
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 25, 2022, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “IHL Commences Manufacturing for Novel Addiction Treatments”, 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 25, 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 25, 2022 – IHL Commences Manufacturing for Novel Addiction Treatments](#)



Date: November 25, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Engages Eurofins to Manufacture Novel Addiction Treatments CannQuit-N and CannQuit-O

Melbourne, Australia, November 25, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing medicinal cannabinoid and psychedelic therapies for unmet medical needs, is delighted to announce that it has engaged multinational contract development and manufacturing organisation (CDMO) Eurofins Scientific ('Eurofins') to manufacture Incannex's two distinct medicated chewable products designed to treat nicotine and opioid addiction disorders.

The CannQuit products are combination drug assets with associated granted patents and patent applications that were transferred to Incannex as a result of the acquisition of APIRx Pharmaceuticals, completed in August of 2022. Eurofins will undertake formulation development and manufacture of CannQuit Nicotine ('CannQuit-N') and CannQuit Opioid ('CannQuit-O').

CannQuit-N combines nicotine and cannabidiol ('CBD') within a controlled-release, functional, medicated chewing gum. CannQuit-O combines CBD and an off-patent prescription opioid antagonist, and/or partial agonist-antagonist within the formulation. The cGMP grade products manufactured by Eurofins will be used in clinical trials designed to assess the safety and efficacy of the CannQuit products for smoking cessation and the treatment of opioid addiction.

Data collected on the quality and stability of the CannQuit anti-addiction products during the development and manufacturing of the two drug candidates at Eurofins will be key components of future regulatory packages. These data packages include investigational new drug (IND) applications and new drug application (NDA) filings with the US Food and Drug Administration (FDA).

Medicated chewing gums deliver their active ingredients directly into the circulation of the oral mucosa, ensuring that the effects of the ingredients are delivered rapidly, but also in a sustained manner to reduce cravings for longer than other delivery methods. Rapid onset and sustained effect are both qualities desirable for the treatment of addiction disorders. Furthermore, the act of chewing, known as mastication, also has an multi-action, anti-anxiety effect that has been demonstrated in other scientific assessments.

Dr Mark Bleackley, chief scientific officer of Incannex, said: "Opioid and nicotine addiction are significant health problems and a major burden on health systems throughout the world. CannQuit products are designed to improve established therapies for the treatment of addiction. They do this by adding CBD, which is known to reduce cravings and anxiety which is critical for breaking the addiction cycle".

"In the case of CannQuit-O, we add CBD and the act of chewing to a well-established opioid antagonist and/ or agonist/ antagonist therapy. Both CBD and the act of chewing, are conducive to stress and anxiety reduction".

"We believe that the synergies between the pharmaceutical ingredients and the form of the product, as a sustained chewable, gives CannQuit strong potential to improve treatment outcomes for people who are addicted to nicotine and opioids. These theorised enhancements to existing treatment options make us excited to test our hypotheses in clinical trials once the products have been manufactured by Eurofins".

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US Opioid Epidemic

The opioid epidemic has reached critical levels in the United States and the industrialized world. Fatal opioid overdoses and opioid use disorder cost the United States \$1.02 trillion in 2017, as measured by the Centre for Disease Control (CDC) in the journal Drug and Alcohol Dependence, which is the most complete accounting of America's opioid crisis to date. Treatments for opioid use disorder total US\$64B per annum and there have been no major new treatment solutions in recent decades.

Cigarette Smoking and Nicotine Addiction

Cigarette smoking causes a wide variety of preventable diseases and remains a leading cause of preventable death in the United States, where it is responsible for more than 480,000 deaths per year, including nearly 42,000 deaths from second-hand smoke exposure. The total economic cost of smoking in the US is estimated at more than US\$300 billion per annum. This includes nearly US\$170 billion in direct medical care for adults and more than \$156 billion in lost productivity.

Nicotine chewing gum is already a long-standing and accepted product throughout the globe with annual sales amounting to \$US5.2B in 2020, however, the progression to complete smoking cessation is limited. By adding CBD in a patented combination, CannQuit-N is hypothesised by Incannex to improve upon the therapeutic outcomes of nicotine only gum. The patented technology of controlled and sustained release of the active ingredients also is believed to improve the therapeutic value of this novel drug candidate.

Nicotine replacement therapy by CBD has a solid pre-clinical basis and encourages Incannex to further develop and investigate CannQuit-N in human clinical trials. CBD has been found to inhibit the $\alpha 7$ nicotinic acetylcholine receptor which plays a role in the reinforcing effects of nicotine. Interactions of endocannabinoids with the CB₁ receptor are essential in mediating behaviours associated with addiction and there are preliminary clinical observations suggesting that CBD may help to reduce the number of cigarettes smoked in a day.

About Eurofins Scientific

Eurofins Scientific through its subsidiaries is the world leader in food, environment, pharmaceutical and cosmetic product testing, discovery pharmacology, forensics, advanced material sciences, and in agrosience Contract Research services. It is also one of the global independent market leaders in genomics and in the support of clinical studies, as well as in BioPharma Contract Development and Manufacturing. In addition, Eurofins is one of the key emerging players in specialty esoteric and molecular clinical diagnostic testing in Europe and the USA. With over 61,000 staff across a network of more than 1,000 independent companies in 59 countries and operating 940 laboratories, Eurofins offers a portfolio of over 200,000 analytical methods for evaluating the safety, identity, composition, authenticity, origin and purity of biological substances and products, as well as for innovative clinical diagnostics. The objective of Eurofins companies is to provide their customers with high-quality services, accurate results on time and expert advice by their highly qualified staff.

Eurofins is listed on the Paris Euronext exchange with a market valuation of approximately 13B Euro. Incannex is investigating the use of Eurofins to develop and manufacture additional drug candidates acquired via the acquisition of APIRx Pharmaceuticals.

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

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Date: November 25, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

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 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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