public rulings with respect to GST.

IHL Shares means fully paid ordinary shares in the capital of the Buyer.

Immediately Available Funds means telegraphic or other electronic means of transfer of cleared funds into a bank account nominated in advance by the payee.

Independent Accountant means a chartered accountant that is independent of the Sellers and the Buyer, who is a partner of a chartered accounting firm selected by agreement between the Sellers and the Buyer or, failing agreement within 5 Business Days after either of them seek such agreement from the other, then such person having the specified qualifications as is selected by the Chair of the Resolution Institute (or the Chair's nominee).

Insolvency Event means:

(a) in respect of an entity, the occurrence of any one or more of the following events or circumstances in relation to that entity:

(i) a winding up, dissolution, liquidation, provisional liquidation, administration or bankruptcy;

(ii) having a Controller or analogous person appointed to it or any of its property;

(iii) being unable to pay any of its debts as and when due and payable or being deemed to be insolvent under any provision of the Corporations Act or any other law;

(iv) seeking protection from its creditors under any law, entering into a compromise, moratorium, assignment, composition or arrangement with, or for the benefit of, any of its members or creditors;

(v) being subject to voluntary administration under any law applicable to it (including Part 5.3A of the Corporations Act)

(vi) any analogous event or circumstance to those described in paragraphs (i) to (iv) under any law; or

(vii) anything occurs under the law of any jurisdiction which has a substantially similar effect to any of the events described in paragraphs (i) to (iv),

unless such event or circumstance occurs as part of a solvent reconstruction, amalgamation, compromise, arrangement, merger or consolidation approved by the other parties (which approval is not to be unreasonably withheld or delayed); and

(b) in relation to an individual, the individual is insolvent or bankrupt, or a trustee in bankruptcy or similar officer has been appointed over any part of its assets.

Insurance Policies means all insurance policies taken out by a Company Group Entity or in respect of which a Company Group Entity is a named insured as at 24 March 2022.

Inter-company Payable means any amount owed by the Company Group to any Seller Group Member.

Inter-company Receivable means any amount owed to the Company Group by any Seller Group Member.

Intellectual Property Rights means all intellectual property and proprietary rights (whether registered or unregistered), existing anywhere in the world, now or in the future, including:

(a) each business name and domain name registered or used by the Company Group;

(b) trade or service marks;

(c) any right to have information (including confidential information) kept confidential; and

(d) patents, patent applications, drawings, discoveries, inventions, improvements, trade secrets, technical data, formulae, computer programs, data bases, know-how, logos, designs, design rights, copyright and similar industrial or intellectual property rights.

Loss means any debt or other monetary liability (including for Tax) or penalty, fine or payment or any damages, losses, costs (including legal costs on a solicitor and client basis and Tax Claim), charges, outgoings or expenses of whatever description (including interest) however arising and whether present, unascertained, immediate, future or contingent and includes any decrease in the value of the assets or the Sale Shares, whether or not realised.

Management Accounts means the monthly unaudited management accounts of each Company Group Entity for the period after the Accounts Date.

Material Adverse Change means any fact, matter, event, change, occurrence, circumstance or development which is or could reasonably be expected to be materially adverse to the Company Group's ownership of the Intellectual Property Rights and the status and operation of the clinical trials conducted by or on behalf of the Company Group.

Non-Pharmaceutical Assets mean each of the non-pharmaceutical assets of the Company listed in Annexure A.

Owned Intellectual Property Rights means all Intellectual Property Rights owned or will be owned pursuant to clause 7.6 by the Company Group in the course of and for the purposes of the Business including the Intellectual Property Rights listed in Schedule 7.

Parties means the parties to this Agreement, and **Party** means any of them.

Payment Recipient has the meaning given to that term in clause 10.4.

Permitted Encumbrance means:

(a) any Encumbrance which the Buyer agrees in writing before Completion is a Permitted Encumbrance; and

(b) any of the following PPSA security interests created in the ordinary course of business after the execution of this Agreement:

  (i) a retention of title arrangement under which title is retained by a supplier over goods supplied to the relevant person or entity until payment for such goods is made; or

  (ii) a lien or charge, arising by operation of law which has not been exercised.

Personal Information means personal data, as that term is defined in the General Data Protection Regulation.

Personnel means any employee, contractor, officer or agent.

PPSA means the *Personal Property Securities Act 2009* (Cth).

PPSR means the Personal Property Securities Register established under the PPSA.

Privacy Act means the *Privacy Act 1988* (Cth).

Privacy Law means any statue, regulation or law in Australia or elsewhere relating to the protection of Personal Information that the Company Group must observe including under the Privacy Act, the US National Institute of Standards and Technology and the General Data Protection Regulation.

Property Lease means the lease in effect on the date of this Agreement between APIRx Pharmaceuticals Holdings B.V and Business center de Burcht in respect of the premises at Industrieweg 40, Unit B4. 3401 MA IJsselstein.

Records means all original and copy documents, books, files, reports, accounts, plans and correspondence, regardless of their form or medium and whether coming into existence before, on or after the date of this Agreement, belonging or relating to or used by the Company Group including certificates of registration, minute books, statutory books and registers, books of account, tax returns, title deeds and other documents of title, customer lists, price lists, computer programs and software, and trading and financial records.

Related Body Corporate has the meaning given to that expression in section 9 of the Corporations Act.

Related Entity has the meaning given to that term in the Corporations Act as if that meaning was modified to apply to both bodies corporate and persons other than bodies corporate.

Remuneration Agreement (Eric) means the remuneration agreement between Eric and the Buyer in the form agreed between Eric and the Buyer.

Remuneration Agreement (George) means the remuneration agreement between George and the Buyer in the form agreed between George and the Buyer.

Remuneration Agreement (Lekhram) means the remuneration agreement between Lekhram and the Buyer in the form agreed between Lekhram and the Buyer.

Respective Proportion means, in respect of a Seller, the proportion set out in Column 4 of the table in Schedule 1 adjacent to that Seller's name.

Restraint Area means:

(a) Europe, North America and Australia; or if that is unenforceable then

(b) North America and Australia; or if that is unenforceable then

(c) Australia.

Restraint Period means the period commencing on the Completion Date and ending on:

(a) the third anniversary of the Completion Date; or if that is unenforceable then

(b) the second anniversary of the Completion Date; or if that is unenforceable then

(c) the first anniversary of the Completion Date.

Ruling means any ruling, determination, arrangement, clearance, consent or advice issued by, or negotiated with, any Tax Authority in respect of any Tax, Duty or Tax Law.

Sale Shares means the entire share capital of the Company**.**

Seller Group means each Seller and each Related Entity of a Seller.

Seller Group Member means any member of the Seller Group.

Sellers' Warranties means the warranties given by the Sellers as set out in Schedule 5.

Shareholders Agreement means the operating agreement between the Sellers and the Company as ratified on 22 April 2020.

Specific Indemnity Claim means a Claim by the Buyer pursuant to clause 11.

Subscription Shares means a total of 218,169,506 IHL Shares to be issued to the Sellers in accordance with the terms of this Agreement.

Sunset Date means 31 July 2022 or such other date as agreed in writing between the Buyer and the Sellers.

Subscription Share Issue Price means $0.573 per Subscription Share.

Subsidiaries means each of the following:

(a) APIRx Pharmaceuticals B.V, The Netherlands; and

(b) APIRx Pharmaceuticals Holdings B.V, The Netherlands.

Tax means any income, gross receipts, license, payroll, employment, excise, severance, occupation, premium, capital gains, windfall profits, environmental, customs duties, escheat, unclaimed property, capital stock, franchise, profits, withholding, social security (or similar), unemployment, disability, real property, personal property, sales, use, transfer, registration, goods and services, value added, alternative or add-on minimum, estimated or other tax, levy, charge, impost, fee, deduction, compulsory loan or withholding, of any kind whatsoever and whenever imposed, in any part of the world, imposed or collected by any Governmental Agency and includes any interest, fine, penalty, charge, fee or any other amount imposed on, or in respect of any of the above, but excludes any Duty.

Tax Authority means any revenue, customs, fiscal, statutory, federal, state, provincial, local, governmental or municipal authority, body or person, competent to impose any Tax or Duty whether in Australia or elsewhere.

Tax Claim means a Claim by the Buyer arising from breach of Sellers' Warranty 13 or under the Tax Indemnity.

Tax Indemnity means the indemnity given by the Sellers under clause 10.

Tax Law means any law in relation to any Tax or Duty.

Tax Liability includes any Loss arising from any obligation of any Company Group Entity to make a payment under any Tax Law in respect of the operations of the Company Group in the period up to and including, or an event occurring within the Company Group up to and including, Completion.

Third Party means any person or entity (including a Governmental Agency) other than a Seller Group Member, any member of the Buyer Group and the Company Group.

Third Party Claim means any Claim or cause of action made or brought by a Third Party which may gave rise to a Claim by the Buyer against the Sellers in respect of this Agreement or the transactions contemplated under this Agreement.

Title and Capacity Warranties means Sellers' Warranties 1, 2, 3 and 7.

Title and Capacity Warranty Claim means any Claim arising out of a breach of a Title and Capacity Warranty.

Total Consideration means the total amount to be paid by the Buyer to the Sellers for all legal and beneficial interests in the Sale Shares in accordance with clause 4.1.

Total Consideration means the issue of the Subscription Shares.

Warranty Claim means any Claim by the Buyer arising out of a breach of a Sellers' Warranty.

1.2 **Interpretation**

In this Agreement, unless the context otherwise requires:

(a) a reference to a person includes a reference to a corporation, an association, joint venture, an unincorporated body, partnership, government or local authority or agency or other entity;

(b) the singular includes the plural and the plural includes the singular;

(c) a reference to any gender includes a reference to all genders;

(d) a reference to money (including $ or dollars) is a reference to Australian currency unless otherwise specified;

(e) a reference to time is to Melbourne, Australia time;

(f) a month means a calendar month;

(g) a reference to a recital, clause, paragraph, schedule or annexure is a reference to a recital, clause or paragraph of, or schedule or annexure to, this Agreement and a reference to this Agreement includes any recital, schedule or annexure;

(h) a reference to a Party includes that Party's executors, administrators, successors, permitted assigns and substitutes;

(i) specifying anything in this Agreement after the words 'including', 'includes' or 'for example' or similar expressions does not limit what else is included;

(j) a reference to legislation or to a provision of a legislation includes a reference to a modification, consolidation, replacement or re-enactment of it, and includes subordinate legislation made under it;

(k) a reference to a body, other than a Party (including an institute, association or authority), whether statutory or not:

(i) which ceases to exist; or

(ii) whose powers or functions are transferred to another body,

is a reference to the body which replaces it or which substantially succeeds to its powers or functions;

(l) a reference to a document or instrument includes the document or instrument as novated, altered, supplemented or replaced from time to time;

(m) a reference to an agreement other than this Agreement includes a legally enforceable deed, undertaking, agreement, arrangement or understanding, whether or not in writing;

(n) where an expression is defined, another part of speech or grammatical form of that expression has a corresponding meaning;

(o) if an act required to be done under this Agreement on or by a given day is done after 5:30pm on that day, it is taken to be done on the following day;

(p) unless otherwise specified, any agreement, representation, warranty or indemnity in favour of two or more Parties (including where two or more persons are included in the same defined term) is for the benefit of them jointly and severally;

(q) unless otherwise specified, any agreement, representation, warranty or indemnity by two or more Parties (including where two or more persons are included in the same defined term) binds them jointly and severally;

(r) a provision of this Agreement must not be construed to the disadvantage of a Party merely because that Party was responsible for the preparation of the Agreement or the inclusion of the provision in the Agreement; and

(s) a reference to **as far as the Sellers are aware**, or words to that effect, in relation to a matter, is a reference to the actual knowledge of any of Lekhram, Kim and Anastassov as at the date of this Agreement, or such knowledge as Lekhram, Kim and Anastassov would have had after having made reasonable and diligent enquiries of their respective direct reports in relation to the relevant matter.

1.3 **Headings**

Headings and the table of contents are inserted for convenience only and do not affect the interpretation of this Agreement.

1.4 **Weekends and holidays**

Where an act is required by this Agreement to be done on a given day and that day is not a Business Day, then the act is required to be done on the next following Business Day.

2 Conditions

2.1 **Conditions**

Completion of the sale and purchase of all legal and beneficial interests in the Sale Shares under this Agreement is subject to and will not proceed unless the Conditions have been satisfied or waived.

2.2 **Cooperation**

(a) Each Party must:

(i) use its reasonable endeavours to ensure that the Conditions are satisfied as expeditiously as possible after execution of this Agreement and in any event no later than the Sunset Date (unless otherwise agreed in writing by the Sellers and the Buyer); and

(ii) must provide all reasonable assistance to the other Parties as is reasonably necessary to satisfy the Conditions.

(b) Without limiting clause 2.2(a), each Party must:

(i) keep the other informed in a timely manner of the progress of any applications made and the status of any discussions or negotiations with relevant Third Parties regarding the Conditions; and

(ii) promptly notify the other on becoming aware of the satisfaction of any Condition or of any Condition becoming incapable of being satisfied.

2.3 **Waiver**

(a) A Condition is only waived if the Buyer notifies the Sellers in writing that the Buyer waives the condition.

(b) A Condition that is waived in accordance with clause 2.3(a) is effective only to the extent specifically set out in that waiver.

2.4 **Obligations to notify**

If the Buyer or any of the Sellers becomes aware:

(a) that a Condition has been satisfied; or

(b) of any facts, circumstances or matters that may result in a Condition not being or becoming incapable of being satisfied,

that Party must promptly notify the other Parties accordingly.

2.5 **Termination**

(a) If a Party has complied with its obligations under clause 2.2, it may terminate this Agreement prior to Completion by giving not less than 5 Business Days' notice to the other Parties if:

(i) the Conditions are not satisfied, or waived in accordance with clause 2.3, by the Sunset Date;

(ii) a Condition is or becomes incapable of being satisfied; or

(iii) a Condition, having been satisfied, does not remain satisfied in all respects at all times before Completion, unless it has been waived in accordance with clause 2.3.

(b) If prior to Completion:

(i) an Insolvency Event occurs in respect of a Seller; or

(ii) there has been a Material Adverse Change since the date of this Agreement,

then the Buyer may terminate this Agreement immediately by giving written notice to each of the Sellers.

2.6 **Rights on termination**

Subject to clause 16, if this Agreement is terminated under clause 2.5 prior to Completion then, in addition to any other rights, powers or remedies provided by law or in equity:

(a) each Party is released from its obligations and liabilities under or in connection with this Agreement and this Agreement will have no further force of effect, other than clause 1 (but only to the extent required to give meaning to any surviving clauses), this clause 2.6, clause 16 and clause 18; and

(b) each Party retains the rights, remedies and powers it has in connection with any past breach or any claim that has arisen before termination.

3 Sale and purchase

3.1 **Agreement to sell and purchase**

Each Seller agrees to sell all legal and beneficial interests in the Sale Shares and the Buyer agrees to purchase all legal and beneficial interests in the Sale Shares from the Sellers:

(a) for the Total Consideration;

(b) free from all Encumbrances other than any Permitted Encumbrances;

(c) with all rights attached or accrued to them on or after the Completion Date; and

(d) subject to the provisions of this Agreement.

3.2 **Title and risk**

Title and risk in the Sale Shares passes to the Buyer on Completion.

3.3 **Waiver of pre-emptive rights**

Each Seller, by its execution of this Agreement, consents to the sale and purchase contemplated by clause 3.1 and irrevocably waives in favour of the Buyer any rights of pre-emption that the Sellers have, or may have, in respect of the Sale Shares, whether conferred by the constituent documents of the Company Group the Shareholders Agreement or otherwise.

4 Total Consideration and payment terms

4.1 **Total Consideration**

The Total Consideration for all legal and beneficial interests in the Sale Shares under this Agreement is the issue of the Subscription Shares.

4.2 **Payment of Total Consideration**

On the Completion Date, the Buyer must issue to the Sellers in their Respective Proportions the Subscription Shares in accordance with clause 4.3.

4.3 **Subscription Shares**

(a) This Agreement serves as an application by the Sellers for the issue and allotment on the Completion Date of the Subscription Shares in their Respective Proportions.

(b) Each Seller agrees to become a member of the Buyer and to be bound by the constitution of the Buyer and consents to entry of its name on the Buyer's register of members.

(c) On the Completion Date, the Buyer must:

(i) ensure that the Subscription Shares issued to the Sellers pursuant to clause 4.2;

(A) are fully paid and validly issued;

(B) are issued at the Subscription Share Issue Price;

(C) are free from any Encumbrance, except for:

(I) any Encumbrance under the constitution of the Buyer; and

(II) the transaction restrictions set forth in the Buyer's share policy for its directors, executives and employees or in the Escrow Deed;

(D) are issued with all rights and entitlements, including dividend, distribution and voting rights attached or accrued to the Subscription Shares after Completion; and

(E) rank equally in all respects with the IHL Shares existing on the Completion Date;

(ii) enter in the Buyer's register the name of the Sellers as the registered holders in respect of the Subscription Shares; and

(iii) apply for official quotation of the Subscription Shares on ASX in accordance with ASX Listing Rule 2.8.

(d) The Subscription Share Issue Price for the Subscription Shares shall be deemed to be paid by way of the transfer of the Sale Shares pursuant to this Agreement, and, otherwise, no money shall be payable by the Sellers in respect of the Subscription Share Issue Price.

5 Conduct prior to Completion

5.1 **Conduct prior to Completion**

Subject to clause 5.2, from the date of this Agreement until Completion, each Seller must (to the extent it reasonably can), unless the Buyer otherwise agrees in writing, ensure that the Company Group:

(a) carries on its Business as a going concern in the ordinary and usual course and otherwise in substantially the same manner as before the date of this Agreement;

(b) discharges current liabilities as they fall due in accordance with its usual practice; and

(c) collects receivables using the same method and policy as before the date of this Agreement.

5.2 **Restricted conduct before Completion**

From the date of this Agreement until Completion, except with the prior written consent of the Buyer (which must not be unreasonably withheld, delayed or conditioned), each Seller (to the extent it reasonably can) must procure that the Company and any Subsidiary does not:

(a) issue or allot any shares or options, securities or other rights convertible into shares;

(b) buy back or redeem any Sale Shares or shares or securities or otherwise reduce its share capital or provide financial assistance for the acquisition of its own shares or shares in any holding company;

(c) convert all or any of its shares into a larger or smaller number of shares;

(d) declare or pay any dividend or other distributions;

(e) alter the provisions of its constituent documents;

(f) dispose of or create any Encumbrances (other than a Permitted Encumbrance) over, or declare itself the trustee of, any asset of the Business (except in the ordinary and usual course of business);

(g) dispose of any part of its Business;

(h) acquire or dispose of any asset;

(i) enter into any transaction or agreement that results in a transfer of value out of the Company to the Seller Group or any associates or affiliates of a Seller or enter into any new or unusual transaction which adversely affects the Company Group or the Business;

(j) change in any material respect the accounting procedures, principles or practices of the Company Group;

(k) in its conduct of the Business make any changes to its policy or practice as to the payment of creditors or collection of receivables;

(l) vary the terms of, or terminate, the employment of any of its employees;

(m) vary the terms of, or terminate, the engagement of any of its contractors, other than in the normal course;

(n) of its own volition, terminate or adversely vary or fail to enforce the terms of any material contract, commitment or arrangement to which it is a party or accept or agree to any variations to services to be performed or prices charged under any such contract, commitment or arrangement without the prior written consent of the Buyer, such consent not to be unreasonably withheld, delayed or conditioned;

(o) grant any power of attorney;

(p) give any guarantee or indemnity;

(q) vary the terms of any key policies for the Company Group;

(r) resolve that any Company Group Entity be wound up; or

(s) authorise, commit or agree to take any action referred to in this clause 5.2.

5.3 **Permitted acts**

Despite anything to the contrary in clause 5.2, prior to Completion, the Company Group may do, or omit to do, anything:

(a) to reasonably and prudently respond to an emergency or disaster (being a situation giving rise to a risk of personal injury or damage to property);

(b) which is necessary for a Seller or the Company Group to meet its legal or contractual obligations (including under this Agreement); or

(c) which has been requested in writing by the Buyer.

5.4 **Notification of warranty breaches**

Prior to Completion, the Sellers must notify the Buyer in writing within 2 Business Days of becoming aware that a material breach of a Sellers' Warranty has occurred or is likely, in the opinion of the Sellers (acting reasonably), to occur. The notice must contain details of that breach known to the Sellers that are reasonably sufficient to allow the Buyer to consider the effect of the breach on the Company Group.

5.5 **Supervised access to the Business prior to Completion**

(a) The Sellers must allow the Buyer and a reasonable number of nominated representatives of the Buyer supervised access to the Business (including the assets, monthly management accounts, records and personnel of the Business) as may be reasonably requested by the Buyer before Completion (such access and times to be agreed between the Buyer and the Sellers acting reasonably), provided always that:

(i) the Buyer obtains the prior permission of the Sellers (which must not be unreasonably withheld, delayed or conditioned); and

(ii) the access is with designated Personnel of the Buyer approved by the Sellers (such approval not to be unreasonably withheld, delayed or conditioned).

(b) The Buyer must ensure that any access under clause 5.5(a) is exercised and conducted in such manner as to avoid disruption to the conduct of the Business and the activities and operations of the Company Group and its Personnel.

5.6 **Changes to Company Group officers**

At least 5 Business Days prior to Completion, the Buyer must notify the Sellers of each person who will be appointed as a director and/or secretary and/or public officer of each Company Group Entity from Completion.

5.7 **Repayment of Inter-company Payables and Inter-company Receivables**

The Sellers must ensure that, immediately prior to Completion:

(a) the Company repays all Inter-company Payables; and

(b) all Inter-company Receivables are paid to the Company.

5.8 **Insurance**

Until Completion, the Sellers must procure that the Company maintains the Insurance Policies.

6 Completion

6.1 **Time and location of Completion**

Completion will take place electronically at 11:00am (Melbourne time) on the Completion Date or at such other place, date and time as the Sellers and the Buyer may agree in writing.

6.2 **Completion**

(a) On or before Completion, each Party must carry out the Completion Steps which it is obliged to carry out it in accordance with Schedule 4.

(b) Completion is taken to have occurred when each Party has performed all its obligations under this clause 6.2 and Schedule 4. However, a Party may not delay Completion on the basis of that Party's own failure to comply with any such obligation.

6.3 **Obligations interdependent**

(a) The transactions provided for in clause 6.2 and Schedule 4 are interdependent and are to be carried out contemporaneously.

(b) No delivery, payment or other event referred to in clause 6.2 or Schedule 4 will be regarded as having been made or occurred until all deliveries and payments have been made and all other specified events have occurred.

7 Post Completion matters

7.1 Conduct until the Sale Shares are registered

After Completion and until the Sale Shares are registered in the name of the Buyer, the Sellers must:

(a) convene and attend a general meeting of the Company; and

(b) vote at general meetings and take all other action in the capacity of the registered holder of the Sale Shares which are not inconsistent with the terms of this Agreement,

as the Buyer may lawfully require from time to time by notice in writing to the Sellers.

7.2 ASIC, ASX, Nasdaq and Governmental Agency notification

The Buyer must ensure that ASIC and any relevant Governmental Agencies are notified, in the prescribed form, within the applicable prescribed period after Completion (as applicable) of the occurrence of those events under this Agreement that must be notified to them.

7.3 Registration

The Buyer must ensure the transfers of the Sale Shares are registered promptly after Completion.

7.4 Wrong pockets

If the Buyer or a Seller becomes aware that any asset relating to the Business remains under the direct or indirect control of a Seller Group Member following Completion, then the relevant Seller shall promptly transfer or cause to be transferred such asset to the Buyer or the Company (at the Buyer's sole election) for no additional consideration.

7.5 Licensing

Following Completion, the Buyer will use its best endeavours to grant to George and Lekhram an exclusive licence to use the Non-Pharmaceutical Assets on mutually agreeable terms to be determined following Completion.

7.6 Transfer and assignment of Owned Intellectual Property Rights

As soon as practicable following Completion, but no later than 3 months after Completion, each Seller Group Member and each Company Group Entity must, if required, procure that the legal and beneficial ownership of each Owned Intellectual Property Rights is transferred and assigned to the Company.

8 Sellers' Warranties

8.1 Sellers' Warranties

(a) The Sellers warrant to the Buyer that each Sellers' Warranty (other than Item 1 and Item 2 in Schedule 5) is true and correct as at the date of this Agreement and at the Completion Date (unless otherwise stated in Schedule 5).

(b) Each Seller (in respect of itself only) warrants to the Buyer that each Sellers' Warranty in Item 1 and Item 2 in Schedule 5 is true and correct as at the date of this Agreement and at the Completion Date (unless otherwise stated in Schedule 5).

(c) Each Sellers' Warranty is a separate warranty and is in no way limited by any other Sellers' Warranty and remains in full force and effect following Completion in accordance with its terms.

8.2 Reliance

Each Seller acknowledges that the Buyer has entered into this Agreement and will complete this Agreement in reliance on the Sellers' Warranties.

8.3 **Indemnified Loss**

The Sellers jointly and severally indemnify the Buyer from all Loss and must pay the Buyer an amount equal to any Loss suffered or incurred by the Buyer in connection with a breach of a Sellers' Warranty, except to the extent that the Sellers' Warranty or the Sellers' liability for the Loss and Claims are excluded, limited or qualified under clause 12.

9 Foreign resident CGT withholding

9.1 **Declaration that Sale Shares are not indirect Australian real property interests**

For the purposes of section 14-225(2) of Schedule 1 of the TAA 1953, each Sellers declares that, for the period from the date of this Agreement up to and including Completion, the Sale Shares sold by that Seller under this Agreement:

(a) are membership interests (within the meaning of the ITAA 1997); and

(b) are not indirect Australian real property interests (within the meaning provided by section 855-25 of the ITAA 1997).

9.2 **Renewal of declaration**

Upon request by the Buyer, each Seller must renew its declaration given under clause 9.1 at intervals of up to six (6) months, up to and including Completion.

10 Tax indemnity

10.1 **Indemnity**

Subject to clause 10.2, the Sellers jointly and severally indemnify and must keep indemnified the Buyer, in their Respective Proportions, for any:

(a) Tax Liabilities payable or incurred by the Company Group net of any additional or increased tax benefit arising and receivable to the Buyer by reason of such Tax Liabilities;

(b) loss or reduction of a tax benefit; and

(c) costs and expenses incurred by or on behalf of the Company Group (including any costs and expenses incurred in connection with any action taken to investigate, dispute, manage, avoid, resist or settle any Tax Liability) to the extent those costs and expenses arise from or relate to any of the matters referred to in clauses 10.1(a) and 10.1(b) (**Tax Costs**),

incurred or arising in respect of any period up to and including Completion incurred or arising as a result of, or in respect of, or by reference to:

(d) any acts or omissions of, or an event occurring, or deemed for Tax or Duty purposes to occur or have occurred on or before the Completion Date, and which affects a Company Group Entity;

(e) an action, decision, direction or election made on or before the Completion Date;

(f) any grouping of the Company Group with any other business or corporation for payroll tax purposes (or similar);

(g) any income, profits or gains (not falling within clause 10.1(d) above) earned, accrued, derived or received, or deemed for any Tax or Duty purposes to be earned, accrued, derived or received on or before or in respect of any period ending on or before the Completion Date;

(h) any deductions or losses deducted on or before the Completion Date, or deemed for any Tax or Duty purposes to be deducted, on or before the Completion Date;

(i) any underpayment of any Taxes or Duties by the Company Group where such Taxes or Duty relate to the period on or before the Completion Date; or

(j) any failure by the Company Group to comply with statutory requirements including failure to provide information or documents to any Governmental Agency where the time or date for compliance with those requirements or the provision of the information or documents occurred or fell on or before the Completion Date.

10.2 **Scope of Tax Indemnity**

(a) The Sellers will not be liable to make any payment under this clause 10 in respect of any Tax Liability to the extent that (except in the event of fraud or evasion on the part of a Seller or the Company Group):

(i) it solely arises as a result of any income derived, loss, outgoing or deductions incurred or activities undertaken, or deemed for Tax or Duty purposes to have been undertaken, after Completion unless arising from an action, decision, direction or election made prior to the Completion Date;

(ii) it arises as a result of the transactions contemplated by this Agreement;

(iii) to the extent an amount has been recovered by the Company Group in respect of the same subject matter (net of liabilities incurred in making that recovery).

(b) The Buyer may not make a Claim under clause 10.1 to the extent the Sellers have compensated the Company Group for the subject matter of that Claim.

(c) The Sellers are not liable for any Tax Claim, and the Buyer must not bring any Tax Claim, to the extent that:

(i) the Claim arises from, or is increased as a result of, the Company Group joining a consolidated group for Tax purposes on or after Completion;

(ii) the Tax or Duty the subject of the Claim would not have arisen but for any change in the accounting policy or practice of the Company Group after Completion; or

(iii) the Tax or Duty the subject of the Claim arises out of the cessation or alteration of the Business after Completion, unless arising from an action, decision or election made prior to the Completion Date.

10.3 **Payment of Tax Liabilities**

Where a Claim under the Tax Indemnity involves an actual payment of Tax or Duty by the Company Group:

(a) the Parties must procure that the Company Group pays the relevant Tax or Duty by the date on which the Tax or Duty in question is due to be paid to the relevant Tax Authority; and

(b) where it is finally agreed by the Parties or determined by judicial determination that the Sellers are liable to make a payment under the Tax Indemnity in respect of the amount of Tax or Duty referred to in clause 10.1(a), the Sellers must pay the amount agreed or determined to the Buyer within 10 Business Days of the final agreement or determination of the Sellers' liability.

10.4 **Tax effect of Claims**

If a Party (**Payer**) is liable to pay an amount to another Party (**Payment Recipient**) in respect of a Claim and that payment is treated as income under Tax Law such that the payment increases the income Tax payable by the Payment Recipient under Tax Law, then the payment must be grossed- up by such amount as is necessary to ensure that the net amount retained by the Payment Recipient after deduction of Tax or payment of the increased income Tax equals the amount the Payment Recipient would have retained had the Tax or increased income Tax not been payable.

11 Specific Indemnity

(a) The Sellers jointly and severally indemnify and must keep indemnified the Buyer and each member of the Buyer Group, in their Respective Proportions, from all Claims suffered or incurred by or made against a member of the Buyer Group or the Company Group arising as a result of, or in respect of, any liability incurred by any Company Group Entity arising in relation to or in connection with the Company Group Entity's failure to comply with any of its obligations arising under law, equity or statute in respect of the Owned Intellectual Property Rights in the period before the Completion Date.

(b) The Sellers acknowledge that the benefit of this clause 11 is held by the Buyer on trust for the Buyer Group and is able to be enforced by the Buyer against the Sellers or any one of them on behalf of each member of the Buyer Group.

12 Limitation of liability

12.1 Exclusion of liability

To the maximum extent permitted by law:

(a) all terms, conditions, warranties, indemnities and statements (whether express, implied, written, oral, collateral, statutory or otherwise) which are not expressly set out in this Agreement are excluded; and

(b) the Buyer must not make any Claim under or in connection with this Agreement unless it is based solely on and limited to the express provisions of this Agreement.

12.2 Buyer acknowledgements

The Buyer acknowledges and agrees that:

(a) it has received independent and professional advice (including legal, accounting, tax and financial advice) concerning this Agreement and has satisfied itself about anything arising from that advice; and

(b) it has had the opportunity to conduct a Due Diligence Investigation and has satisfied itself of the results of that investigation.

12.3 Maximum aggregate amount

The maximum aggregate amount that the Buyer may recover from the Sellers (whether by way of damages or otherwise) for a Claim is an amount equal to the aggregate issue price of the Subscription Shares.

12.4 Threshold limit

(a) Other than in respect of a Title and Capacity Warranty Claim, a Tax Claim or a Specific Indemnity Claim, the Sellers are not liable to make any payment (whether by way of damages or otherwise) for any Claim under or pursuant to this Agreement:

(i) unless the amount of each Claim exceeds $10,000; and

(ii) until the aggregate of the amount in clause 12.4(a)(i) for those Claims exceeds $50,000 in which event the Sellers are liable for the whole of that amount, not merely the excess.

(b) In respect of a Title and Capacity Warranty Claim, a Tax Claim or a Specific Indemnity Claim, the Sellers are not liable to make any payment (whether by way of damages or otherwise) under or pursuant to this Agreement until the aggregate of the amount for those Claims exceeds $5,000 in which event the Sellers are liable for the whole of that amount, not merely the excess.

12.5 **Double recovery**

To the extent that the Buyer or the Company Group (as applicable) has recovered an amount:

(a) under the Tax Indemnity in respect of a matter that is also the subject matter of a Sellers' Warranty, the Buyer is not entitled to recover that amount in respect of a breach of that Sellers' Warranty; or

(b) for a breach of a Sellers' Warranty, the Buyer is not entitled to recover that amount under the Tax Indemnity.

12.6 **Time limits**

Despite any other provision of this Agreement, the Sellers are not liable to make any payment (whether by way of damages or otherwise) for any Claims in respect of this Agreement or the transactions contemplated under this Agreement unless:

(a) in relation to a Tax Claim or a Title and Capacity Warranty Claim or a Specific Indemnity Claim, notice is given by the Buyer to the Sellers before the date that is 7 years after the Completion Date;

(b) in relation to any Claim by the Buyer however arising other than a Specific Indemnity Claim, a Tax Claim or a Title and Capacity Warranty Claim, notice is given by the Buyer to the Sellers before the date that is 3 years after the Completion Date.

12.7 **Later recovery**

After the Sellers have made any payment to the Buyer or the Company Group (as the case may be) for any Claim by the Buyer in respect of this Agreement or the transactions contemplated under this Agreement, if the Buyer receives any benefit or credit, including a reduction or refund of Tax, including by claiming an indemnity against or otherwise recovering from a person other than the Sellers, in respect of any Loss arising in connection with such Claim (including payment under any insurance policy), the Buyer must immediately repay to the Sellers an amount corresponding to the amount of the payment or (if less) the amount of the benefit or credit (net of all costs of recovery).

12.8 **Additional Limits on Buyer Claim**

The Buyer is not entitled to make any Claim in respect of this Agreement or the transactions contemplated under this Agreement to the extent that:

(a) the Claim would not have arisen but for:

(i) the enactment or amendment of any legislation or regulations;

(ii) a change in the judicial or administrative interpretation of the law;

(iii) a change in the practice or policy (including any change in any public ruling or new interpretation by a Tax Authority) of any Governmental Agency, or

(iv) a change in any accounting policy or practice of a Company Group Entity that applied before the Completion Date,

after the date of this Agreement, and this is so whether or not the change purports to be effective retrospectively in whole or in part;

(b) the Claim has arisen directly as a result of any act or omission after Completion by or on behalf of the Buyer or a Company Group Entity;

(c) the Claim has arisen as a result of any act or omission by or on behalf of the Sellers where the Buyer has directed that act or omission;

(d) the Claim arises out of a cessation of the Business after the Completion Date; or

(e) the Loss does not flow directly or arise naturally from the relevant breach irrespective of whether that type of loss may foreseeably arise.

12.9 **Scope of limitation of liability clause**

The limitations in this clause 12 do not apply in the event of fraud, wilful concealment or wilful misconduct or gross negligence by or on behalf of a Seller.

12.10 **Independent limitations**

Each limitation in this clause 12 is independent and not limited by any other qualification or limitation.

13 Procedure for dealing with Claims

13.1 **Notice of Claims**

(a) In respect of any Claim by the Buyer against the Sellers in respect of this Agreement or the transactions contemplated under this Agreement, the Buyer must:

(i) give written notice of the Claim to the Sellers within 90 days of the Buyer becoming aware of the existence of the Claim; and

(ii) include sufficient details in the notice to the extent known by the Buyer including:

(A) all details if applicable, of any other Claims which together with the Claim give rise to the applicable thresholds set out in clause 12.3 and clause 12.4;

(B) if applicable, details of the Third Party Claim; and

(C) the nature of the Claim and the Buyer's estimate of the Loss suffered.

(b) The Buyer and the Sellers must also, on an ongoing basis, keep each other reasonably informed of material developments of which they become aware in relation to the matter.

(c) The Buyer may not make a Claim if it fails to comply with clause 13.1(a).

13.2 **Third Party Claims**

(a) Following receipt of a notice under clause 13.1 which involves a Third Party Claim, the Sellers may, by notice in writing from the Sellers to the Buyer following acceptance of the Claim, assume the conduct of the defence of the Third Party Claim (or any part of the Third Party Claim).

(b) Where a Third Party Claim is brought solely against a member of the Buyer Group (other than the Company Group), or part of a Third Party Claim is brought solely against a member of the Buyer Group (other than the Company Group), the Sellers will not be entitled to assume the conduct of the defence of the Third Party Claim or the relevant part of the Third Party Claim. For the avoidance of doubt, where the Sellers are not entitled to assume conduct of part of a Third Party Claim on the basis that it is brought solely against a member of the Buyer Group (other than the Company Group), they will remain entitled to assume conduct of all other parts of the Third Party Claim.

(c) The Buyer must not:

(i) accept, compromise or pay;

(ii) agree to arbitrate, compromise or settle; or

(iii) make any admission or take any action in relation to,

a Third Party Claim which may lead to liability on the part of the Sellers under a Claim without the prior written approval of the Sellers in respect of any Third Party Claim (or any part of a Third Party Claim) which may not be unreasonably withheld or delayed.

(d) Following acceptance of the Claim the Buyer must take any action and provide any assistance the Sellers reasonably require (at the Sellers' cost or expense) to avoid, contest, compromise or defend any Third Party Claim (or any part of any Third Party Claim), demand or legal proceedings which may lead to liability on the part of the Sellers under any Third Party Claim (or any part of any Third Party Claim), including providing witnesses and documentary or other evidence and allowing the Sellers and their Personnel to inspect and take copies of all relevant documents, records and accounts.

(e) If the Sellers do not assume conduct of the defence of the Third Party Claim (or any part of the Third Party Claim) under this clause 13, the Buyer must ensure that it, or the member of the Company Group which conducts the Third Party Claim (or that part of the Third Party Claim not assumed by the Sellers) on the Buyer's behalf:

(i) acts in good faith;

(ii) keep the Sellers reasonably informed of developments in relation to defence of the Third Party Claim (or that part of the Third Party Claim not assumed by the Sellers);

(iii) uses best endeavours to promptly notify the Sellers about contemplated steps by or on behalf of the Buyer;

(iv) provides the Sellers with copies of all material documents in relation to the defence of the Third Party Claim (or that part of the Third Party Claim not assumed by Sellers), except to the extent any such documents are in the reasonable opinion of the Buyer subject to legal professional privilege which would be waived by disclosure to the Sellers; and

(v) acts reasonably in the circumstances, including, having regard to the likelihood of success.

14 Buyer Warranties

14.1 Buyer Warranties

The Buyer warrants to the Sellers that each Buyer Warranty is true and correct at the date of this Agreement and immediately before Completion. Each Buyer Warranty is a separate warranty in no way limited by any other Buyer Warranty. The Buyer acknowledges that the Sellers have entered into this Agreement in reliance on the Buyer Warranties.

14.2 Buyer indemnity

The Buyer indemnifies the Sellers against all Liability arising from or connected with a breach of any Buyer Warranty.

15 Goods and Services Tax

15.1 Definitions

In this clause 15:

(a) words used in this clause which have a particular meaning in the GST Law have the same meaning, unless the context otherwise requires;

(b) any reference to GST payable by a Party includes any corresponding GST payable by the representative member of any GST group of which that Party is a member; and

(c) if the GST Law treats part of a supply as a separate supply for the purpose of determining whether GST is payable on that part of the supply or for the purpose of determining the tax period to which that part of the supply is attributable, such part of the supply is to be treated as a separate supply.

15.2 **Input Taxed**

(a) The Parties agree that the Supply of Sale Shares under this Agreement is a Financial Supply by the Sellers to the Buyer.

(b) Unless GST is expressly included, any payment expressed to be payable under any other clause for any supply made under or in connection with this Agreement does not include GST.

15.3 **Gross up for GST if the supply is not Input Taxed**

(a) The Buyer acknowledges that the Total Consideration agreed under this Agreement has been agreed on the basis that the supply of the Sale Shares is an Input Taxed Supply under the GST Act.

(b) Subject to clause 15.3(c), if for any reason GST is or becomes payable by the Supplier on a taxable supply under this Agreement, the Recipient must pay an additional amount to the Supplier, as applicable, on account of the GST payable by the Supplier on that Supply (**GST Amount**).

(c) Payment of the GST Amount pursuant to clause 15.3(b) is subject to the Supplier first providing a Tax Invoice to the Recipient and to the extent the Supplier holds them, copies of all correspondence with the Australian Taxation Office (including notices of assessments) confirming that GST is payable.

(d) The Recipient will pay the GST amount to the Supplier at the same time as the consideration for the Supply is paid to the Supplier unless the payment of GST refers to a Supply that had already been paid for by the time the GST liability on that Supply is known in which case the Recipient will pay the GST amount to the Supplier within 30 days after the GST liability is known.

(e) To the extent that any Supply made under or in connection with this Agreement is a taxable Supply, the GST exclusive consideration otherwise payable for that Supply is increased by an amount equal to that consideration multiplied by the rate at which GST is imposed in respect of the Supply, and is payable at the same time as the consideration for the Supply is payable (provided that a tax invoice in respect of the Supply has been received by the relevant party prior to the time at which the consideration for the Supply is payable).

15.4 **Parties' obligations to provide documentation**

Each Party agrees to do all things, including providing tax invoices and other documentation, that may be necessary or desirable to enable or assist each other Party to claim any input tax credit, adjustment or refund in relation to any amount of GST paid or payable in respect of any supply made under or in connection with this Agreement.

15.5 **Payment by reimbursement or indemnity**

If a payment to a Party under this Agreement is a payment by way of reimbursement or indemnity and is calculated by reference to the GST inclusive amount of a loss, cost or expense incurred by that Party, then the payment is to be reduced by the amount of any input tax credit to which that Party is entitled in respect of that loss, cost or expense before any adjustment is made for GST pursuant to clause 15.3.

16 **Confidentiality**

16.1 **General obligation**

(a) Subject to clause 16.1(b), each Party must keep confidential:

(i) the existence and terms of this Agreement (and any draft of this Agreement); and

(ii) all negotiations in connection with it and the transactions contemplated by it, and must ensure that their respective Personnel do likewise.

(b) A Party may disclose information:

(i) to its Related Bodies Corporate and its and their officers and employees and respective professional advisers who need to know the information and who are under an obligation to keep it confidential;

(ii) to a person whose consent is needed in connection with this Agreement if the party seeking consent gets the consenting person to agree to keep the information confidential (and then only to the extent that the consenting person needs to know the information in order to decide whether to consent);

(iii) if that information is in the public domain (other than because the party has disclosed it in breach of this clause);

(iv) if the Party lawfully had the information before it was disclosed to them in connection with this Agreement;

(v) with the consent of each other Party in writing;

(vi) in connection with legal or other proceedings relating to this Agreement;

(vii) if compelled by law or by an authority such as a Governmental Agency, court, tribunal or stock exchange; or

(viii) if this Agreement expressly requires or permits a Party to disclose information.

(c) A Party disclosing under clause 16.1(b)(vii) and clause 16.1(b)(viii) must, as far as practical, consult with each other Party beforehand as to the content and timing of the disclosure.

16.2 **Confidentiality obligations of Buyer**

Subject to any disclosure which is permitted under clause 16.1:

(a) until Completion, the Buyer must and must ensure that its Personnel keep confidential and do not use any confidential information relating to the Business or the Company Group; and

(b) if this Agreement is terminated for any reason before Completion then:

(i) subject to any applicable law, the Buyer must, on demand, return or delete all confidential information in its possession relating to the Business and the Company Group;

(ii) the Buyer must itself and must procure that its Personnel maintain the confidentiality of all confidential information relating to the Business and the Company Group in their possession or under their control, and such obligation shall continue after termination of this Agreement in accordance with clause 16.4; and

(iii) the Buyer may not itself and must procure that its Personnel do not make any use, whether directly or indirectly or howsoever, of any confidential information relating to the Business and the Company Group in their possession or under their control, and such obligation will continue after termination of this Agreement in accordance with clause 16.4.

16.3 **Agreement on press announcements**

(a) Except as may be required by law or to meet the requirements of any securities exchange or other financial market for continuous disclosure or periodic reporting purposes, no Party will make any public or press announcement or statement concerning this Agreement or Completion without the prior written approval of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.

(b) If the Buyer is intending to make any public or press announcement or statement concerning this Agreement and the transactions contemplated by it, then the Parties must use reasonable endeavours to agree at or before Completion on the form of any such announcement or statement that the Buyer will make.

16.4 **Continuing obligation**

This clause 16 continues to bind the Parties after Completion and after the Parties' other obligations under this Agreement terminate.

16.5 **Confidentiality obligations of Sellers**

Following Completion, the Sellers must and must ensure that their Personnel keep confidential, do not disclose to any person, and do not use any confidential information relating to the Business or the Company Group.

17 Restraint

17.1 **Restraint**

Each Seller (in respect of itself only) and each Restrained Individual (in respect of himself only) agrees that it/he/she will not and will procure that each of its Related Bodies Corporate and Related Entities do not, directly or indirectly, on their own account, or for or on behalf of or through any person or entity, do any of the following in the Restraint Area or during the Restraint Period:

(a) carry on, participate in, assist in or otherwise be directly or indirectly involved in as a director, consultant, adviser, contractor, principal, manager, employee, partner, associate, or financier of, any business or venture which is the same as, substantially similar to or competitive with the Business;

(b) solicit, canvass, induce, entice away or encourage any person or entity known to it to leave their employment or engagement with the Company Group;

(c) solicit, canvass, approach or accept any approach from any person or entity who was at any time during the immediately preceding 12 months a customer or supplier of the Company Group, with a view to establishing a relationship with or obtaining the custom of that person or entity; or

(d) interfere or seek to interfere with the relationship between the Company Group and its clients, customers, employees or suppliers in the conduct of the Business.

17.2 **Acknowledgements**

(a) The Parties acknowledge that:

(i) the restraints contained in this clause 17.1(a), resulting from each combination of Restraint Area and Restraint Period and each sub-paragraph in clause 17.1(a), are separate, distinct and several;

(ii) each obligation created by clause 17.1(a), as construed according to this clause 17, is severable from any other such obligation and, if held to be unenforceable, does not affect the enforceability of any other such obligation which would otherwise remain;

(iii) this clause 17 confers a benefit on the Buyer which is no more than that which is reasonably and necessarily required by the Parties for the maintenance and protection of the goodwill of the Business; and

(iv) it is the intention of the Parties that all combinations of such prohibitions and restrictions will apply and be enforceable and that only those which a court, in exercising its discretion, may hold to be an unreasonable restraint of trade will be severed.

(b) The Parties acknowledge and agree that damages would not be an adequate remedy for any breach of the restraints contained in this clause 17 and the remedies of injunction, specific performance and other equitable relief are appropriate for any threatened or actual breach of this clause.

(c) A Seller or a Restrained Individual will not be in breach of clauses 17.1 or 17.2:

(i) if they have an interest in IHL Shares;

(ii) if they have an interest in securities which are listed on a recognised securities exchange or financial market, so long as the interest in the securities is less than 5% of the voting rights (if any) attaching to the issued securities of that class; or

(iii) when performing any employment agreement or contracting arrangement for the Company Group; or

(iv) when undertaking any act required or anticipated by this Agreement, or any act otherwise undertaken with the prior written consent of the Buyer.

18 Continuing obligations

18.1 No merger

The rights and obligations of the Parties (including in relation to warranties, undertakings and indemnities) do not merge on the completion of any transaction contemplated by this Agreement. They also survive the execution and delivery of any conveyance, assignment, transfer or other document entered into for the purpose of implementing any transaction contemplated by this Agreement.

18.2 Survival

Any term by its nature intended to survive termination of this Agreement survives termination of this Agreement.

19 Notices

19.1 Notices

(a) A notice under this Agreement must be in writing and signed by or on behalf of the sender addressed to the recipient and:

(i) delivered by personal service;

(ii) sent by pre-paid mail; or

(iii) transmitted by e-mail,

to the recipient's address set out in this Agreement.

(b) A notice given to a person in accordance with this clause is treated as having been given and received:

(i) if delivered in person, on the day of delivery;

(ii) if sent by pre-paid mail within Australia, on the third Business Day after posting;

(iii) if sent by pre-paid airmail to an address outside Australia or from outside Australia, on the fifth Business Day (at the address to which it is posted) after posting; and

(iv) if transmitted by email, on the day of transmission, provided that the sender does not receive an automated notice generated by the sender's or the recipient's email server that the email was not delivered.

(c) A Party may change its address for service by giving notice of that change to each other Party.

(d) The provisions of this clause 19.1 are in addition to any other mode of service permitted by law.

(e) If a notice is sent by any method other than pre-paid mail, and that notice is received:

(i) on a day which is not a Business Day; or

(ii) after 5:00pm on a Business Day,

that notice is deemed to be received at 9am on the next Business Day.

(f) A notice sent or delivered in a manner provided by clause 19.1 must be treated as validly given to and received by the Party to which it is addressed even if the addressee has been liquidated or deregistered or is absent from the place at which the notice is delivered or to which it is sent.

(g) If the Party to which a notice is intended to be given consists of more than 1 person then the Notice must be treated as given to that Party if given to any of those persons.

19.2 **Sellers' and Restrained Individual's address**

The Sellers' and Restrained Individual's address for service and email address are:

Name: George Anastassov

Email address:
Address:
Copy to: APIRx Pharmaceuticals, LLC

Name: Prasch B.V. and Lekhram Changoer

Attention: Lekhram Changoer
Email address:
Address:
Copy to: Prasch B.V.
APIRx Pharmaceuticals Holding BV

Name: Eric Kim

Email address:
Address: Copy to: APIRx Pharmaceuticals, LLC

19.3 **Buyer's address**

The Buyer's address for service and email address are:

Name: Incannex Healthcare Limited ACN 096 635 246

Attention: Joel Latham, Managing Director
Email address:
Address:
Copy to: Thomson Geer
Attention: David Schiavello
Email:

20 General

20.1 Costs

(a) Each Party will be responsible for its own costs and expenses of and in connection with and incidental to the preparation and carrying into effect of this Agreement and for the preparation of any document contemplated under the terms of this Agreement.

(b) Any Duty or other taxes of a similar nature (including fines, penalties and interest) in connection with this Agreement or any transaction contemplated by this Agreement, must be paid by the Buyer.

20.2 Governing law and jurisdiction

(a) This Agreement is governed by and is to be construed in accordance with the laws applicable in Victoria, Australia.

(b) Each Party irrevocably and unconditionally submits to the non-exclusive jurisdiction of the courts of Victoria, Australia and any courts which have jurisdiction to hear appeals from any of those courts and waives any right to object to any proceedings being brought in those courts.

20.3 Severability

If a provision of this Agreement is illegal or unenforceable in any relevant jurisdiction, it may be severed for the purposes of that jurisdiction without affecting the enforceability of the other provisions of this Agreement.

20.4 Further assurance

Each Party must promptly do whatever any other Parties reasonably require of it to give effect to this Agreement and to perform its obligations under it.

20.5 Consents

Except as expressly stated otherwise in this Agreement, a Party may conditionally or unconditionally give or withhold consent to be given under this Agreement and is not obliged to give reasons for doing so.

20.6 Rights, powers and remedies

(a) Except as expressly stated otherwise in this Agreement, the rights of a Party under this Agreement are cumulative and are in addition to any other rights of that Party.

(b) A Party's failure or delay to exercise a right, power or remedy does not operate as a waiver of that right, power or remedy.

(c) A single or partial exercise or waiver by a Party of a right relating to this Agreement does not prevent any other exercise of that right or the exercise of any other right.

(d) Except as expressly stated otherwise in this Agreement, a Party may exercise a right, power or remedy (including giving or withholding its approval or consent) entirely at its discretion (including by imposing conditions).

(e) In exercising, or deciding not to exercise, a right, power or remedy, a Party is not required to take into account any adverse effect on another Party.

(f) Each Party agrees to comply with the conditions of any approval, consent or waiver given by another Party.

(g) Waiver of a right, power or remedy is effective only in respect of the specific instance to which it relates and for the specific purpose for which it is given.

(h) A Party is not liable for any loss, cost or expense of any other Party caused or contributed to by the waiver, exercise, attempted exercise, failure to exercise or delay in the exercise of a right.

20.7 **Amendment**

This Agreement may only be varied or replaced by a document executed by the Parties.

20.8 **Assignment**

(a) A Party must not assign, subject to clause 20.8(b), create or allow to exist any Third Party interest over or deal with, any right under this Agreement without the prior written consent of the other Parties.

(b) The parties acknowledge and agree that the Buyer may grant a security interest in respect of this Agreement in favour of its financier, the Commonwealth Bank of Australia.

(c) Any purported dealing in breach of clause 20.8 is ineffective.

20.9 **Counterparts**

This Agreement may consist of a number of counterparts and, if so, the counterparts taken together constitute one agreement. Delivery of an image of an executed counterpart of this Agreement by PDF file (portable document format file) shall be as effective as delivery of a physically executed counterpart of this Agreement.

20.10 **Entire understanding**

(a) This Agreement contains the entire understanding between the Parties as to the subject matter of this Agreement.

(b) All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. No Party is liable to any other in respect of those matters.

(c) No oral explanation or information provided by any Party to another:

(i) affects the meaning or interpretation of this Agreement; or

(ii) constitutes any collateral agreement, warranty or understanding between any of the Parties.

20.11 **Execution by attorney**

Where this Agreement is executed by an attorney, that attorney, by executing, declares that it has no notice of revocation, termination or suspension of the power of attorney under which it executes this Agreement.

20.12 **Time of the essence**

(a) Time is of the essence of this Agreement.

(b) If the Parties agree to vary a time requirement (including in this Agreement), the time requirement so varied is of the essence of this Agreement.

(c) An agreement to vary a time requirement set out in this Agreement must be in writing.

Schedule 1

Sellers' Details

Sellers	Number of Sale Shares (legal interest)	Number of Sale Shares (beneficial interest)	Respective Proportion	Details
(Column 1)	**(Column 2)**	**(Column 3)**	**(Column 4)**	**(Column 5)**
Prasch B.V. (RSIN: 818249377 and establishment number: 000013850849)	104,687,500	95,937,500	46%	**Address:** **Attention:** Lekhram changoer **Email address:**
George E. Anastassov	104,687,500	95,937,500	46%	**Address:** **Attention:** George E. Anastassov **Email address:**
Eric Kim	0	17,500,000	8%	**Address:** **Attention:** Eric Kim **Email address:**
Total	**209,375,000**	**209,375,000**	**100%**	-

Schedule 2

Group details

1 Company

Company name	APIRx Pharmaceutical USA, LLC
Previous names	None
Registered office	
Date of registration	9 January 2019
State of registration	Delaware
Share capital	209,375,000 shares
Shareholders	Prasch B.V. (RSIN: 818249377 and establishment number: 000013850849) George Anastassov Eric Kim
Directors	George Anastassov & Lekhram Changoer
Secretary	Eric Kim
Public Officer	George Anastassov

2 Subsidiaries

2.1 **APIRx Pharmaceuticals B.V.**

Company name	APIRx Pharmaceuticals BV
Previous names	None
RSIN	859123066
Establishment Number	000040584488
Registered office	
Date of registration	31 August 2018
State of registration	IJsselstein, The Netherlands
Share capital	100 common shares
Shareholder	APIRx Pharmaceuticals Holding BV
Directors	Lekhram Changoer & George Anastassov
Secretary	Eric Kim
Public Officer	Lekhram Changoer

2.2 **APIRx Pharmaceuticals Holdings B.V.**

Company name	APIRx Pharmaceuticals Holding BV
RSIN	859121872
Establishment Number	000040581861
Registration number	72474386
Registered office	
Date of registration	31 August 2018
Country of registration	The Netherlands
Share capital	100 common shares 2 priority shares
Shareholders	Prasch BV (30228278) George Anastassov
Directors	Lekhram Changoer & George Anastassov
Secretary	Eric Kim

Schedule 3

Conditions

Completion is conditional upon and will not proceed unless prior to the Completion Date:

1 (**Escrow Deed**) Each of the Sellers enters into an Escrow Deed in respect of the Subscription Shares held by them.

2 (**Due Diligence Investigation**) The Buyer confirming that it has had the opportunity to conduct a Due Diligence Investigation and it is satisfied with the results of that investigation.

3 (**Buyer shareholder approval**) The Buyer's shareholders approve the issue of the Subscription Shares to the Sellers, in accordance with ASX Listing Rule 7.1.

4 (**Approvals and consents**) The Buyer obtaining any approvals or consents required in connection with the transactions described in this Agreement (including for the avoidance of any doubt any government, regulatory (including ASX, ASIC and Nasdaq).

5 (**Acquisition**) The Company has completed its acquisition of:

(a) the entire issued share capital of APIRx Pharmaceuticals B.V and APIRx Pharmaceuticals Limited; and

(b) all of the pharmaceutical and non-pharmaceutical assets of APIRx Pharmaceuticals B.V and APIRx Pharmaceuticals Limited.

6 (**Foreign resident CGT withholding**) Each of the Sellers has complied with the most recent request (if any) made by the Buyer to that Seller pursuant to clause 9.2.

Schedule 4

Completion Steps

1 Sellers' Completion obligations

1.1 Seller's delivery obligations

At Completion, the Sellers must deliver to the Buyer:

(a) (**Evidence of Sale Shares being Encumbrance free**) evidence that at Completion, all of the Sale Shares are or will be free of Encumbrances, and all of the assets of the Company Group are or will be free of Encumbrances (other than Permitted Encumbrances);

(b) (**Share transfers**) all documentation required to formally transfer ownership of the Sale Shares to the Buyer, such documentation having been duly executed by the Sellers (if required);

(c) (**Share certificates**) share certificates for the Sale Shares or, where the share certificates cannot be located, a deed poll of indemnity and statutory declaration on terms satisfactory to the Buyer;

(d) (**Certificate**) a certificate from the Sellers in a form acceptable to the Buyer confirming, as far as the Sellers' are aware (having made reasonable and diligent enquires as contemplated in clause 1.2(s)), there has been no breach of a Sellers' Warranty as at the Completion Date;

(e) (**Bank account**) such documents reasonably required by the Buyer to cause the revocation with effect from Completion of all bank accounts of the Company Group;

(f) (**Termination of Shareholders Agreement**) a deed of termination of the Shareholders Agreement duly executed by all persons that are party to it in a form acceptable to the Buyer (acting reasonably);

(g) (**Power of attorney**) any power of attorney or other authority under which the transfers of the Sale Shares are executed;

(h) (**Records**) the Records, including the corporate registers (including any common seals) and constitutions of each Company Group Entity, by making them available to the Buyer at the offices where they are usually retained, other than the corporate register of each Company Group Entity which must be delivered at Completion.

1.2 Completion meetings

At Completion, the Sellers must ensure that the directors of each Company Group Entity pass written resolutions resolving, as applicable:

(a) to register the transfer of the Sale Shares in the register of members of the Company;

(b) to cancel the existing share certificates for the Sale Shares and issue a new share certificate in the name of the Buyer for the Sale Shares;

(c) to appoint as directors, secretary and public officer of the relevant Company Group Entities those persons nominated by the Buyer under clause 5.6, subject to those persons providing their written consent;

(d) to accept the resignations set out in paragraph **Error! Reference source not found.** of this Schedule 4, subject to such persons providing their written resignation to act as officers;

(e) to transfer the registered office of the relevant Company Group Entity to the address nominated by the Buyer;

(f) if required by the Buyer, to revoke all existing banking authorities given by the relevant Company Group Entity (including authorities to operate bank accounts over the internet); and

(g) to revoke all existing powers of attorney or other authorities granted by the relevant Company Group Entity.

2 Buyer's Completion obligations

2.1 Buyer's delivery obligations

At Completion, the Buyer must:

(a) execute all documentation required to formally transfer ownership of the Sale Shares from the Sellers to the Buyer (if required); and

(b) deliver to the Sellers holding statements for the Subscription Shares, duly executed by the Buyer.

2.2 Completion meetings

At Completion, the Buyer must ensure that a written resolution is passed:

(a) to approve the issue and allotment of the Subscription Shares;

(b) to appoint George as a director of the Buyer;

(c) to enter the names of the relevant Sellers in the register of members of the Buyer as the registered holders of the Subscription Shares in their Respective Proportions; and

(d) issue holding statements in the names of the relevant Sellers for the Subscription Shares.

Schedule 5

Sellers' Warranties

1 The Sellers

(a) (**Power and capacity**) Each Seller has complete and unrestricted power and authority to enter into this Agreement and perform its obligations under this Agreement.

(b) (**Binding**) This Agreement constitutes valid and binding obligations of the Sellers, enforceable against the Sellers in accordance with its terms.

(c) (**No legal impediment**) The execution, delivery and performance by each Seller of this Agreement complies with:

(i) each law by which it is bound and which would prevent it from entering into and performing its obligations under this Agreement;

(ii) any instrument to which the Seller is a party or by which the Seller is bound and which is material in the context of the transactions contemplated by this Agreement; or

(iii) any order, judgment or decree of any court or Governmental Agency to which the Seller is a party or by which it is bound and which is material in the context of the transactions contemplated by this Agreement.

(d) (**Solvency**): No:

(i) Insolvency Event has occurred in respect of a Seller;

(ii) trustee or other similar person has been or is appointed in relation to all or any undertaking or material asset of a Seller;

(iii) mortgagee or chargee has taken, attempted or indicated an intention to take, possession of all or any undertaking or material asset of a Seller; and

(iv) event has taken place with respect to a Seller which would make or deem the Seller to be insolvent under any law applicable to it.

(e) (**No adverse proceedings**) No legal proceedings, arbitration, mediation or other dispute resolution process is taking place, pending or threatened, the outcome of which is likely to have a material and adverse effect on the ability of a Seller to perform its obligations under this Agreement.

(f) (**Trust**) Where a Seller enters into this Agreement as trustee of a trust it warrants in its capacity as trustee of the trust that:

(i) in respect of the trust, no action has been taken or is now proposed to be taken to terminate or dissolve the relevant trust; and

(ii) in respect of the trustee:

(A) it has full and valid power and authority under the terms of the relevant trust to enter into this Agreement and to carry out the transactions contemplated by this Agreement;

(B) it has in full force and effect the authorisations necessary for it to enter into this Agreement and perform its obligations under it and allow them to be enforced (including under the relevant trust deed and its constitution (if any));

(C) it enters into this Agreement and the transactions contemplated by this Agreement for the proper administration of the relevant trust and for the benefit of all the beneficiaries of the relevant trust;

(D) it is the sole trustee of the relevant trust and no action has been taken or is now proposed to be taken to remove it as trustee of the relevant trust;

(E) it has a right, including after any set off, to be fully indemnified out of the assets of the relevant trust in respect of obligations incurred by it under this Agreement;

(F) it is not in breach of any of its obligations as trustee of a trust, whether under the trust deed or otherwise; and

(G) it is not in default under the terms of the relevant trust.

2 Sale Shares

(a) (**Owner of Sale Shares**) Each Seller is the registered holder of the Sale Shares set out in Column 2 of the table in Schedule 1 adjacent to its name.

(b) (**No Encumbrances**) At Completion, the Sale Shares will be free from any Encumbrance.

(c) (**Valid**) The Sale Shares:

(i) are fully paid;

(ii) were validly issued; and

(iii) comprise the whole of the issued capital of the Company.

(d) (**No restrictions**) At Completion, there are no restrictions on the transfer of the Sale Shares.

(e) (**No outstanding rights**) At Completion, there will be no outstanding options, warrants, rights, calls, convertible or exchangeable securities or other commitments (other than this Agreement) pursuant to which the Company is obliged to issue, redeem or repurchase, or any third party is entitled to purchase or otherwise acquire, any shares in the capital of or other securities or interests in the Company.

(f) (**No right to acquire**) No person other than the Buyer (in accordance with the terms of this Agreement) has, or will have, any right (including any option or right of first refusal) to acquire any Sale Shares, options, units or any other securities in the capital of the Company or to create or issue any debentures.

3 Status of the Company Group

(a) (**Accurately described**) The details of each Company Group Entity as set out in Schedule 2 are accurate.

(b) (**Incorporated**) Each Company Group Entity is duly incorporated and validly exists under the law of its place of incorporation.

(c) (**Solvency**) No:

(i) Insolvency Event has occurred in respect of a Company Group Entity;

(ii) meeting has been convened, resolution proposed, petition presented or order made for the winding up of a Company Group Entity;

(iii) receiver, receiver and manager, provisional liquidator, liquidator or other officer of the court, or other person of similar function has been appointed in relation to all or any material assets of a Company Group Entity;

(iv) security holder, mortgagee or chargee has taken, attempted or indicated an intention to exercise its rights under any security of which a Company Group Entity is the security provider, mortgagor or chargor;

(v) event has taken place with respect to a Company Group Entity which would make or deem it to be insolvent under any law applicable to it (including within the meaning of section 95A of the Corporations Act);

(vi) Company Group Entity is unable to pay its debts as and when they fall due; or

(vii) Company Group Entity is subject to voluntary administration under any law applicable to it (including Part 5.3A of the Corporations Act).

(d) (**No partnership**) None of the Company Group carry on business in partnership with any other person.

(e) (**Register and statutory books**) The register of members of each Company Group Entity is accurate and:

(i) the statutory books and other statutory registers of each Company Group Entity are up to date and comply with applicable statutory requirements; and

(ii) no person has any right to obtain an order for the rectification of the register of members of a Company Group Entity.

(f) (**No outstanding rights**) At Completion, other than as contemplated by this Agreement:

(i) there will be no outstanding options, warrants, rights, calls, convertible or exchangeable securities or other commitments pursuant to which a Company Group Entity is obliged to issue, redeem or repurchase, or any Third Party is entitled to purchase or otherwise acquire, any Sale Shares in the capital of or other securities or interests in a Company Group Entity; and

(ii) no person has, or will have, any right (including any option or right of first refusal) to acquire any Sale Shares, options, units or any other securities in the capital of a Company Group Entity.

(g) (**No membership**) No Company Group Entity is a member (otherwise than through the holding of share capital) of any corporate or unincorporated body, undertaking or association (other than a trade association) or holds shares in any company.

(h) (**No power of attorney**) No Company Group Entity has granted any power of attorney or similar authority which remains in force.

(i) (**Not trustee**) No Company Group Entity acts as trustee of any trust or settlement.

4 Financial information

(a) (**Historical financial information**) The historical financial information provided to the Buyer in respect of the Company Group is true and correct in all material respects.

(b) (**Status of Accounts**) The Accounts:

(i) comply with all applicable statutory requirements; and

(ii) give a true and fair view of:

(A) the financial position and the assets and liabilities of each Company Group Entity as at the Accounts Date; and

(B) the income, expenses and operational results of each Company Group Entity for the financial period ended on the Accounts Date.

(c) (**Status of Management Accounts**) The Management Accounts:

(i) have been prepared with due care and attention and show an accurate view of the state of affairs, profit and loss and financial position of the Company Group as at and for the period in respect of which, and at the time at which, they have been prepared, but the Buyer acknowledges that they are not audited; and

(ii) have been prepared from the Accounts Date for each month up to and including the month before the Completion Date in a manner consistent with preparations of the Management Accounts before the Accounts Date.

(d) (**Position since the Accounts Date**) Since the Accounts Date:

(i) there has been no Material Adverse Change;

(ii) each Company Group Entity has carried on the Business in the ordinary course (having regard to the nature of the Business) other than the transactions contemplated under this Agreement and actions taken by each Company Group Entity to mitigate adverse impacts on the Business caused by the COVID-19 economic environment;

(iii) no dividend, share buyback, capital return, capital reduction or other distribution of capital or income has been or agreed to be declared, made, paid or determined to be payable in respect of the share capital of a Company Group Entity, whether of cash, specific assets or otherwise other than in accordance with this Agreement;

(iv) no Company Group Entity has incurred any capital expenditure other than in the ordinary course of business and has not entered into any legal or financial commitments to incur any future capital expenditure;

(v) no Company Group Entity has waived any right or a debt owed to it;

(vi) no Company Group Entity has granted any Encumbrances over any of its inventory or assets otherwise than in the ordinary course;

(vii) no Seller nor the Company Group has done, or omitted to do, anything which itself has:

(A) prejudiced the continuing goodwill of the Business; or

(B) resulted in any person ceasing or refusing to transact business or contract with any Company Group Entity other than in good faith or to vary in good faith the terms on which such person/entity transacts business with any Company Group Entity;

(viii) there has been no material adverse change in the assets, liabilities, turnover earnings, financial condition, trading position, affairs or prospects of the Business;

(ix) no Company Group Entity has incurred or undertaken any actual liabilities or obligations, including Tax, except in the ordinary course of business;

(x) no Company Group Entity has acquired or disposed of or dealt with any assets, nor has it entered into any agreement or option to acquire or dispose of an assets other than in the normal course of business for full market value;

(xi) no Company Group Entity has paid or agreed to pay any retiring allowance or superannuation benefit to any of its officers or employees except where the law requires;

(xii) no Company Group Entity has made any adverse changes to its terms of trade, including price;

(xiii) no supplier of any Company Group Entity has:

(A) reduced the level of its supplies to the Company Group Entity; or

(B) indicated an intention to cease or reduce the volume of its trading with the Company Group Entity after Completion; or

(C) altered the terms on which it trades with the Company Group Entity;

(xiv) no customer of any Company Group Entity has:

(A) terminated or has indicated that it may terminate any contract with it;

(B) reduced the level of its custom with the Company Group Entity as a consequence of a breach by the Company Group Entity of its obligations to any major customer, or any major customer being unwilling to deal with the Company Group Entity as a result of service delivery inadequacies on the part of the Company Group Entity;

(C) indicated an intention to cease or reduce the volume of its trading with the Company Group Entity after Completion; or

(D) altered the terms on which it trades with the Company Group Entity;

(xv) no loans have been made by a Company Group Entity to Employees or Contractors, nor have any advances or loan money been accepted from any Employees or Contractors; and

(xvi) no resolutions have been passed by the members or directors of any Company Group Entity except in the ordinary and usual course of business of the Company Group Entity and those necessary to give effect to this Agreement.

(e) (**Share capital**) All dividends, share buy backs, capital returns, capital reductions or other distributions or profits or assets declared, made or paid by each Company Group Entity in the 3 years preceding Completion has been declared, made and paid (as applicable) in accordance with law and its constituent (or equivalent) documents.

(f) (**No completion bonuses**) There are no bonuses or other incentive payments payable by each Company Group Entity to any Employee or Contractor in relation to the transactions contemplated by this Agreement.

5 Information

(a) The information set out in Schedule 1, Schedule 2 and Schedule 7 is complete and accurate in all material respects and the information disclosed to the Buyer in connection with the Due Diligence Investigation is complete and accurate in all material respects.

(b) The information disclosed by the Sellers to the Buyer regarding the Company Group and the Business is, in all material respects, complete, reliable, true and accurate in respect of the facts represented in it.

(c) The Sellers have not disclosed any information to the Buyer regarding the Company Group and the Business that is false or misleading in any material respect.

(d) The Sellers have disclosed to the Buyer all matters concerning the Company Group and the Business which a prospective buyer in the Buyer's position would reasonably require for the purpose of making a decision whether the acquire the Sale Shares.

(e) The Sellers have not intentionally or recklessly omitted to disclose any information which would be likely to affect the Buyer's decision to purchase the Sale Shares on the terms of this Agreement.

6 Property

(a) (**Leases binding**) The Property Lease is registered, legally valid and subsisting.

(b) (**Property Leases**) No lessor or lessee under the Property Lease has:

(i) defaulted in the payment of rent or other moneys;

(ii) breached any other material obligation;

(iii) served any notice to terminate the relevant Property Lease; or

(iv) knowingly waived any breach of covenant, obligation or restriction under a lease.

7 Assets

Any assets required to carry on the Business or any assets held in connection with the Business:

(a) have been Fairly Disclosed to the Buyer;

(b) are held by the Company Group; and

(c) are not Encumbered.

8 Compliance with statutory requirements

(a) (**Holds Authorisations**) Each Company Group Entity:

(i) holds all necessary Authorisations for the proper carrying on of the Business; and

(ii) has complied with the terms of all those Authorisations.

(b) (**Complied with Authorisations**) All Authorisations have been complied with and there is no fact or matter which might prejudice the continuance or renewal, or result in the revocation, of any licence or other Authorisation.

(c) (**Applicable laws**) The Company Group has complied with all requirements of applicable laws and administrative requirements in Australia or any jurisdiction in which any Company Group Entity develops, manufactures, packages, labels, tests, markets or sells products and services and no contravention or allegation of any contravention of any applicable law or administrative requirement is known to the Company Group or any Seller.

(d) (**Disclosure**) The Sellers have Fairly Disclosed to the Buyer:

(i) all Authorisations necessary for the carrying on of the Business which are material to the conduct of the Business as it is being carried on at Completion;

(ii) all conditions and notices attaching or applicable to the licences referred to in paragraph 8(d)(i).

(e) (**Notice**) No Seller nor any Company Group Entity has received any notice that any Authorisation will be revoked, suspended, modified or will not be renewed.

(f) No product of the Company Group has been recalled, suspended or discontinued, nor have any Company Group Entities received any written notice, warning letter or other communication from any Governmental Agency that they are not, or any product is not, in compliance with applicable Authorisations, nor have any Company Group Entities received any written notice from any Governmental Agency that it has commenced, or threatened to initiate, any action to withdraw approval, place sales or marketing restrictions on or request the recall of any product, or that it has commenced or threatened to initiate any action to enjoin or place restrictions on the production of any product by a Company Group Entity.

(g) No officer, employee or agent of the Company Group has made an untrue statement of a material fact or fraudulent statement to any Governmental Agency regarding any product or failed to disclose a material fact required to be disclosed to a Governmental Agency in connection with the Business, in each case in violation of any applicable law.

9 Employees and Contractors

(a) As at the date provided, the Sellers have provided to the Buyer the full and correct particulars of the Employees and Contractors including their:

(i) length of service;

(ii) remuneration;

(iii) annual leave and long service leave entitlements;

(iv) terms of employment or engagement; and

(v) superannuation entitlements and payments.

(b) (**Contracts, arrangements and understandings**) There are no contracts, arrangements or understandings with Employees or Contractors of the Company Group other than as Fairly Disclosed to the Buyer.

(c) (**Investigations**) The Company Group has not been investigated or audited by any regulator in relation to its compliance with workplace laws or instruments within the last 3 years.

(d) (**No commitment**) No Company Group Entity has given any commitment (whether legally binding or not) and is not, as at the date of this Agreement, engaged in any negotiations, to increase or supplement any remuneration, compensation or benefit of any Employee or Contractor other than in the ordinary course of business.

(e) (**Industrial action**) There is no industrial action on foot, and there is no issue which may lead to industrial action by Employees or any industrial organisation of employees which may disrupt the Business or cause it to incur financial expenditure.

(f) (**Compliance**) Each Company Group Entity has complied with all its obligations arising under law, equity, statute (including occupational health and safety, annual leave, long service leave, equal opportunity, anti-discrimination, Tax, superannuation, workers compensation and workplace or industrial laws), award, enterprise agreement or other instrument made or approved under any law with respect to Employees and Contractors.

(g) (**Superannuation obligations**) Each Company Group Entity has complied with, and until the Completion Date will continue to comply with, all its superannuation related obligations and commitments in relation to the Employees and where applicable, Contractors and former contractors.

(h) (**Membership change**) No Company Group Entity has made any contract, arrangement, understanding or representation (whether written or oral) under which one or more employees, contractors or agents will or may be entitled to any benefit (monetary or otherwise) if ownership (direct or indirect) of the Company Group Entity changes as a consequence of Completion, or any other change in control of the Company Group Entity.

(i) (**Ability to terminate**) All contracts of employment between the Company Group Entity and an Employee and any contracts between a Contractor and the Company Group Entity will be capable of being terminated by the Company Group Entity by giving 5 weeks' notice or less, subject to applicable law.

(j) (**No obligation**) Subject to applicable law, no Company Group Entity is under any obligation to pay any of its current or former directors, officers or employees or contractors or former contractors any amount as compensation for loss of office, or any superannuation payment or gratuities.

(k) (**Claims from Employees**) No Claim has been made, and no Company Group Entity has received written notice of any potential claim, by or on behalf of any past or present director, officer, employee or contractor against the Company Group Entity and is not aware of any circumstances which would give rise to a Claim including:

(i) underpayment of salary, wages, allowances, overtime, bonuses, commissions or other similar entitlements;

(ii) working conditions or award requirements;

(iii) contributions to superannuation funds;

(iv) workers compensation claims or common law claims for injury or any kind of disease;

(v) personal or other leave benefits; or

(vi) redundancy or severance payments or payments in lieu of notice.

(l) (**Awards and enterprise agreements**) There are no awards, enterprise agreements or other instruments made or approved under law which apply to the Employees.

(m) (**Bonus scheme**) No Company Group Entity operates a bonus, profit share or employee incentive plan or scheme for its Employees or officers.

(n) (**Injuries**) As far as the Sellers are aware, none of the Employees has any existing injury, disability or illness which may adversely affect their ability to perform their normal duties as an Employee in the Business.

(o) (**Entitlement to work in jurisdiction**) All Employees and Contractors and their personnel who perform work for the Company Group are entitled to work in the jurisdiction in which they perform their services.

(p) (**No wrong classification**) No Contractor engaged by the Company Group is entitled or required to be treated as an employee of the Company Group at law.

(q) (**No notice of dismissal**) No Employee is under notice of dismissal or termination.

10 Litigation

(a) (**No proceedings**) No Company Group Entity is a party to or involved in any investigation, inquiry, litigation, prosecution, arbitration, mediation or any other form of dispute resolution process, proceeding or administrative or governmental proceedings.

(b) (**No threatened proceedings**) There is no litigation, prosecution or arbitration proceedings relating to a Company Group Entity pending, threatened or reasonably likely to arise and the Sellers are not aware of any facts or disputes likely to give rise to any litigation, prosecution or arbitration proceedings relating to the Company Group Entity.

(c) (**Unsatisfied judgments**) There are no unsatisfied judgments, awards, Claims or demands against any Company Group Entity.

(d) (**No customer Claims**) No Company Group Entity is a party to, the subject of, or involved in any existing, pending or threatened Claims brought by or on behalf of any customers of the Company Group Entity whenever or howsoever arising.

11 Insurance

(a) (**Compliance**) Each Company Group Entity has complied with all of the conditions to which the liability of the insurers is subject under the Insurance Policies.

(b) (**No expiry**) No Company Group Entity's Insurance Policies will expire before the Completion Date.

(c) (**Premiums**) All premiums in respect of the Insurance Policies which have become due for payment prior to Completion will have been paid prior to the Completion Date.

(d) (**Unpaid claims**) There are no individual or related claims made but unpaid under the Insurance Policies and there are no material threatened or pending claims or circumstances existing which could lead to such a claim being made.

(e) (**No notice**) No Company Group Entity has been notified by any insurer that it is required or advised to carry out any maintenance, repairs or other works in relation to any of the assets which remain outstanding.

(f) (**Adequate insurance**) Under the Insurance Policies:

(i) all of the assets of the Company Group of an insurable nature are insured in amounts representing their full replacement value against fire and other risks normally insured against; and

(ii) the Company Group is adequately insured for such amounts as would be maintained in accordance with prudent business practice in respect of all risks, whether in relation to damage to property, personal injury, public liability, workers' compensation, business interruptions insurance or otherwise.

12 Intellectual property

(a) (**Completeness**) Schedule 7 contains a complete and accurate list of all Intellectual Property Rights owned, registered or used by the Company Group and all documentation relating to those Intellectual Property Rights has been Fairly Disclosed to the Buyer.

(b) (**Intellectual Property Rights**) The Intellectual Property Rights specified in Schedule 7 comprise all of the Intellectual Property Rights necessary to enable the Business to be operated in the ordinary course.

(c) (**Owned IP**) The Company Group is, or will be pursuant to clause 7.6, the legal and beneficial owner of the Owned Intellectual Property Rights.

(d) (**Licensed IP**) All agreements under which the Company Group has the right to use, but not ownership of, Intellectual Property Rights used in connection with the Business are valid, binding and enforceable and the licensor has not given notice to terminate any of the licenses or intends to do so.

(e) (**No licensing**) The Company Group has not licensed or granted any rights in respect of, assigned or otherwise dealt with any of the Owned Intellectual Property Rights to any person.

(f) (**Fees**) There are no royalties, licence fees or other similar fees payable by the Company Group in connection with the use of any Intellectual Property Rights.

(g) (**Employees and Contractors**) The Company Group has the right, against its Employees and Contractors employed in or engaged in connection with the Business, to claim ownership and title to all the Intellectual Property Rights generated by those persons in the course of, or in connection with, the Business.

(h) (**No breach of IP licences**) The Company Group is not in breach of a material term of an Intellectual Property Licence or other agreement relating to the Intellectual Property Rights to which it is a party (whether as licensor or licensee) and, so far as the Sellers are aware, no Third Party is in breach of any such agreement.

(i) (**No third party infringement**) The use of the Owned Intellectual Property Rights does not infringe any Intellectual Property Rights of any third party, and the Sellers are not aware of any circumstances which are likely to give rise to any infringement.

(j) (**No unauthorised use**) The Sellers are not aware of any unauthorised use by any person of any Intellectual Property Rights or confidential information of the Company Group.

(k) (**No challenge**) There is not currently any unresolved challenge, dispute or claim which has been made, or as far as the Sellers are aware, threatened by any person with respect to any of the Intellectual Property Rights used in connection with the Business.

(l) (**Fees**) All renewal, application and other fees required for the maintenance of the Owned Intellectual Property Rights that have become due have been paid.

13 Taxation

(a) (**Tax and Duty paid**) All Tax and Duty of any nature for which the Company Group is liable and which has become due for payment has been duly paid or will be paid as at Completion.

(b) (**Investigations**) The Company Group is not involved, nor has been involved within the 4 years prior to Completion, in any audit, investigation by, or any dispute with, any Tax Authority in any jurisdiction responsible for the collection of Tax or Duty, and the Sellers are not aware of any circumstances which may give rise to such an audit, investigation or dispute.

(c) (**Tax obligations**) All necessary information, notices, elections, clearances, computations and returns in respect of the Tax or Duty obligations of the Company Group which are required to be lodged or filed prior to the Completion Date have been lodged or filed with the appropriate Tax Authorities in accordance with all applicable laws and within the prescribed times.

(d) (**Information**) Any information, notice, computation or return which has been submitted to a relevant authority by the Company Group in respect of any Tax or Duty matter:

(i) is true, correct and complete;

(ii) discloses all material facts which should be disclosed under any relevant Tax Law;

(iii) does not contain any false or misleading statement; and

(iv) has been made, filed, lodged or submitted on time.

(e) (**Rulings**) Any transaction that any Company Group Entity has entered into in reliance on any Ruling has been implemented in the manner disclosed in the application for the Ruling. No Company Group Entity has acted or failed to act in any way which has or might alter, prejudice or infringe any arrangement which has been negotiated with a Tax Authority or any Ruling which has previously been obtained from or issued by a Tax Authority.

(f) (**Tax or Duty deducted and remitted**) Each member of the Company Group has properly withheld and paid to the appropriate Government Agency all amounts required to have been withheld and paid in connection with amounts paid or owing, whether on its behalf of as agents, to any to any current or former employees, independent contractors, creditors, equity holders and other third parties and each Company has complied with all reporting and recordkeeping requirements in connection therewith.

(g) (**Limitation periods, etc**) No member of the Company Group has waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax or Duty assessment or deficiency.

(h) (**Power of attorney**) There are no powers of attorney relating to any Company Group Entity currently in force with respect to any Tax or Duty matter.

(i) (**Arm's length dealings**) All transactions and other dealings between a Company Group and a third party have been (and can be demonstrated to have been) conducted on arm's length commercial terms.

(j) (**Dividends**) No member of the Company Group:

(i) has made a frankable distribution (as defined in section 202-40 of the ITAA 1997) in breach of the benchmark rule (as defined in section 203-25 of the ITAA 97);

(ii) has made a linked distribution (as defined in section 204-15 of the ITAA 1997);

(iii) has issued tax exempt bonus shares (as defined in section 204-25 of the ITAA 1997);

(iv) has streamed a distribution within the meaning of section 204-30 of the ITAA 1997;

(v) has notified, or is required to notify, the Australian Federal Commissioner of Taxation about variances in its benchmark franking percentage under section 204- 75 of the ITAA 1997;

(vi) is liable, nor will it be liable at or before Completion, to pay franking deficit tax imposed by the *A New Business Tax System (Franking Deficit Tax) Act 2002* (Cth) in accordance with section 205-45 of the ITAA 1997; or

(vii) is a former exempting company.

(k) (**Share capital account**) No Company Group Entity has a tainted share capital account within the meaning of Division 197 of the ITAA 1997 or has taken any action that might cause its share capital account to become a tainted share capital account, nor has an election been made at any time to untaint a Company's share capital account.

(l) (**Losses**)

(i) Nothing has occurred to deny or disallow a Company Group Entity a Tax deduction in respect of any:

(A) current year Tax losses;

(B) carry forward Tax losses under any Tax Law, as at the Accounts Date; or

(C) Tax losses incurred between the Accounts Date and Completion,

other than the entry into this Agreement or the transfer of the Sale Shares as contemplated by this Agreement.

(ii) Nothing has occurred to deny or disallow a Company Group Entity a Tax deduction in respect of any prior year Tax losses allowed or claimed under any Tax Law as at Completion.

(m) (**Debt forgiveness**) No debt owed by a Company Group Entity has been, or has been agreed to be, released, waived, forgiven or otherwise extinguished by a person which would attract the operation of the former Division 245 of Schedule 2C of the ITAA 1936 or Division 245 of the ITAA 1997.

(n) (**Rollover**) No asset of a Company Group Entity as at Completion was acquired by a Company Group Entity under:

(i) a replacement-asset roll-over (as listed in s112-115 of the ITAA 1997);

(ii) a same-asset roll-over (as listed in s112-150 of the ITAA 1997);

(iii) a roll-over under Subdivision 328-G of the ITAA 1997; or

(iv) a roll-over under s40-340 of the ITAA 1997.

(o) (**Interposed entity election**) No Company Group Entity has ever made an interposed entity election (within the meaning provided by s272-85 of Schedule 2F of the ITAA 1936) or will make such an election prior to Completion.

(p) (**Fines**) The Company Group has not within the period of 4 years prior to Completion paid or become liable to pay, nor are there any circumstances before Completion by reason of which the Company Group is likely to become liable to pay, any material penalty, fine, surcharge or interest whether charged by virtue of the provisions of any law relating to Tax.

(q) (**Transactions**) The Company Group has not been involved in any transaction or series of transactions which, or any part of which, may for any Tax or Duty purposes be disregarded or reconstructed by reason of any motive to avoid, reduce or delay a possible liability to Tax.

(r) (**Stamp duty**) All Tax or Duty payable in respect of every agreement (other than this Agreement), document or transaction to which the Company Group is or has been a party or by which the Company Group derives, or has derived, a substantial benefit has been duly paid.

(s) (**Provision**) Adequate provision has been made in the Accounts for any Tax and Duty which is payable or may become payable in respect of any transaction or income occurring or arising before the Accounts Date but which was unpaid as at the Accounts Date.

(t) (**Records**) The Company Group has maintained proper and adequate records to enable it to comply in all material respects with its obligations under any Tax Law and under any agreement.

(u) (**No overseas permanent establishment**) Other than as Fairly Disclosed to the Buyer, no Company Group Entity carries on business through a permanent establishment (as that expression is defined in any Tax Law or any relevant double taxation agreement) in any country other than the country of incorporation.

(v) (**No anti-avoidance**) No Company Group Entity has entered into or been a party to any transaction which will cause any anti-avoidance provisions of any Tax Law to apply or which will allow a Tax Authority, acting reasonably, to apply any such anti-avoidance provisions.

(w) (**No franking account deficit**) No Company Group Entity will have a franking account deficit immediately after Completion. No act or omission of a Company Group Entity at or before Completion will cause a Company Group Entity to be liable for franking tax immediately after Completion. No Company Group Entity expects to receive a refund of Tax within 3 months of Completion.

14 Privacy Laws

(a) (**Compliance**) The Company Group has in all respects complied with Privacy Law.

(b) (**Claims**) No individual has claimed and, to the best of the Sellers' knowledge, no grounds exist for an individual to claim, compensation from the Company Group for a breach of Privacy Law in connection with the Business.

(c) (**Notice**) No notice has been received by the Company Group from a competent authority alleging a breach of Privacy Law in connection with the Business.

(d) (**Breach**) The Company Group has not suffered any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to any Personal Information.

(e) (**Personal Information**) To the extent the Company Group stores or otherwise deals with Personal Information (other than the Personal Information of any officer, employee or service provider of the Company Group), that Personal Information can only be accessed within Australia (or, if it can be accessed from outside Australia, that access is reasonable in the circumstances).

(f) (**Spam**) The Company Group has complied with the *Spam Act 2003* (Cth) and *Do Not Call Register Act 2006* (Cth) and all similar or equivalent legislation in any relevant jurisdiction.

(g) (**Technology and risk controls**) The Company Group has appropriate technology and risk controls in place.

(h) (**Malicious code**) The Company Group's systems are not currently vulnerable to, and do not contain, any malicious code.

15 Contracts

(a) Accurate and complete copies of all material contracts of the Business have been Fairly Disclosed to the Buyer.

(b) (**Legally enforceable**) The material contracts of the Business are in writing, legally binding and enforceable by the Company Group.

(c) (**No breaches**) No Company Group Entity is in breach of any material contract or has received written notice or is aware of any facts or circumstances which might affect any rights or interests of the Company Group or the exercise of any rights by the Company Group in respect of any agreement.

(d) (**No knowledge of breach by other party**) None of the Sellers are aware or have been made aware of any counterparty to a contract being in breach of that contract or any reason which might preclude the counterparty from fulfilling its obligations under such contract.

(e) (**Unusual contracts**) The Company Group is not bound by any material contract which is of an unusual nature or was entered into outside the normal course of business.

(f) (**No contracts liable to be terminated**): The Company Group is not a party to any contractual arrangement which may be terminated by any other party by reason of a change in the ownership of the Sale Shares or by reason of such change being subject to the consent of the other party which consent has not been obtained.

(g) (**No notice**): No Third Party has given notice to the Company Group that it will not renew the term of its agreement with the Company Group when the subsisting term elapses and, so far as the Sellers are aware, there are no Third Parties who are parties to agreements with the Company Group that will not renew the term of their agreement before it elapses.

(h) (**All contracts enforceable**): All contracts of the Company Group are valid, in full force and effect and enforceable in accordance with their respective terms. Each Company Group Entity has fulfilled or taken all action necessary to fulfil when due all of their obligations under such contracts. There has not occurred any material default by any Company Group Entity or any event which with the lapse of time or at the election of any person other than a Company Group Entity will become a material default under any such contract.

(i) (**Generally**) Except as Fairly Disclosed to the Buyer, there are no material agreements, arrangements or understandings to which the Company Group is party or is bound:

(i) that the Company Group will be unable to terminate after the Completion Date on giving 30 days' notice or less without penalty;

(ii) that are material to the operation of the Business;

(iii) that contain any unusual, abnormal or onerous provisions;

(iv) that are incapable of being fulfilled or performed on time without undue or unusual expenditure of money or effort;

(v) that are not arm's length agreements;

(vi) that will result in any indebtedness of the Company Group becoming immediately due and payable;

(vii) which involve either directly or indirectly any offer or payment to any official of a Governmental Agency to improperly influence him or her to assist in the obtaining or retaining of any Business; or

(viii) under which a Company Group Entity is or may be bound to share any profits or to pay any royalties or to waive or abandon any rights in connection with the Business or any of the assets of the Company Group.

(j) (**No guarantee**) No guarantee, surety or indemnity or letter of comfort has been given or entered into:

(i) by a Company Group Entity in relation to the discharge of the liabilities or the performance of the obligations (in either case whether present or future) of any other person; or

(ii) by a Seller in relation to the discharge of the liabilities or the performance of the obligations of the Company Group.

(k) (**Contracts**) No offer, tender, quotation or the like given or made by a Company Group Entity is capable of giving rise to a contract merely by any unilateral act of a Third Party, other than in the ordinary course of business.

16 Competition

(a) (**Non-compete agreements**) There are no agreements which limit or exclude the rights of the Company Group from doing business and/or competing in any area or field with any person.

(b) (**Competition breaches**) No Company Group Entity is currently or has ever been involved in any practice, arrangement or understanding which has, would or may result in the Company Group being in breach or being found to have been in breach of the *Competition and Consumer Act 2010* (Cth) or the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

(c) (**No notice or communication**) No Company Group Entity has received any material notice, communication or process from the Australian Competition and Consumer Commission, ASIC or any other authority having jurisdiction in completion or anti-trust, and corporate regulation matters in relation to any aspect of the Business of the Company Group.

17 Dealings with the Sellers

(a) (**Dealings**) There is no current or outstanding agreement, arrangement or understanding (whether legally binding or not) to which a Company Group Entity is, or was, a party in which:

(i) a Seller or any of its Related Entities;

(ii) any person who at the time of such agreement, arrangement or understanding was beneficially interested in any of the Company Group's shares or any Related Entity of any such person; or

(iii) any director, officer, employee or consultant or former director, officer, employee or consultant of the Company Group,

is or was interested, whether directly or indirectly.

(b) (**Arm's length transactions**) No Company Group Entity is a party to any agreement, arrangement or understanding (whether legally binding or not) which is not and was not entirely of an arm's length nature.

(c) (**Interest in competitors**) No Seller nor any of their Related Entities has any interest, direct or indirect, in any business which competes with that carried on by the Company Group.

18 Records

The Records:

(a) are in the possession of the Company Group;

(b) have been properly and accurately maintained;

(c) include all records required under, or to comply with or support any return or claim under, any applicable law (including any Tax law);

(d) do not contain material inaccuracies or material discrepancies of any kind and are maintained in all material respects in accordance with all applicable laws and are up-to- date where legally required; and

(e) have been prepared in accordance with the requirements of the Corporations Act.

19 Borrowings and bank accounts

(a) At the date of this Agreement, the Company Group does not have outstanding any borrowing or indebtedness in the nature of borrowing, including any finance lease, hire purchase agreement, deferred terms or other transaction having the commercial effect of a borrowing or any factored debts.

(b) No:

(i) event of default has occurred in relation to any loan or security documentation to which any Company Group Entity is a party;

(ii) notices or demands have been served on any Company Group Entity in relation to default or non-compliance with any of the provisions of loan or security documentation; and

(iii) further action has been taken by the lenders to enforce any security granted by any Company Group Entity.

(c) The Sellers have Fairly Disclosed to the Buyer the full details of all mortgages, charges and other security interests created by the Company Group or in respect of any of the assets of the Company Group.

(d) The bank accounts of the Company Group are operated separately from the bank accounts of any other person and there is no right of set off against moneys in the Company's bank accounts or the bank accounts of any other Company Group Entity for the liabilities of any other person.

(e) The bank accounts of the Company Group have been operated in accordance with all legal and administrative requirements.

20 Clinical Trials

(a) All clinical trials conducted by or on behalf of the Company Group have been and are being undertaken in accordance with applicable standards of cGMP.

(b) The Company Group has implemented appropriate insurance and other risk mitigation policies and procedures to ensure that the Company Group is not exposed to the risk of a material adverse change to its financial position or financial performance in the event of a breach of paragraph 20(a).

(c) Each Company Group Entity holds all necessary Authorisations for the proper carrying on of its clinical trial program across all its products in accordance with cGMP.

Schedule 6

Buyer Warranties

1 (**Incorporation**) The Buyer is duly incorporated and validly exists under the law of its place of incorporation.

2 (**Power and capacity**) The Buyer has full corporate power and authority to enter into this Agreement and perform its obligations under this Agreement, to carry out the transactions contemplated by this Agreement, and to own its property and assets and carry on its business.

3 (**Binding**) This Agreement constitutes a valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms.

4 (**Solvency**) The Buyer is not:

(a) wound up, no resolution for its winding up has been passed and no meeting of members or creditors has been convened for that purpose;

(b) the subject of a winding up application which has been made to a court, and no event has occurred which would entitle any person to apply to a court to wind up the Buyer;

(c) a party to a composition or arrangement with any of its creditors;

(d) the recipient of a demand under section 459E of the Corporations Act or any corresponding or analogous provision governing the Buyer in a jurisdiction outside Australia;

(e) in receivership and none of its assets are in the possession of or under the control of a mortgagee or chargee;

(f) subject to administration under Part 5.3 of the Corporations Act or any corresponding or analogous provision governing the Buyer in a jurisdiction outside Australia; or

(g) insolvent (as defined in section 95A of the Corporations Act), and

so far as the Buyer is aware, there are no circumstances that justify the Buyer being the subject of any of the above events.

5 (**No adverse proceedings**) No legal proceedings, arbitration, mediation or other dispute resolution process is taking place, pending or threatened, the outcome of which is likely to have a material and adverse effect on the ability of the Buyer to perform its obligations under this Agreement.

6 (**Not trustee**) The Buyer is not entering into this Agreement as trustee of any trust or settlement.

Schedule 7

Intellectual Property Rights

[insert table]

Executed as an agreement

Executed by **Incannex Healthcare Limited**
ACN 096 635 246 in accordance with section 127 of the
Corporations Act 2001 (Cth):

Director	~~*Director~~/*Company Secretary
/s/ Joel Latham	/s/ Madhukar Bhalla
Joel Latham Name of Director BLOCK LETTERS	Madhukar Bhalla Name of ~~*Director~~/*Company Secretary BLOCK LETTERS *please strike out as appropriate

Executed by **Prasch B.V.** (RSIN:

Director	~~*Director~~/*Company Secretary
/s/ Lekhram Changoer	/s/ Prashant Changoer
Lekhram Changoer Name of Director BLOCK LETTERS	Prashant Changoer Name of ~~*Director~~/*Company Secretary BLOCK LETTERS *please strike out as appropriate

Executed by **Lekhram Changoer**

/s/ Lekhram Changoer
Lekhram Changoer

In the presence of

/s/ Prashant Changoer
Prashant Changoer
Name of Witness

Executed by **George Anastassov**

In the presence of

/s/ George Anastassov	/s/ Lekhram Changoer
George Anastassov	Lekhram Changoer Name of Witness

Executed by **Eric Kim**

/s/ Eric Kim
Eric Kim

In the presence of

/s/ Lisa Kim
Lisa Kim
Name of Witness

Annexure A

Non-Pharmaceutical Assets

[insert table]

Exhibit 8.1

Subsidiary of Incannex Healthcare Limited

Subsidiary	Jurisdiction
Incannex Pty Ltd	Victoria, Australia
Psychennex Pty Ltd	Victoria, Australia
APIRx Pharmaceutical USA, LLC	Delaware

Exhibit 12.1

Certification pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joel Latham, certify that:

1. I have reviewed this annual report on Form 20-F of Incannex Healthcare Limited (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 28, 2022

By: /s/ Joel Latham
Joel Latham
Chief Executive Officer

Exhibit 12.2

Certification pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Madhukar Bhalla, certify that:

1. I have reviewed this annual report on Form 20-F of Incannex Healthcare Limited (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 28, 2022

By: /s/ Madhukar Bhalla
Madhukar Bhalla
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 13.1

Certification pursuant to 18 U.S.C. § 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Incannex Healthcare Limited (the "Company") on Form 20-F for the year ended June 30, 2022 as filed on the date hereof (the "Report"), I, Joel Latham, Chief Executive Officer for the Company, certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2022

By: /s/ Joel Latham
Joel Latham
Chief Executive Officer

Exhibit 13.2

Certification pursuant to 18 U.S.C. § 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Incannex Healthcare Limited (the "Company") on Form 20-F for the year ended June 30, 2022 as filed on the date hereof (the "Report"), I, Madhukar Bhalla, Chief Financial Officer for the Company, certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2022

By: /s/ Madhukar Bhalla
Madhukar Bhalla
Chief Financial Officer

Exhibit 15.1

October 28, 2022

Office of the Chief Accountant
Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Ladies and Gentlemen:

We have read the statements made by Incannex Healthcare Limited (the "Company") in Form 20-F dated October 28, 2022. We agree with the statements concerning our Firm in such Form 20-F; we are not in a position to agree or disagree with the Company's statements that the audit committee decided to engage PKF Brisbane Audit to serve as the Company's new independent registered public accounting firm and related statements contained therein.

Very truly yours,

/s/ WithumSmith+Brown, PC

New York, New York