Date: 26 October 2023
Public Announcement (ASX: IHL) (Nasdaq: IXHL)

Incannex Healthcare September 2023 Quarterly Activities Report and Appendix 4C Cash Flow Statement

Melbourne, Australia, October 26, 2023 - Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL) (NASDAQ: IXHL), ('Incannex' or the 'Company'), is pleased to provide its quarterly activities report and appendix 4C for the period ended 30 September 2023. Incannex is undertaking a multitude of U.S. Food and Drug Administration ('FDA') research and development ('R&D') programs for cannabinoid pharmaceutical products and psychedelic medicine therapies administered by health professionals.

FDA IND approval to commence IHL-42X phase 2/3 clinical trial for patients with obstructive sleep apnoea

During the quarter, Incannex received approval from the US Food and Drug Administration (FDA) to proceed with its Investigational New Drug (IND) opening pivotal IHL-42X Phase 2/3 clinical trial in the United States. The trial, planned for patients with obstructive sleep apnoea who are non-compliant, intolerant, or new to positive airway pressure treatment, will assess the effects of IHL-42X, dronabinol, acetazolamide, and a placebo. Participants will undergo daily sleep quality surveys, monthly clinic visits to evaluate sleep outcomes and safety, and regular polysomnography to assess the impact of treatments on Apnoea Hypopnea Index (AHI) and other sleep parameters. Combining Phase 2 and Phase 3 in a single Phase 2/3 trial allows for a more efficient transition from the early stages of testing (Phase 2) to the final stages required for regulatory approval (Phase 3), potentially accelerating the availability of this new treatment to patients subject to continued clinical success.

At the time, CEO and Managing Director of Incannex, Mr Joel Latham said, "The initial Phase 2 proof of concept clinical trial over IHL-42X demonstrated an average reduction in our primary end point, AHI of 50.7%, with 25% of subjects having a reduced AHI of >80%. Importantly, we also observed a reduction in average patient oxygen desaturation index of 59.7%, markedly improved sleep quality and a reduction in cardiovascular stress. These results were truly remarkable and now allows for this Phase 2/3 trial to be a genuine long-term safety and efficacy trial. If we again observe such remarkable drug efficacy, safely administered over the 52 weeks, Incannex is confident that our product will be marketable."

Since the FDA provided clearance for the IND opening study to begin, startup of the IHL-42X Phase 2/3 clinical trial IHL-42X has progressed rapidly. The trial, which has been given the name **RePOSA**, derived from **R**evealing the **E**fficacy of IHL-42X use in **P**atients with **OSA**, will assess the safety and efficacy of IHL-42X compared to the component active pharmaceutical ingredients, dronabinol and acetazolamide, as well as placebo.

Incannex have been working with Fortrea, the contract research organisation ('CRO') engaged to manage the trial, to assess and formally engage sites in the US, Europe, Australia and New Zealand. The site selection/approval process and preparation of institutional review board (IRB) packages is proceeding as planned. Incannex is also working with vendors for the operation of the study, including central readers for polysomnography, central laboratory services for assessment of blood samples for safety markers, coordination of drug product packaging and labelling for blinded clinical trials, as well as distribution chains to trial sites. These are operational considerations to ensure that the multi-site global clinical trial is run efficiently and according to the necessary regulatory requirements. Trial updates will continue to be provided to investors as major milestones are achieved.

There are no registered pharmacotherapy (drug) treatments available to people with OSA, representing a major economic opportunity to Incannex with IHL-42X, should the study achieve its endpoints as in the proof-of-concept trial.

IHL-42X bioavailability/bioequivalence study update

Screening for the IHL-42X bioavailability/bioequivalence (BA/BE) study commenced on 8 September 2023, and dosing of trial participants commenced on 6th October 2023. Four groups of participants have completed at least one dosing session at CMAX Clinical Research in South Australia. The first group have completed 3 of 4 dosing sessions and will complete their final dosing session on 27th October. Patient recruitment, dosing, and assessment will continue according to the trial schedule towards completion. The aim of the trial is to assess the safety, tolerability and pharmacokinetics of IHL-42X at scale compared to the reference listed drugs for the active pharmaceutical ingredients, dronabinol and acetazolamide, in healthy volunteers. The trial is also assessing the effect of food on the safety, tolerability and pharmacokinetics of IHL-42X. Updates on patient recruitment, dosing and other study milestones will be provided to investors as they occur.

Clarion Clinics: psychedelic-assisted psychotherapy clinics ready to launch services following receival of all approvals

Clarion Clinic, the first of its kind, located on the Yarra Riverfront in Abbottsford, Melbourne has been designed and fitted out specifically to provide the optimal environment for psychedelic-assisted therapy. With seven treatments rooms and a group therapy room, the clinic is a commercial scale prototype and has the capacity to treat approximately 600 people per year in normal working hours and substantially more in extended hour operations. Future clinics are expected to be significantly larger. Photos of the clinic are attached.

In order to be able to treat people with psychedelic-assisted therapy, Clarion is required to attain approval from a Human Research Ethics Committee (HREC), the TGA Authorised Prescriber Scheme and State Health Authorities. This process is well underway and interim feedback has been positive. While Clarion doesn't control the timelines involved in this process making it hard to predict a firm date, it is making good progress and hopes to have all approvals in place to commence treatment in November, assuming no unforeseen issues arise.

Since Clarion launched its website in August, it has received substantial interest in its treatments. Potential patients are being placed on a waiting list in the order of their application. "The level of interest in treatment before any major marketing push is indicative of the pent-up demand. People are actively seeking out places which will be able to perform this type of treatment." Peter Widdows, IHL Director responsible for Clarion Clinics establishment said.

Critically, Clarion has assembled a motivated team of psychiatrists, psychologists and psychotherapists who, along with Clarion's clinical founders, are amongst the most experienced psychedelic-assisted therapy experts in Australia. "People who have experience with this kind of therapy are few and far between in Australia and we're privileged to have such a strong team at Clarion. The quality of our team and our patient centric philosophy are key to making sure Clarion is the clinic patients will seek out to give themselves the best chance of a successful treatment outcome". Widdows added.

Clarion Clinics is at the leading edge of mental healthcare not just locally, but globally and its bespoke treatment protocols offer the hope of sustained improvement for the 670,000 Australians suffering from Post-Traumatic Stress Disorder (PTSD) and Treatment-Resistant Depression (TRD) and potentially, legislation allowing, the tens of millions of people worldwide. "Being the first dedicated clinic to offer this treatment, while having it's challenges, is well worth the effort and will put Clarion well ahead of the pack, giving it a ready model to work with and expand both in Australia and internationally." Widdows commented.

Clarion Clinics is exploring numerous potential patient treatment funding pathways, both governmental and private, and remains optimistic that there should be multiple funding opportunities for eligible patients in the future. While the upfront cost of $22-25,000 is high, due to the requirement for extensive psychotherapy and psychiatry provided over a multi-month period, for potential funding partners, it needs to be assessed versus the lifetime of medication, psychiatry, psychotherapy and lost productivity which they are currently funding. "The most important point will always be that it offers people who are suffering debilitating conditions a chance for sustained improvement in their mental wellness, but the opportunity for funding bodies to reduce their future liabilities and deploy their resources across other areas in need cannot be underestimated." Widdows added.

"I'm very encouraged by the progress Clarion has made in such a short time since the down-scheduling. The level of demand from potential patients shows that this treatment has found its time. The potential for funding pathways is also very positive progress and could make this vital treatment accessible for many more people who need it. Clarion Clinics is a potential multi-billion-dollar initiative which will address a significant community need for better mental health treatments." Joel Latham, Managing Director and CEO of IHL commented.

Images of the interior and exterior of the Melbourne clinic

FDA IND application for Psi-GAD – psilocybin-assisted psychotherapy for generalised anxiety disorder

During the quarter, Incannex commenced preparations for an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for its psilocybin-assisted psychotherapy development program known as Psi-GAD. The IND application is a crucial regulatory step required for conducting clinical trials in the United States. Incannex aims to submit the application after receiving final clinical trial results from the ongoing Phase 2 Psi-GAD clinical trial at Brain Park, Monash University, expected

in Q4 2023 or Q1 2024. The submission will contain comprehensive data on the safety and efficacy of psilocybin-assisted psychotherapy across various mental health indications. An interim analysis of the Phase 2 trial indicated a high likelihood of significant benefit for the psilocybin treatment arm, leading to confidence in the therapy's utility. CEO Joel Latham expressed optimism about the progress and emphasized the company's leading position in the psychedelic research sector.

Incannex Receives HREC Approval for Phase 2 Clinical Trial Assessing IHL-675A for use in Treatment of Pain and Function in Rheumatoid Arthritis

During the quarter, Incannex received HREC approval at the lead site, Emeritus Research, Melbourne to conduct the clinical trial. Following the initial HREC approval Incannex, with assistance from Avance Clinical, the CRO engaged to manage the trial, have selected 12 sites in Australia from where the studies will be conducted. The sites and investigators all have experience in running clinical trials in RA and have established track records in patient recruitment. Sites have been selected in Victoria, New South Wales, Western Australia, Queensland and the Australian Capital Territory, providing access to a substantial patient population. Site start-up at each trial location is progressing according to schedule, with human research ethics committee (HREC) approval received for 5 of the 12 sites. A central reader for the MRI sub-study has been engaged and the imaging assessment methodology for the trial has been refined. Commencement of patient screening is imminent. Updates on study progress will be provided as major milestones are achieved.

The Phase 2 clinical trial aims to assess IHL-675A's impact on pain and function using patient-reported outcomes, disease scores, and inflammatory biomarker analysis over a 24-week period. The trial results will determine the safety and efficacy of IHL-675A in RA patients and contribute to the regulatory application process with the FDA. The decision to prioritize this clinical assessment was based on positive results from an animal model of RA, where IHL-675A demonstrated significant effectiveness in reducing arthritis across various assessments, surpassing the standard dose of HCQ (commonly prescribed for RA) and equivalent doses of CBD.

This Phase 2 clinical trial of IHL-675A is a significant step for Incannex, following positive outcomes in preclinical and Phase 1 studies. The trial will compare the efficacy, safety, and tolerability of IHL-675A against its individual components, CBD and HCQ, as well as a placebo. Avance Clinical will oversee the trial's management, which aims to establish IHL-675A's effectiveness in managing pain and improving function in RA patients.

Incannex Progresses Redomicile to United States, List all Shares on Nasdaq

In July, Incannex announced its intention to redomicile to the United States via a Scheme of Arrangement pursuant to Australian law. A newly formed Delaware corporation (Incannex Healthcare Inc.) will become the ultimate parent company of the group, following implementation of the Schemes

of Arrangement for Shareholders and Optionholders. The shares of common stock issued by Incannex Healthcare Inc. in exchange for all outstanding ordinary shares of Incannex, pursuant to the Scheme of Arrangement, will be listed on Nasdaq. Redomiciling to the US is unanimously supported by the directors of Incannex. The Company anticipates that it will have greater access to a capital market more cognisant of IHL's value proposition with peer comparison companies trading at significantly higher market valuations.

Subsequent to the end of the September quarter, the Federal Court of Australia made orders for the convening of the Scheme Meetings and approving the dispatch of the Scheme Booklet. The Scheme Meetings will be held on Wednesday, 8 November 2023, with the Share Scheme Meeting beginning at 10:00am (Melbourne time) and the Option Scheme Meeting beginning at the later of the conclusion of the Share Scheme Meeting and 10:30am (Melbourne time).

Following approval of the Scheme by the Federal Court of Australia, the Scheme booklet was dispatched to Incannex shareholders and optionholders on around 9th of October 2023. Shareholder and optionholder voting on the Schemes will conclude on the 6th of November and the general meeting of shareholders and optionholders to finalise the vote count on the Schemes of arrangement will occur on the 8th of November.

Also after the quarter end, Incannex provided a voting update for Incannex to redomicile to United States and trade exclusively on Nasdaq. At October 18, 2023, 99.64% of shareholder voting shares in favour of the share scheme resolution to redomicile. At the same date, 99.93% of optionholder voting options in favour of the option scheme resolution to redomicile.

A total of 464 shareholders have voted as at the 18th of October. 433 shareholders representing approximately 788M shares have voted in favour or provided discretion to the Company to vote in favour of the Share Scheme resolution. 16 shareholders representing 2.4M shares have voted against the Share Scheme. A total of 217 optionholders have voted as at the 18th of October. 209 optionholders representing approximately 124M options have voted in favour or provided discretion to the Company to vote in favour of the Option Scheme resolution. 4 optionholders representing 53,336 options have voted against the Option Scheme.

Corporate Activities

At September 30, 2023, Incannex recorded A$25.3M in cash at bank. A$5.3M was recorded as cash outflows associated with R&D activities and comprised significant upfront payments associated with the commencement of IHL-42X and IHL-675A phase 2 and phase 3 clinical trial activities. Incannex is eligible to receive an annual cash rebate equivalent to approximately 43.5% of all monies spent on research and development in Australia. A significant cash rebate of approximately A$2.6M is expected to be received by Incannex in the current December 2023 quarter. The Company's expansive pipeline of clinical development programs remains fully funded into 2025.

Incannex shares trade on the ASX under stock code “IHL”. Incannex American Depository Shares (ADSs) also trade on the NASDAQ under code “IXHL”. Each IXHL ADS represents 25 ordinary shares of the Company. Item 6.1 of Appendix 4C (below) represents amounts paid to directors and related parties.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Incannex Healthcare Limited	

ABN	Quarter ended ("current quarter")
93 096 635 246	30 September 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	research and development	(5,271)	(5,271)
	product manufacturing and operating costs	-	-
	advertising and marketing	(38)	(38)
	leased assets	(70)	(70)
	staff costs	(382)	(382)
	administration and corporate costs	(2,453)	(2,453)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	109	109
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	330	330
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(7,775)**	**(7,775)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	businesses	-	-
	property, plant and equipment	(361)	(361)
	investments	-	-
	intellectual property	-	-
	other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	businesses	-	-
	property, plant and equipment	-	-
	investments	-	-
	intellectual property	-	-
	other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(361)**	**(361)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	33,363	33,363
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,775)	(7,775)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(361)	(361)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	6	6
4.6	**Cash and cash equivalents at end of period**	**25,227**	**25,227**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	328	290
5.2	Call deposits	24,899	33,073
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**25,227**	**33,363**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(412)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7.	Financing facilities *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Not applicable

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(7,775)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	25,227
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	25,227
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	3.2

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: n/a

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: n/a

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: n/a

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: .....26 October 2023.....

Authorised by: .....By the Board.....

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.