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 November, 2022

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 November 17, 2022, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “Incannex Development Update for IHL-42X”, 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: November 17, 2022

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

INDEX TO EXHIBITS

Exhibit No.	
99.1	ASX Announcement, dated November 17, 2022 – Incannex Development Update for IHL-42X

Date: November 17, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Development Update for IHL-42X for Obstructive Sleep Apnoea ('OSA')

Highlights:

- Incannex has engaged CMAX Clinical Research and Novotech CRO to undertake a bioavailability/bioequivalence ('BA/BE') study to assess the pharmacokinetics and tolerability of IHL-42X in 116 participants
- Incannex is well progressed in drafting an Investigational New Drug ('IND') Application for submission to the US Food and Drug Administration ('FDA') in Q1 of 2023
- Once the IND is open, Incannex will commence pivotal, multi-site Phase 2/3 clinical trials investigating the effects of IHL-42X in patients with OSA over a 12-month period
- Phase 2/3 pivotal trials will include between 20 to 30 trial sites, including many in the United States. Sixty-three clinical trial sites have expressed interest in conducting the trial.

Melbourne, Australia, November 17, 2022 – 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 Incannex has initiated a BA/BE study and is targeting submission of an IND application with the FDA in Q1 2023.

The BA/BE study will assess the pharmacokinetics and tolerability of the two active pharmaceutical ingredients ('APIs') in IHL-42X, dronabinol ('THC') and acetazolamide, compared to the respective FDA reference listed drugs, as well as the effect of food on pharmacokinetics of the two APIs.

The study will include 116 participants who will each complete four (4) single dose treatment periods, being dosed with IHL-42X, dronabinol and acetazolamide under fasted conditions as well as IHL-42X under fed conditions. Blood samples will be collected over 48 hours and the concentrations of the APIs and their major metabolites in the samples will be analysed.

The study will be conducted at CMAX Clinical Research in Adelaide, South Australia and managed by Novotech. The design of the BA/BE study is consistent with FDA recommendations for BA/BE and specific advice received by Incannex in the pre-IND meeting.

The results of this study will form a critical component of a future new drug application ('NDA'), providing the necessary bridge to the reference listed drugs, thereby facilitating the use of historic safety data via the FDA505(b)2 regulatory pathway.

In parallel with the BA/BE study, Incannex is preparing an IND application for submission to the FDA. An IND application is a comprehensive information document detailing the safety, efficacy, and quality of the IHL-42X drug product for the treatment of OSA and is precursory to conducting clinical trials at treatment sites in the United States. Once the IND is opened, it is continuously updated with research and development results for the purpose of ongoing assessment by the FDA.

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Incannex aims to submit the IND application in Q1 2023, followed shortly by the commencement of pivotal, multi-site, Phase 2/3 clinical trials investigating the effects of IHL-42X in patients with OSA. The trials will assess the safety and efficacy of IHL-42X at the best performing two doses from the proof-of-concept clinical trial, in patients with OSA over a 12-month treatment period.

Participants will receive one of IHL-42X, dronabinol, acetazolamide or placebo for the entirety of the study. 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 3 months, overnight polysomnography will be conducted to determine the effect of treatment on the patients' AHI. All drug treatments will be compared to placebo.

In preparation for the Phase 2/3 clinical trials, Incannex has undertaken a 12-week feasibility study whereby the trial design was provided to potential investigators along with a survey to gauge interest in conducting the study and identify any region-specific regulatory hurdles. This study involved contacting 195 sites across 14 countries in North American, Europe, South America, and Australasia. Sixty-three sites expressed interest in the conducting the study. Incannex anticipates that 20-30 sites will eventually be selected to conduct the clinical trials.

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 published in 2022. Incannex observed that IHL-42X reduced average apnoea hypopnea index ('AHI') by an average of 50.7% versus baseline assessments and 25% of participants experienced greater than an 80% reduction in AHI measure. 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. Incannex has filed a patent application over IHL-42X, which has been deemed "novel and inventive" by the international patent examiner.

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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.

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 29 pending patents. 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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