Incannex Secures U.S. Patent Grant for IHL-42X in Obstructive Sleep Apnea

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MELBOURNE, Australia and NEW YORK, June 25, 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 announced that the United States Patent and Trademark Office (USPTO) has granted a key patent titled "Compositions and Methods of Treatment for Obstructive Sleep Apnea."

The granted patent includes claims directed to the proprietary IHL-42X composition and its associated therapeutic methods for the treatment of Obstructive Sleep Apnea (OSA). The patent is expected to have a baseline expiry date of 9 July 2040 and the Company is exploring its eligibility for patent term extension following potential U.S. Food and Drug Administration (FDA) approval, with a view to further enhancing the long-term exclusivity of the asset.

The grant of this patent represents a significant milestone in the advancement of IHL-42X and materially strengthens Incannex's intellectual property portfolio supporting its lead clinical program. The Company continues to actively review data generated across the IHL-42X development program with the objective of filing additional patent applications to further expand and protect the commercial and strategic value of the asset.

IHL-42X is being developed as a novel oral combination therapy for the treatment of OSA, a condition with substantial unmet medical need, where long-term patient compliance and treatment effectiveness remain key challenges.

The strengthened U.S. patent position significantly enhances the commercial value of IHL-42X by protecting the Company's proprietary oral combination therapy and supporting long-term market exclusivity. Together with FDA Fast Track designation, positive Phase II clinical data and ongoing advancement into the DReAMzz dose optimisation study, the patent further strengthens the strategic positioning of IHL-42X as a potentially differentiated pharmaceutical treatment for OSA.

Joel Latham, President and Chief Executive Officer of Incannex, commented:

"The grant of this U.S. patent represents another major milestone in the evolution of the IHL-42X program and further validates what we believe is one of the most compelling development opportunities in sleep medicine. OSA affects an estimated one billion people globally and remains a significantly underserved market where current treatment options continue to suffer from poor long-term patient adherence. We believe this creates an extraordinary commercial opportunity for a safe, effective and convenient oral pharmaceutical therapy.

"Over the past twelve months we have continued to build significant momentum across every aspect of the program. Following the successful RePOSA Phase II study, IHL-42X was granted FDA Fast Track designation, our intellectual property portfolio has continued to strengthen, and we are now approaching patient recruitment in our DReAMzz dose optimisation study, which is expected to further de-risk and optimise our Phase III development strategy.

"Importantly, this patent provides protection for our proprietary composition and methods of treatment through at least 2040, with the potential for additional patent term extension following regulatory approval. Combined with the clinical progress we have achieved, we believe IHL-42X is becoming an increasingly valuable pharmaceutical asset with the potential to address one of the largest unmet needs in sleep medicine. We remain focused on executing our development strategy and creating significant long-term value for both patients and shareholders."

IHL-42X Clinical Development Update

Incannex is nearing the commencement of patient recruitment in the DReAMzz Phase 2 study. The study has received central IRB approval along with the first tranche of site-specific IRB approvals. Study-specific Schedule I researcher registrations with the DEA are underway. The first site has received all necessary approvals and will commence screening in the near future, with additional sites to follow as the required approvals are received. Study drug supply has been shipped from the manufacturer to the distribution partner for secondary packaging and clinical trial labelling in preparation for patient dosing.

The DReAMzz study is designed as a crossover dose optimisation 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 optimisation, objective sleep metrics, and patient-reported outcomes, which are becoming increasingly important in both regulatory review and commercial positioning within the OSA market.

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, IHL-675A for rheumatoid arthritis 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

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, potential benefits of equity research coverage, the potential value of the Company's drug candidates and business, 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, the potential risk that equity research coverage may not result in increased investor awareness or liquidity, risks associated with the clinical development of IHL-42X and PSX-001, and other risks described in the section entitled "Risk Factors" described 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