Incannex Healthcare Delivers Transformational 2025 Progress and Outlines Well-Funded Outlook for 2026

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Company enters 2026 with over $70 million in cash, two positive Phase 2 programs, FDA Fast Track Designation and runway well into 2027

MELBOURNE, Australia and NEW YORK, Jan. 14, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), a clinical-stage biopharmaceutical company developing innovative combination therapies, provides a 2025 corporate year-in-review and outlook for 2026, highlighting substantial clinical, regulatory and financial progress that positions the Company for continued execution.

“The year 2025 was a defining one for Incannex,” stated Joel Latham, Incannex Healthcare Chief Executive Officer. “We delivered two independent, positive Phase 2 clinical readouts across distinct CNS programs, achieved FDA Fast Track designation for our lead OSA candidate, and materially strengthened our balance sheet. Importantly, we enter 2026 with more than $70 million in cash with runway extending well into 2027, allowing us to focus primarily on execution. With clinical validation, regulatory momentum and financial flexibility now in place, we are in a very exciting position as we advance our programs toward later-stage development and continue building long-term value for patients and shareholders.”

2025 Corporate Highlights

- Two Positive Phase 2 Clinical Readouts across distinct CNS programs
- FDA Fast Track Designation granted for lead obstructive sleep apnea candidate IHL-42X
- Strengthened balance sheet with over $70 million in cash on hand, providing operating runway well into 2027
- Capital structure optimization, including elimination of legacy warrant overhang and authorization of a share repurchase program
- Formation and expansion of OSA Clinical Advisory Board

Clinical and Regulatory Progress

IHL-42X (Obstructive Sleep Apnea)
During 2025, Incannex advanced IHL-42X, its oral combination therapy for obstructive sleep apnea, through several critical milestones:

- Positive Phase 2 RePOSA topline data demonstrating statistically significant reductions in apnea-hypopnea index (AHI), with reductions of up to 83%
- Clinically meaningful improvements in patient-reported outcomes, reinforcing clinical relevance and potential real-world benefit
- FDA Fast Track designation reflecting unmet medical need for oral pharmacotherapy in OSA and the potential of IHL-42X to address it

PSX-001 (Psi-GAD – Generalized Anxiety Disorder)
In parallel, Incannex reported positive Phase 2 clinical results for PSX-001, its psilocybin-assisted therapy for generalized anxiety disorder:

- Statistically significant and clinically meaningful improvement on the primary efficacy endpoint (HAM-A) compared to placebo
- Favorable secondary endpoint outcomes and tolerability profile, which are supportive of continued development

Clinical Advisory Board Expansion
To support advancing programs toward later-stage development, Incannex established a dedicated Obstructive Sleep Apnea Clinical Advisory Board comprised of leading experts in sleep medicine and respiratory disorders.

Financial Position and Capital Discipline

- Reported cash and cash equivalents exceeding $70 million, providing operating runway well into 2027
- Completed a $12.5 million private placement financing

- Eliminated all outstanding Series A warrants, removing legacy dilution overhang
- Authorized a $20 million share repurchase program
- Maintained disciplined and limited use of its at-the-market (ATM) facility

Outlook for 2026

- Advance IHL-42X toward later-stage development following FDA Fast Track designation
- Progress PSX-001 through next-phase clinical and regulatory planning
- Leverage strong cash position and runway into 2027 to execute development priorities without near-term financing pressure
- Continue disciplined capital allocation aligned with long-term shareholder value

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. Forward-looking statements are statements other than historical facts and relate to future events, future circumstances and Incannex's future performance. These statements are based on management's current assumptions, expectations, and beliefs. Examples of forward-looking statements in this press release include statements about, among other things: Incannex's future intentions regarding its efforts to maintain and/or regain compliance with applicable Nasdaq listing standards; business strategy, future operations; Incannex's ability to execute on its objectives, prospects o plans; evaluations and judgments regarding Incannex's research and development efforts and potential future commercialization, including any implications that the results of earlier clinical trials or interim or topline results will be representative or consistent with later clinical trials or their respective interim or final results; the potential benefits and safety of Incannex's drug candidates and the market opportunity for these candidates; and potential shareholder value. 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: that Incannex may fail to comply with Nasdaq listing standards within the applicable extended grace period or following the applicable extended grace period; that Incannex may fail to comply with Nasdaq listing standards other than the bid price rule; the closing price of the common stock may fall below $0.10 for ten consecutive trading days and be subject to Nasdaq's low bid price rules and subject to delisting or denial of compliance periods; the continued availability of financing; Incannex's ability to raise capital to fund continuing operations and to maintain or potentially further improve its capital structure; Incannex's ability to maintain the listing of its shares of common stock on the Nasdaq Stock Market; 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 and to obtain necessary regulatory approvals for commercialization of its product candidates; the effects of competition from other providers and products as currently existing or that may be developed in the future; that the market for its drug candidates may not grow at the rates anticipated or at all or that estimates for these markets may ultimately be incorrect; that Incannex may be unable to successfully execute upon any commercial discussions; Incannex's ability to comply 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 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, 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, 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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