Incannex Healthcare PSX-001 Program Aligns with White House Executive Order Accelerating Access to Psychedelic Treatments for Serious Mental Illness

April 22, 2026

Company's oral synthetic psilocybin program advances within significantly improved regulatory environment

MELBOURNE, Australia and NEW YORK, April 22, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), a clinical-stage biopharmaceutical company developing innovative combination therapies, today supports the White House Executive Order signed by President Donald J. Trump on April 18, 2026, titled, "Accelerating Medical Treatments for Serious Mental Illness." The Company believes its PSX-001 development program aligns with the goals outlined in the Executive Order and believes the data demonstrated to date, along with a more amenable regulatory environment, may provide significant hope for those suffering from anxiety disorders.

"We agree with the Administration's recognition that the mental health crisis in America demands a new level of regulatory urgency and scientific ambition," commented Incannex CEO Joel Latham. "For years, patients suffering from debilitating anxiety disorders have had limited options, particularly for those who fail first-line treatments. PSX-001, our oral synthetic psilocybin therapeutic for Generalized Anxiety Disorder, is designed for exactly these patients and this Executive Order represents a meaningful step toward ensuring that novel, evidence-based therapies like ours can reach them without unnecessary delay."

PSX-001: Rigorous Science, Compelling Data, a Clear Path Forward

PSX-001 is an oral, fixed-dose synthetic psilocybin formulation in development for Generalized Anxiety Disorder (GAD), a condition affecting an estimated 280 million people globally and approximately 6.8 million in the United States. In Incannex's completed Phase 2 clinical trial, PSX-001 demonstrated statistically significant and clinically meaningful improvements across all primary and secondary endpoints:

- 12.8-point reduction in HAM-A anxiety scores versus 3.6 points for placebo ($p<0.0001$)
- 44% rate of clinically meaningful response (≥50% anxiety reduction) — four times the placebo rate
- 27% remission rate (HAM-A ≤7) — five times the placebo rate, sustained through 11 weeks
- No serious adverse events and a single discontinuation across 73 patients

The Executive Order's direction to the FDA to prioritize review of psychedelic compounds with Breakthrough Therapy designations create Right to Try pathways for investigational psychedelics, and initiate DEA rescheduling upon successful Phase 3 completion. The move also addresses systemic barriers that have historically constrained the development and commercialization of this entire therapeutic category. Incannex views these measures as meaningfully reducing regulatory and commercial risk for the psilocybin class broadly.

"This Executive Order underscores what the clinical evidence has been telling us for years, that psilocybin and related compounds represent a genuinely transformative opportunity in mental health," Mr. Latham continued. "We are well-funded with over $70 million in cash and no debt, our U.S. IND is active, and we believe our Phase 2 data is among the strongest in the oral psilocybin space. We are advancing PSX-001 with urgency and scientific rigor, and we welcome a regulatory environment that shares that sense of urgency."

About PSX-001

PSX-001 is an investigational oral synthetic psilocybin therapeutic in development for Generalized Anxiety Disorder. Incannex completed a 73-patient Phase 2 clinical trial in Australia in 2025, reporting statistically significant and durable improvements in anxiety, functioning, depression, and quality of life measures. PSX-001 is the first oral synthetic psilocybin therapeutic in development for GAD.

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 share repurchase program, 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 or suspend the share repurchase program 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