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 (Date of earliest event reported): **June 18, 2025**

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 Other Events.

On June 18, 2025, Incannex Healthcare Inc. achieves key milestone with database lock for RePOSA Phase 2 trial of 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 June 18, 2025.
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: June 18, 2025

/s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and President

Exhibit 99.1

Incannex achieves key milestone with database lock for RePOSA Phase 2 trial of IHL-42X

Top-line results expected July 2025 as development of first-in-class OSA drug advances

NEW YORK and MELBOURNE, Australia – June 18, 2025 – Incannex Healthcare Inc. (Nasdaq: IXHL) ("Incannex" or the "Company"), a clinical-stage biopharmaceutical company advancing combination drug therapies for high-impact indications, is pleased to announce that it has achieved database lock for the RePOSA Phase 2 clinical trial of IHL-42X, its lead drug candidate for obstructive sleep apnoea (OSA), on schedule as of 16 June 2025.

This marks a major milestone in the development of IHL-42X, confirming the completion of clinical data collection and enabling final statistical analysis to begin. The Company is on track to deliver top-line results in July 2025, reinforcing confidence in the program's momentum and execution.

Joel Latham, President and CEO of Incannex, commented, "Achieving database lock on schedule demonstrates our strong clinical capabilities and commitment to advancing a much-needed therapy for obstructive sleep apnoea. IHL-42X represents a breakthrough opportunity to address a condition affecting hundreds of millions of people globally, with no approved oral pharmacological treatment available. We are excited by what lies ahead."

The RePOSA Phase 2 trial is evaluating IHL-42X in patients with moderate to severe OSA who are unable or unwilling to use continuous positive airway pressure (CPAP). The proprietary fixed-dose combination therapy is designed to reduce apnoea episodes, improve sleep quality, and offer a patient-friendly alternative to current treatment options.

With over 900 million people affected by OSA worldwide and growing awareness of its impact on cardiovascular and metabolic health, IHL-42X is positioned to disrupt the treatment paradigm and deliver meaningful clinical benefit to a vastly underserved patient population.

This achievement builds on positive results from earlier studies and marks the next step in the Company's strategy to commercialise IHL-42X as a first-in-class, market-leading therapeutic solution for OSA

About IHL-42X

IHL-42X is designed to treat obstructive sleep apnea ("OSA") by targeting its underlying pathophysiology. An oral fixed-dose combination of dronabinol and acetazolamide, IHL-42X is currently advancing through the RePOSA Phase 2/3 clinical trial, which is expected to enroll more than 560 patients at sites worldwide.

Designed to act synergistically, IHL-42X uniquely targets two physiological pathways associated with the intermittent hypoxia ("IH") and hypercapnia that characterize OSA. In a prior Australian Phase 2 clinical trial, IHL-42X was shown to reduce the Apnea-Hypopnea Index ("AHI") in all dosage strengths, with the lowest dose reducing AHI by an average of 51 percent relative to baseline. RePOSA, a global Phase 2/3 clinical trial is underway, evaluating IHL-42X in individuals with OSA who are either non-compliant, intolerant, or naïve to positive airway pressure devices, including CPAP, with the Phase 2 portion conducted in the United States. A topline readout from the U.S. Phase 2 portion is anticipated in July 2025.

Unlike weight loss therapies, IHL-42X is uniquely engineered to target two key physiological pathways, intermittent hypoxia (IH) and hypercapnia, that underlie the pathology of OSA. By targeting these core mechanisms, IHL-42X offers a differentiated approach that may benefit a wider range of patients, including the 67% of individuals with OSA who are not classified as obese. OSA affects an estimated 1 billion people globally and approximately 30 million people in the United States. Despite its high prevalence OSA remains significantly underdiagnosed and undertreated. IHL-42X has the potential to address this critical gap in care and improve outcomes for millions living with this serious, chronic condition.

About Incannex Healthcare Inc.

Incannex is leading the way in developing combination medicines that target the underlying biological pathways associated with chronic conditions, including obstructive sleep apnea, rheumatoid arthritis and generalized anxiety disorder. The company is advancing three clinical-stage product candidates based on evidence-based innovation, and supported by streamlined operations. Incannex's lead clinical program, IHL-42X, is an oral fixed-dose combination of dronabinol and acetazolamide designed to target underlying mechanisms and act synergistically in the treatment of obstructive sleep apnea. In a Phase 2 development program, IHL-675A is an oral fixed-dose combination of cannabidiol and hydroxychloroquine sulfate designed to act synergistically to alleviate inflammatory conditions, such as rheumatoid arthritis. Approved for Phase 2 clinical development, PSX-001 is an oral synthetic psilocybin treatment for the treatment of generalized anxiety disorder. Incannex's programs target disorders that have limited, inadequate, or no approved pharmaceutical treatment options. For additional information on Incannex, please visit our website at www.incannex.com.

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. Examples of forward-looking statements in this press release include statements about, among other things: Incannex's business strategy, future operations; Incannex's judgements regarding the potential benefits from the cancellation of its Series A Warrants; Incannex's ability to execute on its objectives, prospects, or plans, evaluations and judgments regarding Incannex's research and development efforts, including any implications that the results of earlier clinical trials will be representative or consistent with later clinical trials or final results; the expected timing of enrollment for these trials and the availability of data or results of these trials, and the potential benefits, safety or of Incannex's drug candidates. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or Incannex's future performance, and they are based on management's current assumptions, expectations, and beliefs concerning future developments and their potential effect on Incannex's business; Incannex's ability to potentially benefit from its improved capital structure or to maintain or further improve its capital structure in the future. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: the continued availability of financing; Incannex's ability to raise capital to fund continuing operations, to complete capital raising transactions and to maintain or potentially further improve its capital structure; the impact of any infringement actions or other litigation brought against Incannex; the success of Incannex's development efforts, including Incannex's ability to progress its drug candidates through clinical trials on the timelines expected; competition from other providers and products; that the market for its drug candidates may not grow at the rates anticipated or at all; Incannex's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; and Incannex's ability to protect its proprietary technology and intellectual property; and other factors relating to Incannex's industry, its operations and results of operations. The forward-looking statements made in this press release speak only as of the date of this press release, and Incannex assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law. Incannex's reports filed with the U.S. Securities and Exchange Commission (SEC) including its annual report on Form 10-K for the fiscal year ended June 30, 2024, filed with the SEC on September 30, 2024, and the other reports it files from time to time, including subsequently filed annual, quarterly and current reports, are made available on Incannex's website upon their filing with the SEC. These reports contain more information about Incannex, its business and the risks affecting its business, as well as its results of operations for the periods covered by the financial results included in this press release. For additional information on Incannex, please visit our website at www.incannex.com.

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