



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

May 15, 2025

NEW YORK and MELBOURNE, Australia, May 15, 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 March 31, 2025.

"The third quarter of 2025 represents a pivotal period of progress for Incannex as we continue to execute on our IHL-42X development program," said Joel Latham, President and CEO of Incannex. "With the rapid completion of Phase 2 enrollment in the Phase 2/3 RePOSA, recent positive and confirmatory PK and safety clinical results, and the addition of expert sleep medicine clinical advisory leadership, we are well-positioned to deliver on key upcoming milestones and to advance IHL-42X as a potential treatment for millions of underserved patients living with OSA."

Operational Highlights

- Secured \$12.5 million USD in private placement funding, priced at-the-market under Nasdaq rules. Proceeds will support the ongoing IHL-42X Phase 2/3 obstructive sleep apnea (OSA) clinical program, including completion of the Phase 2 study, topline data readout, and expansion into Phase 3.
- Announced the formation of an OSA Clinical Advisory Board and the appointment of Alison Wimms, Ph.D., representing ResMed. Dr. Wimms brings over 20 years of sleep medicine industry and research expertise. The establishment of this new advisory board marks an important step in advancing collaboration and the late-stage clinical development of IHL-42X for the treatment of OSA, as the Incannex progresses its ongoing Phase 2/3 RePOSA clinical study.

Clinical Highlights

- Completed dosing of more than 120 patients across 11 clinical trials sites in the Phase 2 portion of the RePOSA Phase 2/3 study of IHL-42X, an oral once-daily treatment for OSA. The trial is evaluating two doses of IHL-42X (2.5 mg dronabinol/125 mg acetazolamide and 5 mg dronabinol/250 mg acetazolamide) compared to placebo over a four-week treatment period. The results from this study will inform the selection of the optimal dose to advance into the larger, pivotal Phase 3 study. The study is structured to support potential regulatory submissions, including a future 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). End-of-study follow-up assessments are expected to conclude May 17, 2025 and topline data is anticipated in July 2025.
- RePOSA Phase 3 planning is underway and will be conducted exclusively at U.S. sites to improve operational efficiency. This decision was supported by U.S. clinical site and patient enthusiasm.
- Reported positive topline results from a pharmacokinetics (PK) and safety study of IHL-42X. The data demonstrated that both active components in the fixed-dose combination were bioavailable, with pharmacokinetic profiles comparable to their respective reference listed drugs—further de-risking the program and establishing a clear scientific bridge to existing safety and toxicology data.

Financial Results

- General and Administration (G&A) expenses for the three months ended March 31, 2025 were \$2.27 million USD, compared to \$4.14 million USD for the same period in 2024, due to cost-saving initiatives and reduced overhead expenditures.
- Research and Development (R&D) expenses for the three months ended March 31, 2025 totaled \$2.74 million USD, compared to \$3.28 million USD for the same period in 2024.
- Net loss for the three-month period ended March 31, 2025 was \$3.97 million USD, compared to \$6.03 million USD for the three months ended March 31, 2024.
- Cash and cash equivalents as of March 31, 2025 were \$6.71 million USD, compared to \$2.09 million USD as of December 31, 2024, including proceeds from financing activities and R&D tax incentive receivables.

About IHL-42X

IHL-42X is designed to treat OSA by targeting its underlying pathophysiology. An oral fixed-dose combination of dronabinol and

acetazolamide, IHL-42X is currently advancing through the RePOSA Phase 2/3 clinical trial, which is expected to enroll more 560 patients at sites worldwide.

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. A topline readout from the U.S. Phase 2 portion is anticipated in July 2025.

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. 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)

March 31, 2025	June 30, 2024
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Assets**Current assets:**

Cash and cash equivalents	\$	6,711	\$	5,858
Prepaid expenses and other assets		416		507
Assets pledged as security for short-term debt		1,397		-
Research and Development ("R&D") tax incentive receivable		7,105		9,837

Total current assets		<u>15,629</u>		<u>16,202</u>
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Property, plant and equipment, net		277		472
Operating lease right-of-use assets		291		373

Total assets	\$	<u>16,197</u>	\$	<u>17,047</u>
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Liabilities and stockholders' equity**Current liabilities:**

Trade and other payables	\$	1,067	\$	612
Accrued expenses and other current liabilities		4,718		4,845
Short-term debt		1,397		-
Operating lease liabilities, current		186		163

Total current liabilities		<u>7,368</u>		<u>5,620</u>
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Operating lease liabilities, non-current		104		210
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Long-term debt		-		-
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Warrant liabilities		1,322		-
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Convertible rights		-		-
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Total liabilities		<u>8,794</u>		<u>5,830</u>
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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
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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		-		-
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Additional paid-in capital		136,849		125,218
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Accumulated deficit		(125,953)		(110,671)
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Foreign currency translation reserve		(3,495)		(3,332)
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Total stockholders' equity		<u>7,403</u>		<u>11,217</u>
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Total liabilities and stockholders' equity	\$	<u>16,197</u>	\$	<u>17,047</u>
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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 9-months ended		For the 3-months ended	
	March 31,		March 31,	
	2025	2024	2025	2024
Revenue from customers	84	-	-	-
Operating expenses:				
Research and development	(7,045)	(8,520)	(2,735)	(3,277)
General and administrative	(9,302)	(11,777)	(2,268)	(4,138)
Total operating expenses	<u>(16,347)</u>	<u>(20,297)</u>	<u>(5,003)</u>	<u>(7,415)</u>
Loss from operations	(16,261)	(20,297)	(5,003)	(7,415)
Other income/(expense), net:				
R&D tax incentive	2,188	8,150	421	1,320
Foreign exchange income/(expense)	(290)	(17)	41	(11)
Interest expense	(303)	-	(132)	
Interest income	60	166	4	75

Change in fair value of convertible rights	(176)	-	3	-
Change in fair value of warrant liabilities	1,721	-	1,824	-
Loss on extinguishment	(994)	-	(994)	-
Other expenses	(1,095)		(2)	
Total other income/(expense), net	<u>979</u>	<u>8,299</u>	<u>1,035</u>	<u>1,384</u>
Loss before income tax expense	<u>(15,282)</u>	<u>(11,998)</u>	<u>(3,968)</u>	<u>(6,031)</u>
Income tax expense	-	-	-	-
Net loss	<u>\$ (15,282)</u>	<u>\$ (11,998)</u>	<u>\$ (3,968)</u>	<u>\$ (6,031)</u>
Other comprehensive income/(loss):			-	
Currency translation adjustment, net of tax	(163)	(403)	(88)	(820)
Total comprehensive income/(loss)	<u>\$ (15,445)</u>	<u>\$ (12,401)</u>	<u>\$ (4,056)</u>	<u>\$ (6,851)</u>
Net loss per share: Basic and diluted	<u>\$ (0.84)</u>	<u>\$ (0.76)</u>	<u>\$ (0.20)</u>	<u>\$ (0.38)</u>
Weighted average number of shares outstanding, basic and diluted	<u>18,238,863</u>	<u>15,873,113</u>	<u>19,632,539</u>	<u>15,873,113</u>