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 July, 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 ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On July 21, 2023, “IHL Submit IND Application for IHL42x”, 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.

Incannex Healthcare Limited

Date: July 21, 2023

By: /s/ Joel Latham
Name: Joel Latham
Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.	
99.1	ASX Announcement, dated July 21, 2023 – IHL Submit IND Application for IHL42x

Date: July 21, 2023
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Submits IND Application to the US FDA for IHL-42X for Obstructive Sleep Apnoea

Melbourne, Australia, July 21, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has successfully submitted an Investigational New Drug ('IND') application to the US Food and Drug Administration ('FDA') for IHL-42X for treatment of obstructive sleep apnoea.

The IND dossier compiled by the Incannex team includes comprehensive modules on the safety and efficacy of IHL-42X and its component active pharmaceutical ingredients. It also includes detailed information on the development, manufacturing, quality and stability of the IHL-42X drug product, as well as the clinical protocol and investigator information for the Phase 2/3 IND opening clinical trial.

The modules of the IND are:

- Module 1 – Administrative Information and Prescribing Information
- Module 2 – Nonclinical/Clinical Overviews and Summaries
- Module 3 – Quality data
- Module 4 – Nonclinical Study Reports and Key Literature References
- Module 5 – Clinical Study Reports, Clinical Protocol and Investigator Information

Submitting an IND to the FDA is crucial for companies to gain regulatory approval, conduct clinical trials, and engage in scientific dialogue with FDA whilst they progress investigational drugs through the stages of development in the United States. The FDA review process for an IND application involves evaluation of the scientific, clinical, and safety aspects to ensure that the proposed clinical trial meets regulatory requirements.

The IND application details the clinical trial protocol for the IND opening clinical trial, which is a multi-site phase 2/3 clinical trial investigating IHL-42X for the treatment of Obstructive Sleep Apneoa ('OSA'). This pivotal trial will assess IHL-42X at the best performing two doses from the successful phase 2 proof-of-concept clinical trial, in patients with OSA who are intolerant, non-compliant, or naïve to positive airway pressure, over a 52-week treatment period.

Participants will receive one of IHL-42X, dronabinol, acetazolamide or placebo for the entirety of the trial. All participants will complete daily surveys on their sleep quality, attend monthly clinic visits to assess functional outcomes of sleep, cognitive function and other measures of safety and efficacy. Every three (3) months, overnight polysomnography will be conducted to determine the effect of treatment on the patients' Apneoa Hypopnea Index score ('AHI') along with a range of other sleep parameters. All drug treatments will be compared to placebo.

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The two Principal Investigators of the clinical trial were appointed in June and are highly experienced research clinicians. John Douglas Hudson, MD, is board certified in Neurology and Sleep Medicine. He serves as the Principal Investigator for FutureSearch Trials of Neurology, Austin, Texas. Dr. Hudson has supervised over 300 clinical trials over the past 20 years mostly related to neurological and sleep disorders and has been a national and international speaker for these disorders. Dr. Russell Rosenberg is currently Chief Science Officer and CEO of NeuroTrials Research in Atlanta, Georgia. Dr. Rosenberg, a native of St. Louis, obtained his doctorate in clinical and research psychology from The Ohio State University and received specialized training in sleep disorders medicine and research at Rush Presbyterian - St. Luke's Medical Center in Chicago. He has more than 35 years' experience in clinical sleep medicine and research, acting as an investigator in over 300 clinical trials including 14 in OSA and 211 in other sleep related disorders.

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

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About IHL-42X

IHL-42X is a synergistic composition of dronabinol, a synthetic form of tetrahydrocannabinol (THC), and acetazolamide, a carbonic anhydrase inhibitor. Results from a Phase 2 proof of concept clinical trial undertaken by Incannex were released in 2022. Incannex observed that IHL-42X reduced average apnoea-hypopnoea index ('AHI') by an average of 50.7% versus baseline assessments and 25% of participants experienced greater than an 80% reduction in the AHI. No serious treatment emergent adverse events were reported during the clinical trial. Furthermore, THC concentrations in blood were below the limits for impaired driving the morning after nocturnal dose administration of IHL-42X.

About Obstructive Sleep Apnoea

OSA is the most common sleep-related breathing disorder. It involves the narrowing of the upper airway during sleep, interfering with a person's breathing, decreasing oxygen uptake, resulting in poor-quality sleep[1]. Untreated OSA leads to serious long-term adverse health outcomes including hypertension, cardiovascular disease, heart attack, cognitive impairments, anxiety and depression, irritability and daytime fatigue increasing the risk of accidents. There are no pharmacotherapy (drug) treatments available to those afflicted.

The current 'standard of care' is the Continuous Positive Airway Pressure ('CPAP') machine. However, patient compliance to CPAP is low due to various factors related to patient discomfort. Incannex anticipates greatly improved treatment compliance and outcomes from a pharmaceutical product, such as IHL-42X, subject to further clinical assessment and approval from regulators.

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Regardless of the discomfort caused by CPAP, the global annual market for OSA detection and treatment using CPAP and other breathing aides is approximately US$10 billion per annum and growing[2]. OSA is highly prevalent, affecting approximately 30 million adults in the United States alone. It is estimated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately US$149.6 billion per annum. These costs include US$86.9 billion in lost productivity, US$26.2 billion in motor vehicle accidents and US$6.5 billion in workplace accidents[3].

References

1 https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090
2 https://www.fortunebusinessinsights.com/industry-reports/sleep-apnea-devices-market-100708
3 https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf

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”.

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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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