UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of Mar, 2023

Commission File Number: 001-41106

Incannex Healthcare Limited

(Exact name of Registrant as specified in its charter)

not applicable (Translation of Registrant's name into English)

Australia (Jurisdiction of incorporation or organization)

Joel Latham
Chief Executive Officer and Managing Director
Level 39, Rialto South Tower
525 Collins Street
Melbourne 3000
Australia
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:
Form 20-F ⊠ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
Yes □ No ⊠
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):
Yes □ No ⊠

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On March 16, 2023, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned "Incannex Launches Psychedelic Clinics Business", a copy of which announcement is attached to this Form 6-K as Exhibit 99.1.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2023

Incannex Healthcare Limited

By: /s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.

99.1 <u>ASX Announcement, dated March 16, 2023 – Incannex Launches Psychedelic Clinics Business</u>



Incannex to Commercialise its Psychedelic Clinics Business in Collaborative Partnership with Leading Psychedelic Experts

Highlights:

- Incannex plans to open multiple psychedelic-assisted psychotherapy clinics in Australia and overseas.
- First clinic will open in Melbourne in 2023, followed by rapid expansion based on development of sound operating model.
- Dr. Paul Liknaitzky, Professor Suresh Sundram and Sean O'Carroll to join the Board of Directors of a subsidiary company and take key roles
 within the venture.
- Incannex owned subsidiary is being led by long time Incannex director, Mr Peter Widdows.
- Advanced stage of negotiation on riverfront premises in Melbourne for first clinic.
- Incannex believes the market will mature into a multi-billion-dollar opportunity.

Melbourne, Australia, March 16, 2023 – Incannex Healthcare Ltd (Nasdaq: IXHL). (ASX: IHL) ('Incannex' or 'the Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic assisted psychotherapies for unmet needs is pleased to announce that it has developed plans for the commercialisation of its psychedelic-assisted psychotherapy business ('Psychedelic Clinics').

Incannex has been developing the commercialisation plans for psychedelic clinics for some time, well before the TGA decision to down-schedule psilocybin for treatment-resistant depression (TRD) and MDMA for Post-Traumatic Stress Disorder (PTSD) was announced, under the leadership of Peter Widdows, a long-standing Director of the Company.

Peter Widdows, Incannex Director and psychedelic clinics business lead said: "We initially intended to use only ketamine-assisted psychotherapy, with the possibility of expanding into psilocybin-assisted psychotherapy for Generalised Anxiety Disorder subject to regulatory approval. When the TGA announced the down-scheduling of MDMA and psilocybin for two indications, we were in a perfect position to expand our plans to cover this wider set of related therapies for certain indications."

The Company has entered a partnership with Australia's leading clinical psychedelic professionals, all of whom have extensive experience within clinical psychedelic research, treatment, and training.

Dr Paul Liknaitzky: Co-Founder, Director, Chief Strategy Officer, and Chief Scientific Officer

Paul has played a central role in establishing the clinical psychedelic field in Australia and leads the largest group of psychedelic researchers and clinicians in the country. Paul is the Chief Principal Investigator on a program of psychedelic trials and collaborates on numerous others nationally. He has led the development of psychedelic trial protocols, treatment design, trial coordination, therapist selection and training, and has established active collaborations with an extensive network of international experts and organisations in the field. Paul's work is focused on developing innovative psychedelic therapies, evaluating benefits, exploring potential drawbacks, predicting treatment response, mitigating risks, understanding therapeutic mechanisms, and translating research into practice.



Dr. Paul Liknaitzky said; "The safe, useful, and ethical translation of clinical psychedelic research into practice has been at the forefront of my mind for some years, as we conduct trials and learn first-hand about the potential and the complexity of providing psychedelic therapies. I feel motivated now to contribute to a community-based service where we can draw on our substantial experience in coordinating and delivering this treatment, alongside a wealth of treatment and training resources, and an extensive network of mentors and collaborators from around the world."

Professor Suresh Sundram: Co-Founder, Director, Chief Medical Officer, and Head of Psychiatry

Suresh is a Fellow of the Royal Australian and New Zealand College of Psychiatrists and a consultant psychiatrist. He holds senior leadership positions in academic and clinical psychiatry and has published more than 150 scientific articles, books, book chapters, and conference abstracts. He has presented as plenary and invited speaker at international and national conferences, served as Deputy Editor for the Asian Journal of Psychiatry, and as an advisor to the United Nations (UN), and to national and state governments. Prof. Sundram has led over 50 clinical trials and studies in psychiatric disorders. He has extensive experience with the use of psychedelics within psychotherapy and has overseen multiple research projects in this field.

Prof. Sundram said: "The down-scheduling of certain psychedelic treatments for certain conditions is an important transition point to establish the utility and role of psychedelic-assisted psychotherapy in mental illness. Providing a custom-tailored environment in order to deliver the best possible therapeutic experience is critical. To enable this, and to evaluate and deliver outcomes, is a rare opportunity."

Sean O'Carroll: Co-Founder, Director, and Head of Psychotherapy

Sean is an integrative psychotherapist and academic – specialising in experiential, relational, and transpersonal psychotherapy. Since 2019, he has developed and delivered psychedelic-assisted psychotherapy training for several clinical psychedelic research teams. He has served as lead psychotherapist on two clinical research trials, continues to supervise one of these teams, and works as a psychedelic-assisted psychotherapy consultant within industry, with an emphasis on psychotherapy training and protocol development. Sean began lecturing in transpersonal psychology in 2011 and has over ten years' experience working with what he calls "psychedelic casualties". Through the Wild Mind Institute, he offers training for mental health practitioners in psychedelic-assisted psychotherapy, "bad trip" integration, and eco-psychotherapy.

Sean O'Carroll said: "Many of us in the research community were surprised by the recent TGA announcement, understanding this research is still in its early stages here in Australia, and that a good deal of necessary infrastructure is not yet in place. With this decision, those of us who have the experience and expertise in this field feel a responsibility to contribute to the best possible care and provide a benchmark for safe and ethical practice. There are very few experienced psychedelic-assisted psychotherapists in Australia, and the team we are assembling includes many of the most experienced practitioners in the country. We take this responsibility seriously and are uniquely placed to support the emergence of psychedelic-assisted psychotherapy as a safe and efficacious new treatment modality."



Peter Widdows: Co-Founder, Director, and Business Lead

Peter has been a Director of Incannex since 2018 and is also the Chairman of Sunny Queen Ltd and a non-executive director of Youi Insurance. He has extensive business experience in the FMCG sector and was the CEO for a large part of Asia and Australasia, responsible for 18,500 people and multibillion-dollar revenues for H. J. Heinz Inc, an NYSE listed multinational food company. Peter has senior business experience across multiple geographies, throughout Asia, Australasia, Europe, and North America.

Peter Widdows has been driving this project since its inception and will continue to lead the Incannex owned subsidiary for the foreseeable future.

Peter Widdows said: "This is both an amazing opportunity to do some good for humankind by delivering high-quality, effective treatments for debilitating conditions that often don't respond to available treatments, and a great business opportunity, with a market that is predicted to mature into a multi-billion-dollar industry segment."

Joel Latham, Incannex Managing Director, and CEO said; "This opportunity is something the IHL team have been working towards for some time now and presents a pivotal point in the journey of the Company, turning from pure research into service delivery. The opportunity is to deliver the highest-quality care and make a real difference in people's lives, alongside substantial and imminent revenue potential. The implementation of the Psychedelic Clinics Business will not have an impact on the development of our core clinical assets and will be run as an Incannex owned subsidiary in parallel. The implementation of this strategy will in part provide the platform to allow an accelerated path to commercialisation for our drug assets post clinical success ".

The Company is at an advanced stage of negotiations over premises in Melbourne, Australia, which has a population of 5.2M people. This first 'model' clinic is expected to open before the end of 2023. Once the operation of the model clinic is running smoothly, the Company will begin rapid expansion within Australia and overseas, where legislation allows.

Dr. Paul Liknaitzky said: "Very few people in Australia have the unique expertise and experience in delivering psychedelic therapies, and it is incumbent on those who do, to set the highest standards in patient safety, quality of care, ethical conduct, and accessibility. I'm grateful to Incannex for providing the resources to do this work and trusting us to build the clinics of the future. And I'm grateful to be part of a brilliant multidisciplinary team of sensible, compassionate, skilled and highly experienced professionals who already do fantastic work within clinical psychedelic research, all motivated towards supporting real and lasting improvements in the lives of patients experiencing mental ill-health within the community."

This announcement has been approved for release to ASX by the Incannex Board of Directors.

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About Incannex Healthcare Limited

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of obstructive sleep apnoea (OSA), traumatic brain injury (TBI) and concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, inflammatory bowel disease, anxiety disorders, addiction disorders, and pain, among other indications.

U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication under investigation currently has no, or limited, existing registered pharmacotherapy (drug) treatments available to the public and represent major global economic opportunities to Incannex and its shareholders.

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. The Company holds 19 granted patents and 30 pending patent applications. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and has American Depository Shares listed on NASDAQ under code "IXHL".

Website: www.incannex.com.au Investors: investors@incannex.com.au

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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