

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report May 7, 2024

Incannex Healthcare Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)	001-41106 (Commission File Number)	93-2403210 (IRS Employer Identification No.)
Suite 105, 8 Century Circuit Norwest, NSW 2153 Australia (Address of Principal Executive Offices)		Not applicable (Zip Code)

Registrant's Telephone Number, including Area Code: +61 409 840 786

(Former Name or Former Address, if Changed Since Last Report): Not Applicable

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	IXHL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, 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.

Item 8.01

On May 7, 2024, Incannex Healthcare Inc. announced that it has successfully completed a Pre-IND Meeting with the FDA for CannQuit-O for treatment of opioid use disorder. Further information is included in the press release attached as Exhibit 99.1 hereto, which is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Incannex Healthcare Inc., dated May 7, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

Date: May 7, 2024

Incannex Healthcare Inc.

/s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and President



Date: May 7, 2024
Public Announcement (NASDAQ: IXHL)

Incannex Complete Successful Pre-IND Meeting with the FDA for CannQuit-O for treatment of opioid use disorder

MELBOURNE, Australia and NEW YORK, May 7, 2024: Incannex Healthcare Inc. (Nasdaq: IXHL), (Incannex or the Company), a leading cannabinoid and psychedelic medicine biotechnology company, is pleased to announce the successful completion of a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development of CannQuit-O for treatment of Opioid Use Disorder (OUD).

The pre-IND teleconference included representatives from various divisions of the FDA providing input on the CannQuit-O development program. The Agency had reviewed the CannQuit-O meeting package and provided recommendations on the proposed clinical development strategy, including patient populations, the selection and timing of efficacy endpoints and safety monitoring. These recommendations were discussed during the preIND teleconference where the company had the opportunity to seek further clarification on the agency's initial response.

The productive discussion with the FDA is an important milestone for the development of CannQuit-O and provides Incannex with clarity on the data required to open an IND with the FDA for this product and provides valuable guidance for successful clinical development in the OUD indication.

Incannex Chief Scientific Officer Dr Mark Bleackley said: "Opioid use disorder is a significant issue impacting millions of patients and their families. Developing new therapies, such as CannQuit-O, is critical for helping control the disease and improve quality of life for those who are suffering from the disease and those around them. Feedback from the FDA on the proposed development strategy for CannQuit-O will be taken on board so that the outcomes of research activities meet agency expectations and ensure that the appropriate steps are being taken towards drug registration."

About CanQuit-O

CannQuit-O is a chewable tablet with unique characteristics provided by novel combination of registered/ FDA-approved polymers allowing for rapid and sustained release of its active ingredients, including an opioid agonist, antagonist and cannabidiol (CBD). The working hypothesis is that the bioavailability profile of the drugs can be significantly improved when formulated as water-soluble, chewable tablet. Incannex owns patents on chewable formulations cannabinoids and opioid agonists and/or antagonists and it is hypothesised that this combination of active pharmaceutical ingredients and delivery system will provide benefits for sufferers of OUD, of which there are estimated 26.8 million people worldwide¹. In the USA the opioid epidemic has been declared a public health emergency, affecting millions with the misuse of prescription opioids and illicit substances. According to the National Institute of Health (NIH), by far the largest components of the overall economic burden, however, are the value of reduced quality of life from opioid use disorder (\$390.0 billion) and life lost to opioid overdose (\$480.7 billion). These two cost components account for over 85% of the total economic burden².

¹ <https://www.nature.com/articles/s41572-019-0137-5>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8091480>

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The Global OUD market size was valued at USD 2.8 Billion in 2022 and is estimated to grow at CAGR of 10.7% from 2022-2032, reaching USD 7.8 Billion in 2032. Asia Pacific is expected to grow the fastest during the forecasted period³.

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

END

About Incannex Healthcare Inc.

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 NASDAQ as 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.

³ <https://www.sphericalinsights.com/reports/opioid-use-disorder-oud-market>

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Contact Information:

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