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

November 14, 2024

NEW YORK and MELBOURNE, Australia, Nov. 14, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), (Incannex), a clinical-stage biopharmaceutical company developing innovative medicines for people with chronic diseases and significant unmet medical needs, today reported fiscal first quarter financial results and provided business highlights for the quarter ended September 30, 2024.

"The first quarter reflects ongoing progress for Incannex, building on the momentum of a transformative year. Our commitment to pioneering novel oral synthetic cannabinoid combination therapeutics and our oral synthetic psilocybin treatment remains strong, and we look forward to sharing further updates in the months ahead," said Joel Latham, Incannex's President and Chief Executive Officer. "To support our investment in clinical development, we recently brought on industry veteran Lou Barbato, whose expertise will be invaluable as we drive our therapeutic programs forward."

Operational Highlights

- Filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission in connection with the company's recent strategic financing in the first quarter of 2024.
- Appointed Lou Barbato, M.D. as Chief Medical Officer in October 2024. Dr. Barbato brings over 25 years of experience working with pharmaceutical and biotechnology companies, with expertise in psychiatric and neurological disorders. He has held leadership roles in medical affairs and as a medical director at companies such as Jazz Pharmaceuticals, AbbVie, and Novartis, contributing to the approval and launch of therapeutics in areas including depression, anxiety, and multiple sclerosis. His work spans a variety of drug classes, including synthetic cannabinoids, SSRIs, and MAO inhibitors.
- Announced a strategic financing for up to $59.0 million USD in gross proceeds with Arena Investors, comprising a $50 million USD equity line of credit and the sale of convertible debentures totalling up to $9.0 million USD. The funds are intended to support ongoing clinical trials for Incannex's drug candidates, as well as for general corporate purposes and working capital. Capital use will be determined based on Incannex's strategic requirements.

Clinical Highlights

- Granted Investigational New Drug (IND) application clearance by the U.S. Food and Drug Administration (FDA), and Clinical Trial Authorisation (CTA) from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to initiate the Phase 2b "PsiGAD2" clinical trial, evaluating PSX-001 in combination with psychotherapy for the treatment of patients with moderate-to-severe GAD. The PsiGAD2 trial will assess changes in HAM-A anxiety scores and additional efficacy and safety outcomes. Conducted at sites in the U.S. and UK, the study is expected to enroll approximately 94 patients with GAD, including those currently treated with SSRIs, who meet the inclusion criteria.

  In addition, full clinical results from the completed Australian Phase 2 PsiGAD1 trial are expected in the first half of 2025.
- Completed dosing of 115 participants in a bioavailability and bioequivalence (BA/BE) clinical trial in Australia for IHL-42X, an investigational treatment for obstructive sleep apnea in July 2024. Data analysis is currently in progress, with no serious adverse events reported to date. Top-line results are anticipated later in 2024.

Financial Results

- General and Administration (G&A) expenses for the three months ended September 30, 2024 were $3.4 million USD, as compared to $2.3 million USD for the three months ended September 30, 2023.
- Research and development (R&D) expenses were $2.9 million USD for the three months ended September 30, 2024 compared to $2.6 million USD for the three months ended September 30, 2023.
- Net loss for the three-month period ended September 30, 2024 was $5.4 million USD, as compared to $0.7 million USD for the three months ended September 30, 2023.
- Cash and cash equivalents were $3.6 million USD as of September 30, 2024, compared to $5.9 million USD as of June

30, 2024.

About IHL-42X

IHL-42X is Incannex's oral fixed dose combination of dronabinol and acetazolamide designed to act synergistically, targeting two different physiological pathways associated with the intermittent hypoxia (IH) and hypercapnia that characterize OSA. In an Australian Phase 2 clinical trial, IHL-42X was observed to reduce the apnea hypopnea index (AHI) and be well-tolerated in OSA patients. A global Phase 2/3 clinical trial investigating the safety and efficacy of IHL-42X is underway 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 top-line readout from the U.S. Phase 2 portion of the Phase 2/3 trial is anticipated in the first half of 2025. In addition, top-line results from an ongoing pharmacokinetic and safety study in Australia are expected in late 2024.

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 anticipates reporting full data results from the PsiGAD1 trial in the first half of 2025. 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 IHL-675A

IHL-675A is an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate designed to target two different pathways, 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. IHL-675A is in an Australian Phase 2 trial investigating the safety and efficacy in rheumatoid arthritis (RA) patients, enrolling 128 subjects with pain and reduced function regardless of current treatment regimen.

About Incannex Healthcare Inc.

Incannex is a clinical-stage biopharmaceutical company focused on developing innovative medicines for patients living with chronic diseases and significant unmet needs. The company is advancing oral synthetic cannabinoid and psilocybin drug candidates targeting sleep apnea, anxiety, and inflammatory diseases. Incannex's lead programs include IHL-42X, an oral fixed dose combination of dronabinol and acetazolamide, designed to act synergistically in the treatment of OSA, in a global Phase 2/3 study for the treatment of obstructive sleep apnea, PSX-001, an oral synthetic psilocybin treatment in combination with psychotherapy, for the treatment of generalized anxiety disorder, in a Phase 2 trial conducted in the United States and United Kingdom, and IHL-675A, an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate, acting synergistically to alleviate inflammation, in an Australian Phase 2 trial. 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.

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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)

	September 30, 2024	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 3,627	$ 5,858
Prepaid expenses and other assets	489	507
Research and Development ("R&D") tax incentive receivable	11,093	9,837
Total current assets	**15,209**	**16,202**
Property, plant and equipment, net	428	472
Operating lease right-of-use assets	411	373
Total assets	**$ 16,048**	**$ 17,047**
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 1,555	$ 612
Accrued expenses and other current liabilities	7,487	4,845
Operating lease liabilities, current	190	163
Total current liabilities	**9,232**	**5,620**
Operating lease liabilities, non-current	221	210
Total liabilities	**9,453**	**5,830**
Commitments and contingencies		
Stockholders' equity:		
Common Stock, $0.0001 par value per share – 100,000,000 shares authorized; 17,642,832 and 17,642,832 shares issued and outstanding at September 30, 2024 and June 30, 2024, respectively	2	2
Preferred Stock, $0.0001 par value per share, 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2024 and June 30, 2024, respectively	—	—
Additional paid-in capital	125,677	125,218
Accumulated deficit	(116,091)	(110,671)
Foreign currency translation reserve	(2,993)	(3,332)
Total stockholders' equity	**6,595**	**11,217**
Total liabilities and stockholders' equity	**$ 16,048**	**$ 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 September 30,	
	2024	**2023**
Revenue from customers	74	-
Operating expenses:		
Research and development	$ (2,896)	$ (2,608)
General and administrative	(3,432)	(2,284)
Total operating expenses	**$ (6,328)**	**$ (4,892)**
Loss from operations	(6,254)	(4,892)
Other income, net:		
R&D tax incentive	811	4,097
Foreign exchange gains/(losses)	(5)	(2)
Interest income	28	71
Total other income, net	**$ 834**	**$ 4,166**
Loss before income tax expense	**(5,420)**	**(726)**
Income tax expense	-	-
Net loss	**$ (5,420)**	**$ (726)**
Other comprehensive income/(loss):		
Currency translation adjustment, net of tax	339	(510)
Total comprehensive loss	**$ (5,081)**	**$ (1,236)**
Net loss per share: Basic and diluted	$ (0.29)	$ (0.08)
Weighted average number of shares outstanding, basic and diluted	17,642,832	15,873,113