Incannex Healthcare Inc. Reports Fiscal Second Quarter 2025 Financial Results and Business Updates

February 14, 2025

- Positive IHL-42X PK findings for the treatment of Obstructive Sleep Apnea (OSA) support future 505(b)(2) New Drug Application (NDA) submission
- New OSA Clinical Advisory Board Announced; Appoints Dr. Alison Wimms, Representing ResMed

NEW YORK and MELBOURNE, Australia, Feb. 14, 2025 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), (Incannex), a clinical-stage biopharmaceutical company leading the way in developing oral combination medicines, today reported fiscal second quarter financial results and provided business highlights for the quarter ended December 31, 2024.

“Patients with obstructive sleep apnea need new and convenient therapeutic options to manage this serious, chronic and life-threatening disease. We are enthusiastic about the potential for IHL-42X, an oral, once-daily treatment that uniquely targets physiological pathways responsible for the airway obstruction characteristic of OSA. We achieved a key milestone for our OSA program, reporting positive top-line results from a pharmacokinetics (PK) and safety study of IHL-42X, conducted alongside our global Phase 2/3 RePOSA study,” said Joel Latham, Incannex’s President and Chief Executive Officer.

“Our new OSA clinical advisory board brings together leading scientific and industry experts, and we are pleased to welcome Dr. Alison Wimms, representing ResMed, a recognized leader in the sleep medicine field. The OSA advisory board will provide valuable insights and guidance for our ongoing global IHL-42X Phase 2/3 RePOSA clinical trial. Looking ahead, we are committed to executing our clinical programs and are energized by the upcoming catalysts, including the top-line readout from the U.S. Phase 2 portion of the IHL-42X trial expected in the first half of 2025.”

Operational Highlights

- Established an IHL-42X OSA Clinical Advisory Board and appointed Alison Wimms, Ph.D. as an advisor, representing ResMed. Dr. Wimms brings two decades of sleep medicine industry and research expertise to Incannex’s new OSA advisory board. The CAB marks an important step in fostering collaboration as we advance our global Phase 2/3 ‘RePOSA’ clinical study in OSA.

  The RePOSA Global Phase 2/3 clinical trial is progressing well, with strong recruitment and enrollment at the U.S. sites. Building on the positive momentum and continued interest in patient recruitment, the trial design includes expansion to both U.K. and U.S. sites for the Phase 3 trial. Additionally, we have successfully completed manufacturing of the IHL-42X clinical supply needed to initiate Phase 3.

Clinical Highlights

- Announced positive top-line results from the completed pharmacokinetics (PK) and safety study of IHL-42X, a novel, oral fixed-dose combination of acetazolamide and dronabinol for the treatment of OSA. In line with expectations, the study demonstrated bioavailability of IHL-42X, confirming delivery of both drug components. Moreover, the PK profiles of the active ingredients in IHL-42X were similar to those established for the reference listed drugs, and total drug exposure levels from IHL-42X were found to be equivalent to those of the reference listed drugs, building a scientific bridge to the established safety and toxicology data. These results have the potential to support a future FDA 505(b)(2) new drug application (NDA) and will aid in the analysis of the global Phase 2/3 RePOSA study.

Financial Results

- General and Administration (G&A) expenses for the three months ended December 31, 2024 were $3.6 million USD, compared to $5.3 million USD for the same period in 2023. The decrease was primarily attributable to lower other employee benefits, resulting from a reduction in the amount of restricted stock issued to our directors and officers.

- Research and development (R&D) expenses for the three months ended December 31, 2024 totaled $1.4 million USD, compared to $2.6 million USD for the same period in 2023. The primary R&D expense for the period was associated with the global Phase 2/3 RePOSA clinical trial for OSA, while the primary decrease in expense was due to the completion of the IHL-42X safety and pharmacokinetics clinical trial, in addition to pausing the Phase 2 IHL-675A Australia study in rheumatoid arthritis in order to re-allocate use of resources to a larger U.S. Phase 2 IHL-675A clinical study, where an

expedited regulatory pathway may be available.

- Net loss for the three-month period ended December 31, 2024 was $6.3 million USD, compared to $4.3 million USD for the three months ended December 31, 2023.

- Cash and cash equivalents as of December 31, 2024 were $2.1 million USD, compared to $3.6 million USD as of September 30, 2024.

About IHL-42X

IHL-42X, an oral fixed-dose combination of acetazolamide and dronabinol, is currently in Phase 2/3 clinical studies for the treatment of obstructive sleep apnea (OSA). Designed to act synergistically, IHL-42X uniquely targets two physiological pathways associated with the intermittent hypoxia (IH) and hypercapnia that characterize OSA. In a prior Australian Phase 2 clinical trial, IHL-42X was shown to reduce the Apnea-Hypopnea Index (AHI) in all dosage strengths, with the lowest dose reducing AHI by an average of 51 percent relative to baseline. RePOSA, a global Phase 2/3 clinical trial is underway, evaluating IHL-42X in individuals with OSA who are either non-compliant, intolerant, or naïve to positive airway pressure devices, including CPAP, with the Phase 2 portion conducted in the United States. The expanded Phase 3 portion will include sites in the United Kingdom and European Union. A topline readout from the U.S. Phase 2 portion is anticipated in the first half of 2025.

About IHL-675A

IHL-675A is an oral fixed-dose combination of cannabidiol and hydroxychloroquine sulfate designed to target two distinct pathways, while acting synergistically to alleviate inflammation. IHL-675A was observed to be well tolerated and bioavailable in an Australian Phase 1 clinical trial. IHL-675A was also observed to reduce inflammatory markers and disease scores across multiple animal inflammatory disease models and in vitro assays in preclinical evaluation. Moving forward the company plans to focus resources on a larger U.S. Phase 2 study, where an expedited regulatory pathway may be available, enrolling patients with rheumatoid arthritis (RA).

About PSX-001

PSX-001 is Incannex's oral synthetic psilocybin drug candidate, administered in combination with psychotherapy, for patients diagnosed with moderate-to-severe Generalized Anxiety Disorder (GAD). In the Australian Phase 2 "PsiGAD1" clinical trial, PSX-001 was observed to reduce anxiety scores and be well-tolerated in GAD patients. Forty-four percent of the subjects in the psilocybin group exhibited a clinically meaningful improvement of at least 50% in anxiety score from baseline; a ‘response rate' more than four times higher than that of the placebo group. Incannex plans to submit full results from the PsiGAD1 Phase 2 trial for publication in a peer-reviewed scientific journal. The "PsiGAD2" Phase 2 trial is expected to recruit 94 patients with GAD, including those currently treated with selective serotonin reuptake inhibitors (SSRIs), who meet the study inclusion and exclusion criteria in the United States and United Kingdom.

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 novel oral fix-dosed treatments and therapeutic regimens based on evidence-based innovation. Incannex's lead Phase 2/3 and Phase 2 clinical programs include IHL-42X, an oral fixed-dose combination of dronabinol and acetazolamide, designed to act synergistically in the treatment of obstructive sleep apnea; IHL-675A, an oral fixed-dose combination of cannabidiol and hydroxychloroquine sulfate, acting synergistically to alleviate inflammatory conditions, such as rheumatoid arthritis, and PSX-001, an oral synthetic psilocybin treatment in combination with psychotherapy, for the treatment of generalized anxiety disorder. Incannex's programs target disorders that have limited, inadequate, or no approved pharmaceutical treatment options.

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. Examples of forward-looking statements in this press release include statements about, among other things: Incannex's business strategy, future operations; Incannex's ability to execute on its objectives, prospects, or plans, the skills and experience of the newly appointed officer of Incannex and expectations with respect to his future contributions to the Company and statements, evaluations and judgments regarding Incannex's research and development efforts, including any implications that the results of earlier clinical trials will be representative or consistent with later clinical trials or final results; the expected timing of enrollment for these trials and the availability of data or results of these trials, and the potential benefits, safety or of Incannex's drug candidates. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or Incannex's future performance, and they are based on management's current assumptions, expectations, and beliefs concerning future developments and their potential effect on Incannex's business. 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: the continued availability of financing; Incannex's ability to raise capital to fund continuing operations and to complete capital raising transactions; 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; competition from other providers and products; that the market for its drug candidates may not grow at the rates anticipated or at all; Incannex's compliance 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 to 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, 2024, filed with the SEC on September 30, 2024, 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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INCANNEX HEALTHCARE INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	December 31, 2024	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 2,098	$ 5,858
Prepaid expenses and other assets	417	507
Assets pledged as security for short-term debt	1,383	-
Research and Development (“R&D”) tax incentive receivable	6,606	9,837
Total current assets	**10,504**	**16,202**
Property, plant and equipment, net	273	472
Operating lease right-of-use assets	329	373
Total assets	**$ 11,106**	**$ 17,047**
Liabilities and stockholders’ equity		
Current liabilities:		
Trade and other payables	$ 845	$ 612
Accrued expenses and other current liabilities	3,435	4,845
Short-term debt	1,383	-
Operating lease liabilities, current	177	163
Total current liabilities	**5,840**	**5,620**
Operating lease liabilities, non-current	152	210
Long-term debt	2,385	-
Warrant liabilities	1,286	-
Convertible rights	478	-
Total liabilities	**10,141**	**5,830**
Commitments and contingencies (Note 8)		
Stockholders’ equity:		
Common stock, $0.0001 par value – shares 100,000,000 authorized; 17,785,235 and 17,642,832 shares issued and outstanding at December 31, 2024 and June 30, 2024 respectively	2	2
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2024 and June 30, 2024, respectively	-	-
Additional paid-in capital	126,354	125,218
Accumulated deficit	(121,984)	(110,671)
Foreign currency translation reserve	(3,407)	(3,332)
Total stockholders’ equity	**965**	**11,217**
Total liabilities and stockholders’ equity	**$ 11,106**	**$ 17,047**

INCANNEX HEALTHCARE INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	For the three months ended December 31,		For the 6 months ended December 31,	
	2024	2023	2024	2023
Revenue from customers	12	-	86	-
Operating expenses:				
Research and development	(1,414)	(2,638)	(4,310)	(5,247)
General and administrative	(3,602)	(5,345)	(7,034)	(7,629)
Total operating expenses	**(5,016)**	**(7,983)**	**(11,344)**	**(12,876)**
Loss from operations	(5,004)	(7,983)	(11,258)	(12,876)
Other income, net:		-		-
R&D tax incentive	956	2,727	1,767	6,824
Foreign exchange gains/(losses)	(326)	(5)	(331)	(6)
Interest income	28	20	57	90
Interest expense	(171)	-	(171)	-
Change in fair value of convertible rights	(179)	-	(179)	-
Change in fair value of warrant liabilities	(103)	-	(103)	-
ELOC commitment fee	(1,095)	-	(1,095)	-
Total other income, net	**(890)**	**2,742**	**(55)**	**6,908**
Loss before income tax expense	**(5,894)**	**(5,241)**	**(11,313)**	**(5,968)**
Income tax expense	-	-	-	-
Net loss	**$ (5,894)**	**$ (5,241)**	**$ (11,313)**	**$ (5,968)**
Other comprehensive income/(loss):				-
Currency translation adjustment, net of tax	(414)	927	(75)	418
Total comprehensive loss	**$ (6,308)**	**$ (4,314)**	**$ (11,388)**	**$ (5,550)**
Net loss per share: Basic and diluted	$ (0.33)	$ (0.33)	$ (0.65)	$ (0.38)
Weighted average number of shares outstanding, basic and diluted	17,624,422	15,873,113	17,563,200	15,873,113