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): **May 14, 2026**

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.)

Rialto South Tower **Level 23, 525 Collins Street** **Melbourne, VIC 3008 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 7.01 Regulation FD Disclosure.

On May 14, 2026, Incannex Healthcare Inc. (the "Company") issued the press release furnished as Exhibit 99.1.

The information contained in Item 7.01 in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated as of May 14, 2026
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: May 14, 2026

/s/ Joel Latham

Name: Joel Latham
Title: Chief Executive Officer and President

Exhibit 99.1

Incannex Healthcare Officially Commences DReAMzz Clinical Study for IHL-42X in Obstructive Sleep Apnea

Major operational milestone achieved as Incannex advances late-stage development of IHL-42X, with all clinical sites identified and trial infrastructure activated

MELBOURNE, Australia and NEW YORK, May 14, 2026 (GLOBE NEWSWIRE) — Incannex Healthcare Inc. (Nasdaq: IXHL), a clinical-stage biopharmaceutical company advancing innovative combination therapies for high-impact indications, today announced the official commencement of its DReAMzz clinical study evaluating IHL-42X for the treatment of obstructive sleep apnea (OSA).

The commencement of DReAMzz represents a major operational and strategic milestone for the Company as it advances IHL-42X toward late-stage clinical development and potential registration pathways. The Company has now completed extensive site feasibility assessments, identified all 14 clinical trial sites, completed manufacturing of IHL-42X drug product, secured all required import and export permits, and onboarded its newly appointed global distribution partner in preparation for site activation and patient dosing.

The DReAMzz study is designed as a crossover dose optimization study intended to further refine the dosing profile of IHL-42X and strengthen the design of the planned Phase III development program. The study is expected to generate additional data evaluating the relationship between dose optimization, objective sleep metrics, and patient-reported outcomes, which are becoming increasingly important in both regulatory review and commercial positioning within the OSA market.

Importantly, the DReAMzz program is designed to further optimize and de-risk the Phase III pathway following the positive Phase II RePOSA clinical trial, where IHL-42X demonstrated statistically significant and clinically meaningful reductions in apnea-hypopnea index (AHI), alongside improvements in oxygenation, sleep quality, fatigue-related outcomes and broader patient-reported measures. Incannex believes the DReAMMZ study has the potential to provide the Company with a more efficient pathway toward potential registration by optimizing the Phase III design prior to commencement, while also supporting more disciplined and effective capital deployment.

In recognition of the significant unmet need in obstructive sleep apnea and the encouraging clinical profile demonstrated by IHL-42X to date, the U.S. Food and Drug Administration (FDA) previously granted IHL-42X Fast Track designation for the treatment of OSA. The designation is intended to facilitate the development and expedite the review of therapies targeting serious conditions where there is the potential to address unmet medical need.

The Company believes the combination of strong Phase II efficacy data, encouraging patient-reported outcomes, operational advancement through DReAMzz and FDA Fast Track designation positions IHL-42X as one of the leading oral pharmacotherapy programs currently in development for obstructive sleep apnea.

“This is a significant milestone for Incannex and reflects the substantial operational progress made by the team over recent months,” said Dr. Lou Barbato, Chief Medical Officer of Incannex Healthcare Inc. “We have now transitioned from planning into active execution of the DReAMzz study, with critical infrastructure across manufacturing, logistics, clinical sites and trial operations established and ready to support the next stage of development.”

“Importantly, this study is designed to further optimize and de-risk the Phase III pathway for IHL-42X following the highly encouraging RePOSA data. We believe IHL-42X has the potential to become a transformative oral therapy in obstructive sleep apnea, a market where there remains a substantial unmet need despite the size and maturity of existing treatment approaches. The commencement of DReAMzz represents another major step toward realizing that opportunity.”

The Company confirmed that all 14 sites selected for the DReAMzz study have been identified following an extensive feasibility review process focused on sleep medicine expertise, patient recruitment capabilities, operational execution, and experience conducting complex overnight sleep studies. Site contracting activities are now underway, with contracts in place with high recruiting sites from RePOSA, enabling activation activities to progress efficiently.

In parallel, Incannex has completed manufacturing activities for IHL-42X clinical trial supply. Required import and export permits have also been secured, allowing the Company to efficiently distribute clinical material as sites become activated. A newly appointed distribution partner has now been fully onboarded to support supply chain management and study logistics.

The DReAMzz study forms part of Incannex’s broader strategy to position IHL-42X as a differentiated, late-stage asset targeting one of the largest and most underserved markets in sleep medicine. Obstructive sleep apnea affects hundreds of millions of people globally, with current standards of care limited by significant adherence and tolerability challenges. Incannex believes IHL-42X’s multi-mechanistic approach has the potential to address important gaps in existing treatment paradigms.

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

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to management's expectations regarding the development, regulatory progress and commercialization of the Company's drug candidates, including IHL-42X, expectations regarding use of the Company's cash on hand, the potential value of the Company's drug candidates and business, including these values as compared to available cash, opportunities, the strategy, timing and future development of the Company's drug candidates, the potential value of the Company and its drug candidates and potential shareholder value. When or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to the Company, its operations or its management, may identify forward-looking statements. The forward-looking statements contained in this press release are based on management's current expectations and projections about future events. Nevertheless, actual results or events could differ materially from the plans, intentions, and expectations disclosed in, or implied by, the forward-looking statements. These risks and uncertainties, many of which are beyond our control, include: the risk that the Company's estimates and current projections regarding the sufficiency of its current cash on hand to fund the Company's planned operations may be incorrect and the Company may use these resources faster than anticipated, and other risks described in the section entitled "Risk Factors" described in the prospectus supplement and in the Company's annual report on Form 10-K for the fiscal year ended June 30, 2025, filed with the SEC on September 29, 2025, and the other reports it files from time to time, including subsequently filed annual, quarterly and current reports, which can be obtained on the SEC website at www.sec.gov and are made available on the Company's website upon their filing with the SEC. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

Investor & Media Contacts

CORE IR
(212) 655-0924
investors@incannex.com
media@incannex.com.au