Incannex Healthcare Provides Corporate Update on Clinical Progress, Intellectual Property and Capital Position

September 9, 2026

- *Patient dosing commenced in the DReAMzz Phase 2 dose-optimization study of IHL-42X in obstructive sleep apnea*
- *U.S. composition and methods of treatment patent granted covering IHL-42X with baseline expiry in 2040*
- *Approximately $70 million in cash and no debt, including more than A$11.2 million in non-dilutive capital received during 2026*

NEW YORK and MELBOURNE, Australia, Sept. 09, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL) ("Incannex" or the "Company"), a clinical-stage biopharmaceutical company developing innovative combination therapies for high-impact indications, today provides a corporate update reporting the dosing of the first patient in its DReAMzz Phase 2 study of IHL-42X in obstructive sleep apnea, the grant of a U.S. composition patent covering IHL-42X, and a cash position of approximately $70 million with no debt.

Incannex President and CEO Joel Latham stated, “The commencement of patient dosing in DReAMzz marks a key milestone in the clinical development of IHL-42X. The protocol, which was shaped by our clinical advisory board and incorporates feedback from the FDA, was designed to produce the dose-selection data we need to enter a Phase 3 registration program with confidence. The program is well protected, with the recently granted composition patent extending protection to 2040, and well funded by our healthy cash position.”

IHL-42X for Obstructive Sleep Apnea

On August 25, 2026, Incannex announced the commencement of patient dosing in DReAMzz, a Phase 2 crossover dose-optimization study of IHL-42X in patients with obstructive sleep apnea. The study is being conducted across 13 clinical trial sites in the United States, each of which has received Institutional Review Board approval.

DReAMzz is designed to refine the dosing profile of IHL-42X and to inform the design of a subsequent Phase 3 registration program. The study protocol was developed with input from the Company's Obstructive Sleep Apnea Clinical Advisory Board, comprising physicians and researchers in sleep medicine and respiratory disease, and was reviewed by the U.S. Food and Drug Administration, with agency feedback incorporated into the final design.

Incannex previously completed the RePOSA Phase 2 study, which enrolled 121 subjects across 16 sites in the United States and reported positive topline results in August 2025. Patients enrolled in RePOSA were non-compliant with, intolerant of, or naive to positive airway pressure therapy. Both the low-dose and high-dose IHL-42X groups demonstrated greater percentage reductions in the apnea-hypopnea index relative to baseline than placebo, and greater reductions in the oxygen desaturation index than placebo, in each case with statistical significance. Individual reductions in apnea-hypopnea index of up to 83 percent were observed. The FDA granted Fast Track designation to IHL-42X in December 2025.

PSX-001 for Generalized Anxiety Disorder

PSX-001, the Company’s oral synthetic psilocybin therapeutic, continues to advance as a differentiated potential treatment for generalized anxiety disorder (GAD), a significant and underserved mental health condition.

In August 2025, the Company reported positive topline results from the completed 73-subject PsiGAD1 Phase 2 study. These encouraging results provide a strong clinical foundation for the program’s next stage of development. The Company also has an open U.S. Investigational New Drug application for PsiGAD2, a Phase 2b dose-comparison study, supporting continued regulatory and clinical progress in the United States.

To sharpen PSX-001’s competitive positioning and expand its potential, the Company has assembled a clinical advisory board of leading experts in psychiatry, psychiatric drug development and mental health treatment. Working with these key opinion leaders, the Company has developed innovative strategies for advancing psilocybin-based therapies in GAD and other high-value mental health indications.

The Company has also presented a refined development strategy to the UK Medicines and Healthcare products Regulatory Agency (MHRA) through a scientific advice meeting. Feedback from the MHRA, combined with continued input from the clinical advisory board, is actively informing the program’s clinical and regulatory pathway.

With positive Phase 2 results, an open U.S. IND, regulatory engagement in the UK and guidance from internationally recognized experts, PSX-001 has multiple catalysts supporting its continued advancement. The Company believes these achievements strengthen the program's differentiation and position PSX-001 to address substantial unmet patient need while creating meaningful long-term value for shareholders.

Intellectual Property

On June 25, 2026, the United States Patent and Trademark Office granted Incannex a patent titled, "Compositions and Methods of Treatment for Obstructive Sleep Apnea," with claims directed to the IHL-42X composition and associated methods of treatment. The patent carries a baseline expiry of July 9, 2040. The Company is evaluating eligibility for patent term extension in the event of future marketing approval.

Financial Position

As of 31 August 2026, Incannex held approximately $70 million in cash and cash equivalents and carried no debt.

During 2026, the Company received more than A$11.2 million in non-dilutive capital through the Australian Research and Development Tax Incentive program, comprising an A$6.0 million refund announced in June 2026 in respect of fiscal year 2025 and an additional A$5.1 million refund announced in August 2026.

About IHL-42X

IHL-42X is an oral fixed-dose combination of dronabinol and acetazolamide being developed for the treatment of obstructive sleep apnea. The two components act on distinct physiological processes associated with the condition. Dronabinol activates muscles in the upper airway and dampens afferent vagal feedback, stabilizing respiratory patterns and dilating the upper airway. Acetazolamide inhibits carbonic anhydrase, prompting respiratory drive at lower carbon dioxide levels. IHL-42X holds Fast Track designation from the U.S. Food and Drug Administration.

About PSX-001

PSX-001 is an oral synthetic psilocybin therapeutic being developed for the treatment of generalized anxiety disorder.

About Incannex Healthcare Inc.

Incannex Healthcare Inc. is a clinical-stage biopharmaceutical company developing innovative combination therapies and next-generation medicines for conditions with significant unmet medical need. The Company's lead programs include IHL-42X for obstructive sleep apnea and PSX-001 for generalized anxiety disorder. Incannex is committed to advancing therapies that address multiple biological pathways with the goal of improving patient outcomes and creating long-term shareholder value. For more information, please visit www.incannex.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the development, clinical performance, regulatory progress and potential commercialization of the Company's drug candidates; the design, conduct, timing and anticipated outcomes of clinical trials; the potential benefits of regulatory designations; the Company's intellectual property protection and potential patent term extension; the sufficiency of its capital resources; and potential shareholder value. Words such as "may," "could," "should," "anticipate," "believe," "continue," "estimate," "expect," "intend," "plan," "potential," "predict," "project," "will," "would" and similar expressions identify forward-looking statements.

Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially. These include the risks that clinical trials may be delayed, may not meet their endpoints or may identify safety concerns; earlier clinical results may not predict later outcomes; regulatory authorities may require additional studies or may delay or deny approval; regulatory feedback and Fast Track designation may not result in an accelerated or successful approval pathway; and the Company may experience difficulties with patient enrollment, clinical sites, contractors or manufacturing. Intellectual property risks include the possibility that patents may be challenged, narrowed, invalidated, circumvented or found unenforceable; may not prevent competing products; may not provide protection in all relevant jurisdictions; or may not qualify for patent term extension. The Company may also face third-party intellectual property claims. Additional risks include the possibility that the Company's cash resources may be used more quickly than anticipated and that additional financing may be required.

Other risks are described under "Risk Factors" 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 in its subsequent filings with the SEC, available at www.sec.gov. Readers should not place undue reliance on forward-looking statements, which speak only as of their date. Except as required by law, the Company undertakes no obligation to update them.

Investor & Media Contacts

CORE IR

(212) 655-0924

investors@incannex.com

media@incannex.com.au