Incannex Healthcare Inc. Reports Fiscal Full Year 2024 Financial Results and Business Updates

September 30, 2024

- *Announced strategic financing with Arena Investors, providing access to up to $59.0 million USD in gross proceeds to Incannex*
- *Announced positive top-line results from our Phase 2 proof-of-concept clinical trial of PSX-001, known as the PsiGAD1 study, in which synthetic psilocybin in combination with psychotherapy was observed to significantly reduce anxiety scores and to be well tolerated in patients with generalised anxiety disorder (GAD)*
- *Commenced dosing in the RePOSA Phase 2/3 clinical trial of IHL-42X, an oral investigational treatment for patients with obstructive sleep apnea*
- *Received Investigational New Drug (IND) application clearance from the U.S. Food and Drug Administration (FDA) to initiate PsiGAD2, a Phase 2 clinical trial of PSX-001*
- *Successfully completed redomiciliation to the United States and listing shares of Incannex common stock on Nasdaq under the ticker "IXHL" in late 2023*

NEW YORK and MELBOURNE, Australia, Sept. 30, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), (Incannex), a clinical-stage biopharmaceutical company developing innovative medicines for people with serious chronic diseases and significant unmet medical needs, today reported fiscal full year financial results and provided business updates.

"The past year has been transformative for Incannex as we successfully completed our transition to the Nasdaq as a company domiciled in the United States, reported positive top-line data from our proof-of-concept clinical trial of PSX-001, known as PsiGAD1, and initiated dosing in our Phase 2/3 IHL-42X RePOSA trial. These achievements demonstrate our commitment to advancing new oral cannabinoids and psychedelic treatments. With our recent strategic financing and clinical trials underway for three programs, we are excited to share updates later this year," said Joel Latham, Incannex's President and Chief Executive Officer. "We are grateful to all of the physicians, investigators and patients involved in our U.S. and Australian clinical trials for their support of our investigational synthetic cannabinoid and psilocybin-based therapeutic programs."

Operational Highlights

- Announced strategic financings with Arena Investors, which may provide up to $59.0 million USD in gross proceeds to Incannex through a $50 million USD equity line of credit and the sale in future closings of convertible debentures with an aggregate principal amount of up to $9.0 million USD. Incannex intends to use the proceeds from this strategic financing to support the ongoing clinical trials of its drug candidates, and for working capital and other general corporate purposes. Drawdown of the capital will be determined according to the Incannex's strategic needs.
- Announced the opening of Clarion Clinics, one of the first psychedelic-assisted psychotherapy clinics in Australia, which will serve as a model for potential future sites. Incannex believes this first clinic will provide real-world experience in treating mental health patients utilizing psychedelic-assisted psychotherapy. Assuming regulatory approval of PSX-001, the Clarion Clinics model has the potential to provide insight into the potential commercialization of PSX-001.
- Completed the redomiciliation of Incannex from Australia to the United States, effective November 28, 2023 and listing our common stock on the Nasdaq Global Market under the ticker "IXHL." With no material changes to its operations, Incannex believes this will provide access to a broader set of investors, streamline financial reporting comparably with industry peers, and provide greater flexibility in accessing capital.

Clinical Highlights

- Commenced dosing in the RePOSA Phase 2/3 clinical trial of IHL-42X, an oral fixed dose combination of dronabinol and acetazolamide for the treatment of patients with obstructive sleep apnea (OSA). RePOSA, a randomized, double-blind trial, is designed to assess the safety and efficacy of IHL-42X in patients with OSA who are intolerant, non-compliant, or naïve to positive airway pressure. The Phase 2 portion of this clinical trial is being conducted in the United States, and the expanded Phase 3 portion will include sites in the United Kingdom and European Union. Incannex plans to recruit 560 subjects, with an estimated 355 participants in the active study arms, and anticipates reporting top-line data from the

Phase 2 portion of this clinical trial in the first half of 2025.

- Completed dosing of 115 subjects in a bioavailability/bioequivalence (BA/BE) clinical trial conducted in Australia assessing the pharmacokinetics and tolerability of IHL-42X, our drug product for the treatment of obstructive sleep apnea. Data analysis is underway, with no serious adverse events reported to date. Incannex expects to release top-line results from this BA/BE clinical trial in 2024.

- Announced positive results from its proof-of-concept Australian Phase 2 clinical trial, PsiGAD1, of PSX-001. In the PsiGAD2 trial the combination of an oral synthetic psilocybin with psychotherapy was observed to significantly reduced anxiety scores and was well tolerated in patients with generalized anxiety disorder (GAD). The reduction in HAM-A from baseline, the trial's primary endpoint, in the psilocybin group was 12.8 points from baseline, representing a 9.2-point improvement over psychotherapy with placebo ($p<0.0001$).

- Received IND clearance from the FDA to initiate PsiGAD2, a Phase 2b clinical trial of PSX-001 evaluating change in the HAM-A anxiety score, and other measures of efficacy and safety at sites in the U.S. and UK. The trial is expected to include approximately 94 patients, including those currently treated with selective serotonin reuptake inhibitors (SSRIs), who meet the study inclusion and exclusion criteria.

- Initiated dosing in an Australian Phase 2 clinical trial of IHL-675A for patients with rheumatoid arthritis (RA). IHL-675A is an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate designed to target two different pathways, acting synergistically to alleviate inflammation. The trial is planned to include approximately 128 subjects. Incannex anticipates reporting top-line data in the second half of 2025.

Financial Results

- General and Administration (G&A) expenses for the twelve months ended June 30, 2024 were $17.2 million USD, as compared to $8.0 million USD for the twelve months ended June 30, 2023, due to associated completed the redomicilation to the United States, listing of common stock on Nasdaq, and expanded U.S. operations.

- Research and development (R&D) expenses were for $12.9 million USD for the twelve months ended June 30, 2024 compared to $6.3 million USD for the twelve months ended June 30, 2023, due to increased clinical research activities.

- Net loss for the twelve-month period ended June 30, 2024 was $18.5 million USD, as compared to $48.8 million USD for the twelve months ended June 30, 2023.

- Cash and cash equivalents were $5.9 million USD as of June 30, 2024, compared to $22.1 million USD as of June 30, 2023.

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 a proof-of-concept Australian Phase 2 clinical trial, IHL-42X was observed to reduce the apnea hypopnea index and be well tolerated in OSA patients. An ongoing pivotal Phase 2/3 clinical trial investigating the safety and efficacy of IHL-42X is underway with the Phase 2 portion conducted in the U.S., the expanded Phase 3 portion will also include the UK and EU. Top-line results from an ongoing pharmacokinetic and safety study in Australia are expected in late 2024. The top-line readout from the U.S. Phase 2 portion of the pivotal Phase 2/3 trial is anticipated in the first half of 2025.

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 GAD. In the Australian Phase 2 proof-of-concept PsiGad1 clinical trial, PSX-001 was observed to reduce anxiety scores and was well tolerated in GAD patients. In this trial, 44% of subjects in the psilocybin group were observed to show a clinically meaningful improvement of at least 50% subjects in anxiety score from baseline; a ‘response rate' more than four times higher than that of the placebo group. The FDA has cleared Incannex's IND application for PsiGAD2 to conduct a U.S. Phase 2b clinical trial, which is expected to include approximately 94 patients with GAD, including those currently treated with selective serotonin reuptake inhibitors (SSRIs), who meet the study inclusion and exclusion criteria. Incannex anticipates reporting full data results from PsiGAD1 trial in the first half of 2025.

About IHL-675A

IHL-675A is an oral drug candidate currently in an ongoing Australian Phase 2 trial for the treatment of inflammatory conditions, with an initial focus on RA. 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 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. A Phase 2 trial investigating the safety and efficacy of IHL-675A in RA patients is ongoing, enrolling 128 subjects with pain and reduced function regardless of

current treatment regimen. Top-line data from this Phase 2 trial is anticipated in the second half of 2025.

About Incannex Healthcare Inc.

Incannex is a clinical-stage biopharmaceutical company focused on developing innovative medicines for patients living with serious 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 in a Phase 2 trial conducted in the U.S. and UK to assess the combination of an oral synthetic psilocybin treatment with psychotherapy for patients with generalized anxiety disorder, and IHL-675A, an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate, acting synergistically to alleviate inflammation, in an Australian Phase 2 trial. Each of these programs target indications 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 benefits of the redomiciliation and the Nasdaq common stock listing, future closings of the strategic financings with Arena, which are subject to conditions and may not occur, 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.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	June 30, 2024	June 30, 2023
Assets		

Current assets:		
Cash and cash equivalents	$ 5,858	$ 22,120
Prepaid expenses and other assets	507	877
R&D tax incentive receivable	9,837	-
Total current assets	16,202	22,997
Property, plant and equipment, net	472	294
Operating lease right-of-use assets	373	492
Total assets	$ 17,047	$ 23,783
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 612	$ 1748
Accrued expenses and other current liabilities	4,845	689
Operating lease liabilities, current	163	113
Total current liabilities	5,620	2,550
Operating lease liabilities, non-current	210	408
Total liabilities	5,830	2,958
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value – 100,000,000 shares authorized; 15,873,113 and 15,873,113 shares issued and outstanding at June 30, 2024 and 2023, respectively	2	2
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2024 and 2023, respectively	-	-
Additional paid-in capital	125,218	116,290
Accumulated deficit	(110,671)	(92,212)
Foreign currency translation reserve	(3,332)	(3,255)
Total shareholders' equity	11,217	20,825
Total liabilities and stockholders' equity	$ 17,047	$ 23,783

INCANNEX HEALTHCARE INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	June 30, 2024	**June 30, 2023**
Revenue from customers	12	-
Operating expenses:		
Research and development	(12,879)	(6,309)
Acquisition of in-process research and development	-	(35,347)
General and administrative	(17,174)	(8,012)
Total operating expenses	(30,053)	(49,668)
Loss from operations	(30,041)	(49,668)
Other income, net:		
R&D tax incentive	11,434	683
Foreign exchange expense	(28)	(67)
Interest income	206	241
Total other income, net	11,612	857
Loss before income tax expense	(18,429)	(48,811)
Income tax expense	(30)	-
Net loss	$ (18,459)	$ (48,811)
Other comprehensive loss:		

Currency translation adjustment, net of tax	(77)	(2,292)
Total comprehensive loss	$ (18,536)	$ (51,103)
Net loss per share: Basic and diluted	$ (1.15)	(3.32)
Weighted average number of shares outstanding, basic and diluted	16,164,338	15,384,704

