Date: 27 April 2023
Public Announcement (ASX: IHL) (NASDAQ: IXHL)

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

Melbourne, Australia, April 27, 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 31 March 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.

Launch of Psychedelic Assisted Psychotherapy Clinics in Collaboration with Australia's Foremost Psychedelic Assisted Psychotherapy Experts

In March of 2023, Incannex announced that it had developed plans for the commercialisation of its psychedelic-assisted psychotherapy business ('Psychedelic Clinics'). The Company estimates that the addressable market for psychedelic assisted psychotherapy in Australia will grow to over $2 billion per annum within 3 years.

Clarion Clinics Group, the collaboration between Australia's foremost clinical experts and IHL (84.5% owned by IHL subsidiary Psychennex Pty Ltd), will provide treatment under the TGA regulated authorised prescriber scheme, for the use of psilocybin for treatment-resistant depression (TRD) and the use of MDMA for Post-Traumatic Stress Disorder (PTSD). A number of other depression and anxiety related disorders will be treated with ketamine-assisted psychotherapy.

Incannex, through Clarion Clinics Group, plans to open multiple psychedelic-assisted psychotherapy clinics in Australia and overseas, with the first 'model' clinic to open in Melbourne in Q3, 2023, followed by rapid expansion of much larger clinics to other Australian major centres based on the development of sound operations at the model clinic.

The model clinic will be a commercial scale prototype, capable of treating 600+ patients per year in normal working hours and substantially more in extended hours of operation. The Company expects its inner-North Melbourne premises to be ready before September 2023, facilitating first patient treatments shortly after.

The Company has entered a collaboration agreement with Australia's leading clinical psychedelic professionals, all of whom have extensive experience within clinical psychedelic research, treatment, and training. Dr. Paul Liknaitzky, Professor Suresh Sundram and Sean O'Carroll have joined the Board of Directors of a Clarion Clinics Group Pty Ltd and Clarion Model Clinic Pty Ltd and taken key executive roles within the business. The venture is being led by long time Incannex Director, Peter Widdows.

Dr Paul Liknaitzky: Co-Founder, Director, Chief Strategy Officer, and Chief Scientific Officer

Paul has played a central role in establishing the clinical psychedelic field in Australia and leads the largest group of psychedelic researchers and clinicians in the country. Paul is the Chief Principal Investigator on a program of psychedelic trials and collaborates on numerous others nationally. He has led the development of psychedelic trial protocols, treatment design, trial coordination, therapist selection and training, and has established active collaborations with an extensive network of international experts and organisations in the field. Paul's work is focused on developing innovative psychedelic therapies, evaluating benefits, exploring potential drawbacks, predicting treatment response, mitigating risks, understanding therapeutic mechanisms, and translating research into practice.

Professor Suresh Sundram: Co-Founder, Director, Chief Medical Officer, and Head of Psychiatry

Suresh is a Fellow of the Royal Australian and New Zealand College of Psychiatrists and a consultant psychiatrist. He holds senior leadership positions in academic and clinical psychiatry and has published more than 150 scientific articles, books, book chapters, and conference abstracts. He has presented as plenary and invited speaker at international and national conferences, served as Deputy Editor for the Asian Journal of Psychiatry, and as an advisor to the United Nations (UN), and to national and state governments. Prof. Sundram has led over 50 clinical trials and studies in psychiatric disorders. He has extensive experience with the use of psychedelics within psychotherapy and has overseen multiple research projects in this field.

Sean O'Carroll: Co-Founder, Director, and Head of Psychotherapy

Sean is an integrative psychotherapist and academic – specialising in experiential, relational, and transpersonal psychotherapy. Since 2019, he has developed and delivered psychedelic-assisted psychotherapy training for several clinical psychedelic research teams. He has served as lead psychotherapist on two clinical research trials, continues to supervise one of these teams, and works as a psychedelic-assisted psychotherapy consultant within industry, with an emphasis on psychotherapy training and protocol development. Sean began lecturing in transpersonal psychology in 2011 and has over ten years' experience working with what he calls "psychedelic casualties". Through the Wild Mind Institute, he offers training for mental health practitioners in psychedelic-assisted psychotherapy, "bad trip" integration, and eco-psychotherapy.

Peter Widdows: Co-Founder, Director, and Business Lead

Peter has been a Director of Incannex since 2018 and is also the Chairman of Sunny Queen Ltd and a non-executive director of Youi Insurance. He has extensive business experience in the FMCG sector and was the CEO for a large part of Asia and Australasia, responsible for 18,500 people and multi-billion-dollar revenues for H. J. Heinz Inc, an NYSE listed multinational food company. Peter has senior business experience across multiple geographies, throughout Asia, Australasia, Europe, and North America. Peter Widdows has been driving this project since its inception and will continue to lead the Incannex owned subsidiary for the foreseeable future.

Psilocybin-Assisted Psychotherapy for Generalised Anxiety Disorder (Psi-GAD): Interim Review of Phase 2 Clinical Trial

During the quarter, Incannex completed a confidential and blinded review of the interim data from the first 29 participants to complete the Psi-GAD treatment protocol. The Company also completed a conditional power analysis using the interim data to model and project total study data.

Given the strong results to date, the Company found that there is a high probability (greater than 85%, alpha error 0.05 or 95% confidence level) that, at completion, the clinical trial will show a statistically significant benefit for the psilocybin treatment arm over the placebo treatment arm. This projection is made by assuming the effect size observed in the interim analysis for 29 participants is representative of the effect size through the remaining 43 participants. The end point used in this modelling was a reduction in Hamilton Anxiety Rating Scale (HAM-A) score at 11 weeks relative to baseline, which is the primary endpoint in the trial.

A review was also conducted by an independent DSMB, which reviewed the available data from the first 37 out of 72 participants. The DSMB recommended no adjustments to the original study design or sample size. The study design is based on the hypothesis that psilocybin-assisted psychotherapy will show a large treatment effect, as measured by a reduction in HAM-A scores compared to the control condition (active-placebo-assisted psychotherapy).

The trial continues to progress well and on time, with retention of all participants who have been enrolled. As at the 27th April, 2023 a total of 55 participants have been enrolled in the trial. The trial team have identified no safety concerns to date. The interim results from the trial gave the Company the confidence to proceed with engaging Catalent for development and cGMP manufacture of Incannex's psilocybin drug products for use in future clinical trials and the psychedelic clinics.

Phase 2 Clinical Trial to Assess IHL-675A in Patients with Rheumatoid Arthritis Commences

In February, Incannex commenced a Phase 2 clinical trial to assess IHL-675A for use in the treatment of pain and function associated with rheumatoid arthritis ('RA'). IHL-675A is a fixed dose combination drug comprising cannabidiol ('CBD') and hydroxychloroquine ('HCQ'), both drugs are currently prescribed or taken to treat the symptoms of RA.

The Phase 2 trial follows a successful Phase 1 trial, where IHL-675A was observed to be well tolerated in patients, and animal studies whereby IHL-675A was observed to reduce RA inflammatory disease scores to a greater extent than CBD or HCQ when taken alone.

The trial is being managed by Avance Clinical, an Australian and US contract research organisation, who will engage a total of 8-10 clinical trial sites across Australia and New Zealand, recruiting 120 patients in total. The results of the trial will establish the safety and efficacy of IHL-675A and contribute to the combination rule assessment in a FDA505(b)2 new drug application dossier.

In parallel with the preparations for the Phase 2 trial in Australia and New Zealand the company is also preparing for a pre-IND meeting with the FDA regarding the development of IHL-675A for treatment of pain and function in patients with rheumatoid arthritis to facilitate the conduct of future clinical trials with sites in the US.

Incannex Development Update for IHL-42X for Obstructive Sleep Apnoea ('OSA')

During the quarter, Incannex continued development activities associated with the dosing of trial participants in the bioavailability and bioequivalence ('BA/BE") clinical trial. The BA/BE study is assessing the pharmacokinetics and tolerability of the two active pharmaceutical ingredients ('APIs') in IHL-42X, dronabinol ('THC') and acetazolamide, compared to the respective FDA reference listed drugs, as well as the effect of food on pharmacokinetics of the two APIs.

The BA/BE study includes 116 participants who will each complete four (4) single dose treatment periods, being dosed with IHL-42X, dronabinol and acetazolamide under fasted conditions as well as IHL-42X under fed conditions. Blood samples will be collected over 48 hours and the concentrations of the APIs and their major metabolites in the samples will be analysed. The study will be conducted at CMAX Clinical Research in Adelaide, South Australia and managed by Novotech. The design of the BA/BE study is consistent with FDA recommendations.

Further to the BA/BE clinical trial, Incannex is targeting submission of an IND application with FDA in the current June quarter of 2023. The company has developed the study protocol for the proposed IND opening Phase 2/3 clinical trial, commenced the process of engaging US based investigators and clinical trial sites for the IND opening clinical trial, finalised the modules on the pharmacology and toxicology of the IHL-42X drug product and are finalising the chemistry and manufacturing controls module.

Corporate Activities

At March 31, 2023, Incannex recorded A$37.1M in cash at bank. A$4.29M was recorded as cash outflows associated with R&D activities. Notably, Incannex is eligible to receive an annual cash rebate equivalent to approximately 43.5% of all monies spent on research and development in Australia. Eligible R&D expenditures typically include costs associated with pre-clinical and clinical trial activities in Australia and internal and external research consultancy personnel.

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	31 March 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,982)	(8,825)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(120)	(633)
	(d) leased assets	-	-
	(e) staff costs	(270)	(926)
	(f) administration and corporate costs	(1,261)	(3,624)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	76	178
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	217	1,332
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(4,286)**	**(12,498)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	12,144
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	-	-
3.6	Repayment of borrowings	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
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**	-	**12,144**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	41,424	37,502
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,286)	(12,498)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	12,144
4.5	Effect of movement in exchange rates on cash held	3	(7)
4.6	**Cash and cash equivalents at end of period**	**37,141**	**37,141**

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	14	1,013
5.2	Call deposits	37,127	40,411
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)**	**37,141**	**41,424**

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	(317)
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)	(4,286)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	37,141
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	37,141
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	8.7

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: .....27 April 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.