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

Incannex Healthcare December 2022 Quarterly Activities Report and Appendix 4C Cash Flow Statement

Melbourne, Australia, January 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 December 2022. Incannex is undertaking a multitude of U.S. Food and Drug Administration ('FDA') programs for cannabinoid pharmaceutical products and psychedelic medicine therapies administered by health professionals.

Incannex Completes Positive Pre-IND Meeting with FDA on IHL-216A for Treatment for Concussion and Traumatic Brain Injury ('TBI')

During the quarter, IHL completed a constructive pre-Investigational New Drug Application ('pre-IND') meeting with FDA for drug product IHL-216A. IHL-216A is Incannex's proprietary combination of cannabidiol ('CBD') and isoflurane ('ISO') that is being developed for treatment of TBI.

Incannex submitted a pre-IND meeting package to the FDA in August 2022. The meeting package included a description of the unique formulation developed by Incannex, an overview of the proposed clinical development plan and specific questions Incannex submitted on the regulatory requirements for opening an Investigational New Drug application ('IND'). Opening an IND is required to conduct trials in the United States and ensures that trials are designed to meet the data requirements necessary for FDA marketing approval.

In written correspondence, FDA provided valuable, multidisciplinary feedback on the proposed clinical development of IHL-216A and acknowledged that treatment of TBI is a significant unmet medical need that requires innovative treatment solutions. FDA also confirmed that the FDA505(b)2 application was the appropriate regulatory pathway for IHL-216A, whereby some of the information required for marketing approval may derive from studies already completed on the drug components of IHL-216A and in the public domain.

IHL-216A has demonstrated neuroprotective activity in two separate animal models of traumatic brain injury, one representing moderate to severe injury and the other representing mild injury, or concussion. Incannex has engaged Curia Global, Inc. to optimise and manufacture GMP-grade IHL-216A in compliance with Current Good Manufacturing Practice ('cGMP'), also generating data on the quality and stability of IHL-216A to support future regulatory filings and undertake clinical trials.

Incannex Completes Dosing in Phase 1 Clinical Trial to Assess Multi-Use, Anti-Inflammatory Drug IHL-675A; Proceeds to Phase 2 Clinical Trials

During the quarter, Incannex completed patient dosing in the Phase 1 clinical trial measuring the safety, tolerability, and pharmacokinetic profiles of IHL-675A. The trial measured the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, CBD (Epidiolex) and HCQ (Plaquenil). Three cohorts of 12 participants (n = 36) received either IHL-675A, CBD or HCQ and the clinical

assessments were identical across the three arms of the trial. The trial was conducted by CMAX Clinical Research in Adelaide, South Australia and managed by Avance Clinical. IHL-675A has been well tolerated, with no reported adverse events of concern.

The full clinical study report will be available to Incannex in the current March 2023 quarter following complete analysis by the contract research organisation, however, the absence of adverse events of concern reasonably permits Incannex to plan and arrange Phase 2 studies, initially in patients with rheumatoid arthritis.

Incannex is arranging Phase 2 studies for patients with rheumatoid arthritis and planning Phase 2 studies for patients with Inflammatory bowel disease and lung inflammation. Simultaneously, IHL is preparing for a pre-IND meeting with FDA on the development of IHL-675A specifically for the treatment of patients with arthritis and the Company intends to open an IND over IHL-675A for arthritis in parallel with the Australian Phase 2 study.

IHL-675A was observed to outperform either CBD and HCQ in various pre-clinical models of inflammation, including in vivo models of rheumatoid arthritis, inflammatory bowel disease and lung inflammation. Synergistic anti-inflammatory activity of CBD and HCQ was observed in these distinct preclinical studies and was evidence to support the Company's international patent application over the drug.

HCQ is widely used for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate; marketed as Plaquenil. As HCQ is already approved for treatment of rheumatoid arthritis, arthritis is the first indication for which IHL-675A will be assessed. Incannex is arranging a Phase 2 clinical trial of more than 100 trial participants to assess IHL-675A in arthritis patients in Australia and will update the ASX and Nasdaq once this study has formally commenced. An improvement to patient wellbeing achieved by IHL-675A would potentially open a major economic opportunity for Incannex in the treatment of arthritis.

Planning of Phase 2 studies in patients with inflammatory bowel disease and lung inflammation is underway. The treatment of these three indications has a combined global annual market size exceeding US$125B per annum.

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

During the quarter, Incannex initiated a Bioavailability and Bioequivalence ('BA/BE") study and is targeting submission of an IND application with FDA in the current March quarter of 2023. 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 will include 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.

The results of this study will form a critical component of a future new drug application ('NDA'), providing the necessary bridge to the reference listed drugs, thereby facilitating the use of historic safety data via the FDA505(b)2 regulatory pathway.

In parallel with the BA/BE study, Incannex is preparing an IND application for submission to the FDA. The IND application will detail the safety, efficacy, and quality of the IHL-42X drug product for the treatment of OSA and is precursory to conducting clinical trials at treatment sites in the United States. Once the IND is opened, it is continuously updated with research and development results for the purpose of ongoing assessment by the FDA. Incannex aims to submit the IND application in Q1 2023, followed shortly by the commencement of pivotal, multi-site, Phase 2/3 clinical trials on the effects of IHL-42X in patients with OSA.

In June 2022, Incannex announced positive results from full analysis of its Phase 2 clinical trial on the effect of IHL-42X to treat patients with OSA. In particular, IHL-42X reduced AHI in trial participants by an average of 50.7%, compared to baseline, with 25% of participants experiencing a reduction in AHI of greater that 80%. Oxygen desaturation index was reduced by an average of 59.7%, relative to baseline, which improved patient sleep quality and reduced cardiovascular stress. In IHL-42X samples, THC blood concentrations were well below the limits for impaired driving the morning after dose administration. Importantly, IHL-42X was well tolerated with the preferred dose of IHL-42X observed to have a lower number of total treatment emergent adverse events than placebo.

Incannex Expands Intellectual Property Position over IHL-42X

In December, IHL announced the filing of a provisional patent application directed to the use of IHL-42X for the treatment of OSA. With this latest provisional patent application, Incannex intends to pursue additional patent protection for its IHL-42X clinical program, consistent with the Company's ongoing commercial strategy to accrue a patent position across the development, manufacture, and use of the Company's drug candidates. IHL-42X was designed to combine two drugs, THC and acetazolamide, with therapeutic effects on OSA that act via different mechanisms.

Acetazolamide induces metabolic acidosis, raises the drive to breathe and reduces the sensitivity of body system that controls breathing, which helps to reduce the incidence and severity of apnoeas and hypopnoeas. Dronabinol is believed to activate muscles in the upper airway during sleep, thereby reducing incidence of airway collapse. Incannex previously discovered that the two drugs act synergistically to reduce the Apnoea Hypopnea Index (AHI) in patients with OSA. Incannex engaged Dr Brad Edwards, Associate Professor of Physiology at Monash University, to further assess the polysomnography data from the Company's Phase 2 proof-of-concept clinical trial that investigated the effect of IHL-42X on OSA.

Dr Edwards is an expert on mechanisms of OSA, having contributed to the development of a method to characterise the underlying causes (or endotypes) of OSA. Working in collaboration with the Phase 2 trial's principal investigator, Dr Jen Walsh and her team at the University of Western Australia, Dr Edwards and his team have characterised the effects of IHL-42X on the different endotypes of OSA. IHL-42X was shown to have a dose dependent effect on loop gain. Low dose IHL-42X showed a statistically significant improvement in airway collapsibility.

This validates why low dose IHL-42X was observed to be more effective than the medium or high doses. The efficacy of low dose IHL-42X in the phase 2 proof of concept trial has been an ideal outcome for the Company. Low dose IHL-42X encompasses low doses of THC and acetazolamide such that the side effect profile was observed to be similar to that of the placebo arm. IHL-42X did not have a significant effect on the arousal threshold (propensity to wake up from sleep) at any dose. These findings shed important light on the mechanism of action of IHL-42X. In particular, the relationship between OSA endotypes and response to IHL-42X is useful in identifying patients who will best respond to IHL-42X, as set out in the new provisional patent application.

Incannex Engages Eurofins to Manufacture Novel Addiction Treatments CannQuit-N and CannQuit-O

In November, IHL announced that it has engaged multinational contract development and manufacturing organisation (CDMO) Eurofins Scientific ('Eurofins') to manufacture Incannex's two distinct medicated chewable products designed to treat nicotine and opioid addiction disorders. The CannQuit products are combination drug assets with associated granted patents and patent applications that were transferred to Incannex as a result of the acquisition of APIRx Pharmaceuticals, completed in August of 2022.

Eurofins has commenced formulation development and manufacture of CannQuit Nicotine ('CannQuit-N') and CannQuit Opioid ('CannQuit-O'). CannQuit-N combines nicotine and cannabidiol ('CBD') within a controlled-release, functional, medicated chewing gum. CannQuit-O combines CBD and an off-patent prescription opioid antagonist, and/or partial agonist-antagonist within the formulation.

The cGMP grade products manufactured by Eurofins will be used in clinical trials designed to assess the safety and efficacy of the CannQuit products for smoking cessation and the treatment of opioid addiction. Data collected on the quality and stability of the CannQuit anti-addiction products during the development and manufacturing of the two drug candidates at Eurofins will be key components of future regulatory packages including IND and NDA applications with FDA.

Medicated chewing gums deliver their active ingredients directly into the circulation of the oral mucosa, ensuring that the effects of the ingredients are delivered rapidly, but also in a sustained manner to reduce cravings for longer than other delivery methods. Rapid onset and sustained effect are both qualities desirable for the treatment of addiction disorders.

Incannex Engages Eurofins to Manufacture ReneCann Therapeutic Topical Application for Immune Disordered Skin Diseases

Also in November, Incannex engaged Eurofins to manufacture the ReneCann therapeutic for topical applications. ReneCann is Incannex's proprietary topical cannabinoid formulation for treatment of dermatological conditions caused by disorders of the immune system, including vitiligo, psoriasis, and atopic dermatitis, otherwise known as eczema. The ReneCann formulation is commercially protected by granted and pending patents acquired by Incannex as part of the APIRx acquisition that was finalised in August of 2022.

The unique formulation combines Cannabigerol ('CBG') and Cannabidiol ('CBD'). CBG is a non-psychoactive cannabinoid with potent anti-inflammatory properties. A previous version of ReneCann was used in an in

human proof of concept study with dosing over a 6-week period. The study was conducted at the Maurits Clinic, The Netherlands, and led by a world-renowned dermatologist Dr. Marcus Meinardi, MD, PhD. In the study, ReneCann reduced disease scores in patients with each of the target skin diseases. Patients with vitiligo, psoriasis and atopic dermatitis were observed to experience improvements in symptoms of 10%, 33% and 22% respectively. In particular, the results for study participants with vitiligo are highly encouraging, partly because the incidence of the disease is high at 0.5-1.0% of the global population and treatments for it are limited.

Vitiligo is observed when pigment-producing cells (melanocytes) stop producing melanin, causing the loss of skin colour in patches and the discoloured areas generally become larger over time. ReneCann was associated with diffuse re-pigmentation (usually perifollicular or from the borders of the lesion) and efficacy lasted for weeks eventually before depigmentation recurred. The ReneCann Drug product that is produced by Eurofins CDMO will be used in clinical trials confirming the therapeutic effect of ReneCann. Data from those trials will be used in regulatory submissions.

Independent Data Review Commences for Phase 2 Trial of Psilocybin-Assisted Psychotherapy for Anxiety

Subsequent to the end of the December quarter, IHL achieved its interim milestone of 29 patients completing primary endpoint assessments. Independent analysis of the interim study data has commenced. The 10-week treatment program includes two dosing sessions with either psilocybin or active placebo. Safety, efficacy, quality of life, and other aspects of mental and physical health are assessed. The study is being conducted at Monash University's BrainPark under the leadership of Dr Liknaitzky, alongside co-investigators Professor Suresh Sundram (Head of the Dept of Psychiatry, Monash) and Professor Murat Yücel (Director of BrainPark).

The PsiGAD1 treatment protocol was developed in collaboration with Dr Paul Liknaitzky, Head of the Clinical Psychedelic Lab at Monash University. He is also a member of the Incannex scientific advisory board. The trial is designed to assess the safety and efficacy of the Company's unique psilocybin program in an active placebo-controlled study. Treatment of anxiety with currently accepted medications and therapies remains inadequate, with less than half of patients achieving remission. Psilocybin-assisted psychotherapy has shown promise in the treatment of several mental health conditions.

Dr Liknaitzky has recruited a team of experienced and qualified clinicians and researchers to undergo specialist training, and deliver and assess the treatment. To date, 45 participants have been enrolled in the study, with 29 participants having now completed the treatment protocol and main outcome assessment following treatment. The interim analysis of the study data to date, conducted by an independent Data Safety Monitoring Board ('DSMB') comprising experts who are not part of the trial, has commenced. The independence of the DSMB is critical to maintain a blinded study and consequent integrity of the final data readout and analysis. Recommendations from the DSMB will be provided in March 2023, at which time the Company will provide another public announcement.

Corporate Activities

At December 31, 2022, Incannex recorded A$41.4M in cash at bank. A$4.35M was recorded as cash outflows associated with research and development 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.

In December of 2022, undertook an institutional placement totalling approximately A$13M at $0.205 per share (Placement). The Placement was undertaken by a small consortium of U.S. and international investors with significant healthcare experience, following an extensive campaign of due diligence. Collectively, the consortium has extensive experience in providing long term support to emerging healthcare companies in the U.S., Europe, and Asia. The funds raised under the Placement will be applied to continued research and development of Incannex drug candidates, including the candidates acquired as part of the acquisition of APIRx Pharmaceuticals. Additional funding ensures that the Company's expansive pipeline of clinical development programs will be 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.

This announcement has been approved for release to ASX by the Incannex Board of Directors.

END

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. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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 December 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	research and development	(3,587)	(5,843)
	product manufacturing and operating costs	-	-
	advertising and marketing	(329)	(513)
	leased assets	-	-
	staff costs	(295)	(656)
	administration and corporate costs	(1,142)	(2,363)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	83	102
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	916	1,061
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
1.9	**Net cash from / (used in) operating activities**	**(4,354)**	**(8,212)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	businesses	-	-
	property, plant and equipment	-	-
	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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,144	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	-	-
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**	**12,144**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	33,643	37,502
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,354)	(8,212)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	12,144	12,144
4.5	Effect of movement in exchange rates on cash held	(9)	(10)
4.6	**Cash and cash equivalents at end of period**	**41,424**	**41,424**

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	1,013	559
5.2	Call deposits	40,411	33,084
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)**	**41,424**	**33,643**

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	(274)
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)	(4,354)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	41,424
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	41,424
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	9.5

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 January 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.