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 July 30, 2024

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

Delaware	001-41106	93-2403210
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Suite 105, 8 Century Circuit Norwest, NSW 2153 Australia	Not applicable
(Address of Principal Executive Offices)	(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 July 30, 2024, Incannex Healthcare Inc. announced that dosing completed in 115 participant bioavailability/bioequivalence clinical trial for proprietary sleep apnea drug candidate IHL-42X. 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 July 30, 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.

Incannex Healthcare Inc.

Date: July 30, 2024

/s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and President

Date: July 30, 2024
Public Announcement (NASDAQ: IXHL)

Dosing completed in 115 participant bioavailability/bioequivalence clinical trial for proprietary sleep apnea drug candidate IHL-42X

- IHL-42X is a fixed dose combination drug targeting obstructive sleep apnea (OSA), a medical condition with no available registered pharmaceutical treatment for millions of sufferers in the USA alone.
- bioavailability/bioequivalence ('BA/BE') clinical trial assessed the pharmacokinetics and tolerability of IHL-42X consistent with FDA development plan.
- Analysis of data underway, however, no serious adverse events were reported.
- Phase 2/3 FDA IND-enabling RePOSA clinical trial continues after dosing commenced in May 2024.

NEW YORK, USA and MELBOURNE, Australia, 30 July, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), ('Incannex' or the 'Company'), a clinical-stage pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic-assisted psychotherapies, is pleased to announce that it has completed participant dosing in the IHL-42X Bioavailability/Bioequivalence (BA/BE) clinical trial.

IHL-42X comprises two drugs, dronabinol (synthetic delta-9-tetrahydrocannabinol (THC)), and acetazolamide. The BA/BE clinical trial was designed to compare the bioavailability of dronabinol and acetazolamide in IHL-42X as a fixed dose combination drug to the FDA reference listed drugs Marinol and Taro acetazolamide administered in isolation. The BA/BE study also assessed the effect of food on the bioavailability of the drug substances in IHL-42X. All participants in the study completed four treatment periods, each consisting of a single dose each of IHL-42X, Marinol or acetazolamide under fasted conditions, or IHL-42X under fed conditions. Blood samples were then collected at predefined intervals and analysed for levels of acetazolamide, THC and major THC metabolites. Participants were also monitored for adverse events throughout the study. 115 participants completed all four treatment periods and no serious adverse events were reported during the study.

Data collected during the study will be processed and analysed over the coming months. This will generate information on the pharmacokinetics of each of the active pharmaceutical ingredients in IHL-42X compared to the relevant reference listed drugs. These comparative pharmacokinetic profiles will facilitate the Company's ability to rely on safety and toxicology data for the reference listed drugs in future regulatory submissions. The adverse event data from the BA/BE study will also contribute to the safety profile of IHL-42X as a combination product.

Incannex Chief Scientific Officer Dr Mark Bleackley said "Completion of dosing in the BA/BE study is an important milestone in the IHL-42X research program. The pharmacokinetics of cannabinoids are highly-variable so having data across the four treatment periods from this many subjects will provide incredibly valuable data for Incannex in the continued development of IHL-42X. The ability to rely on safety and toxicology data for the refence listed drugs reduces the burden on Incannex and allows us to focus on safety and efficacy of the drug product in OSA patients. Thank you to the trial sites, our clinical research organisation and, most importantly, the volunteers who participated in the study."

Incannex Healthcare Inc.
Level 39, Rialto South Tower, 525 Collins Street, Melbourne VIC 3000
Email: admin@incannex.com.au

Date: July 30, 2024
Public Announcement (NASDAQ: IXHL)

About IHL-42X

IHL-42X is a synergistic composition of dronabinol, a synthetic form of Delta-9 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-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. Incannex currently has three separate patent familes covering different aspects of IHL-42X and its use in treatment of OSA at various stages of review in key jurisdictions.

About Obstructive Sleep Apnea

Sleep apnea 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 sleep apnea 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 sleep apnea detection and treatment using CPAP and other breathing aides is approximately US$10 billion per annum and growing[2]. Sleep apnea is highly prevalent, affecting approximately 30 million adults in the United States alone. It is estimated that the annual economic burden of undiagnosed sleep apnea 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

END

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About Incannex Healthcare Inc.

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabinoid 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 20 granted patents and over 30 pending patent applications. Incannex is listed and publicly traded on Nasdaq (NAS: IXHL), providing investors an opportunity to participate in the Company's growth.

Website: www.incannex.com
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.

Contact Information:

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