Date: October 28, 2022
Public Announcement (ASX: IHL) (NASDAQ: IXHL)

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

Melbourne, Australia, October 28, 2022 - 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 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.

Positive preliminary results from Phase 1 clinical trial of IHL-675A

During the quarter, Incannex received approval from the Bellberry Human Research Ethics Committee ('HREC') for a Phase 1 clinical trial investigating its proprietary multi-use, anti-inflammatory drug IHL-675A. IHL-675A is a combination cannabinoid drug comprising cannabidiol ('CBD') and hydroxychloroquine ('HCQ') in a fixed dose combination. 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.

Participant recruitment for the trial commenced in August, and the preliminary results from the trial were released to ASX and Nasdaq after the end of the quarter in October. The trial measured the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ). Three cohorts of 12 participants (n = 36) received either IHL-675A, CBD or HCQ and the assessments will be identical across the three arms of the trial.

IHL-675A was observed to be well tolerated, with no adverse events of concern to the conclusion of the 4-week observation period. Furthermore, no serious adverse events have been reported. The pharmacokinetics of each active pharmaceutical ingredient will be reported in the full clinical study report, which will be available to Incannex in Q1 2023.

As a result of positive preliminary observations, Incannex has commenced the arrangement of Phase 2 clinical studies, initially in patients with rheumatoid arthritis. Phase 2 studies to assess IHL-675A in patients with inflammatory bowel disease and lung inflammation are also being planned.

Scale-up manufacture of cGMP IHL-216A and pre-IND meeting

In August, Incannex engaged Curia Global, Inc. ('Curia') to further develop and manufacture GMP-grade IHL-216A, Incannex's proprietary inhaled drug product for the treatment of concussion and traumatic brain injury ('TBI'). Curia's engagement follows proof-of-concept studies which established the optimal inhaled formulation of IHL-216A at an experimental scale. Curia is engaged to scale-up the fill-finish manufacture of

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.

Subsequent to the end of the quarter, Incannex participated in a constructive pre-Investigational New Drug Application ('pre-IND') meeting with FDA over IHL-216A. Incannex submitted a pre-IND meeting package to 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').

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. The 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.

Advancement of IND opening clinical trial for IHL-42X

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 obstructive sleep apnoea ('OSA'). In particular, low dose IHL-42X exhibited superior safety and efficacy metrics to mid and high doses. Low dose 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 low dose 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 low dose IHL-42X observed to have a lower number of total treatment emergent adverse events than placebo.

As stated in the June quarterly, Incannex considers the trial results to be a major success and step forward to provide confidence for further assessment in pivotal studies necessary for drug registration. During the quarter, the Company continued with the arrangement of operational imperatives necessary to open an IND with FDA and expects to release a standalone update on the IHL-42X program within the December quarter.

Advancement of manufacturing and development of APIRx cannabinoid drug candidates

During the quarter, Incannex finalised all matters related to the acquisition of APIRx Pharmaceuticals USA LLC ('APIRx') to aggregate the world's largest portfolio of patented medicinal cannabinoid drug formulations. Twenty-two (22) additional clinical and pre-clinical research and development projects have been transferred to Incannex, representing aggregate addressable markets of approximately US$400B per annum. These projects are underpinned by an intellectual property portfolio that includes 19 granted patents and 23 pending patents.

Initial high-priority drug candidates resulting from the acquisition are:

- MedChew Dronabinol for chemotherapy induced nausea and vomiting
- MedChew Rx for pain and spasticity in patients with multiple sclerosis
- CanQuit and CanQuitO – chewables that combine nicotine and cannabinoids and cannabinoids and opioid antagonists for smoking cessation and opioid addiction, respectively
- CheWell – high-bioavailability chewable tablet to be implemented in adolescent drug addiction studies, among other indications
- CanChew – patented high-bioavailability and long-acting CBD chewing gum for the over-the-counter market
- Renecann - topical cannabinoid development candidates for various skin diseases.

The Incannex scientific advisory team has been arranging for the manufacture of the high-priority drug candidates in preparation for further research and development activities.

Incannex appoints FDA regulatory affairs expert Mr Robert B. Clark to the Board of Directors

During the quarter, Incannex announced the appointment of experienced pharmaceutical executive Mr Robert B. Clark to the Board of Directors. Mr Clark is a senior-level strategic regulatory affairs expert with over 38 years of US and Global regulatory experience, including >20 years with Pfizer Inc. and >10 years with Novo Nordisk A/S. He is an internationally recognized expert on US Food and Drug Administration ('FDA') and the European Medicines Agency (EMA) liaison interactions, US pharmaceutical advertising practices and regulatory aspects related to healthcare professionals and sales force activities.

Mr Clark is Vice President, US Regulatory Affairs for Novo Nordisk where he provides strategic leadership to a team of over 50 regulatory staff and scientists in the development of new medicines. He advises the global executive team on matters related to drug development programs, FDA liaison strategies, managing FDA-related compliance issues, and monitoring emerging US regulatory trends and opportunities. He and his team manage all interactions with FDA on behalf of Novo Nordisk and have secured FDA approvals for twelve (12) significant new drugs for the company since his tenure began in 2012.

Prior to joining Nova Nordisk, Mr Clark was Vice President of Worldwide Regulatory Strategy and US Regulatory Affairs at Pfizer, leading a team of up to 150 regional regulatory professionals supporting the drug development continuum. During his time at Pfizer, he led or supported FDA approval of many new medicines and represented Pfizer at critical interactions with FDA, and other global health authorities, including key project milestone meetings. Mr Clark has senior level experience in managing regulatory aspects of large-scale pharmaceutical acquisitions, significant compliance matters and business development due diligence activities. He also has documented success with FDA accelerated approval programs including Fast-Track, Orphan Drug, Breakthrough Therapy Designations, and Priority Reviews, which are areas of interest for Incannex management due to the nature of its drug candidate mix.

At the time of his appointment, Mr Robert B. Clark said, "I look forward to working with the Board and the management team, and I am excited about the broad Incannex portfolio of products to treat patients who

have few or no other available treatments. Cannabinoid and psychedelic pharmacotherapies represent a growing area of research and hold the potential to treat various conditions for which effective options are limited". Mr Clark holds a Master's in Science in Pharmacology from the New York Medical College.

Psychedelic therapies: psilocybin and psychotherapy for Generalised Anxiety Disorder ("Psi-GAD")

During the September 2022 quarter, the Psi-GAD Phase 2a clinical trial led by Dr Paul Liknaitzky at Monash University ('Monash') continued. The aim of the trial is to assess participants with generalised anxiety disorder following the administration of psilocybin and specialised psychotherapy sessions. Importantly, the trial protocol and development plan incorporate treatment innovations currently unseen in the field of psychedelic therapy and have been discussed with FDA officials in a pre-IND meeting undertaken in the December quarter of 2021.

Primary outcomes from the trial are safety, efficacy and tolerability, and secondary outcomes are assessments of quality of life, functional impairment, and comorbidities. A preliminary analysis of patient data will be conducted by an independent statistician after 30 patients have completed primary endpoint assessment. This preliminary analysis will allow the trial investigators to inform the second part of the trial (n=42) and/or the follow-up Phase 2b clinical trial that Incannex is actively planning.

Participant therapy continues and approximately 30 participants are anticipated to complete their therapies in the current December quarter. The preliminary analysis of patient data is anticipated to be released in Q1 in 2023.

Also, during the September quarter, Incannex advanced negotiations with Monash University over a new psychedelic treatment paradigm for severe forms of one or more anxiety disorders. Negotiations involve a research agreement for the development of a new therapy that involves virtual reality ('VR') exposure response therapy ('ERP') combined with psychedelics. The associated research and development will be led by Dr Paul Liknaitzky at Monash University, a highly reputable, globally recognised, and innovative university that ranked #40 in the world in the US News and World Report 2022. It is anticipated that the initial clinical trial will assess efficacy, safety, tolerability, and optimal dose of the treatment method.

Corporate Activities

At September 30, 2022, Incannex recorded A$33.4M in cash at bank. A$2.256M 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.

In September of 2022, Incannex was included in the Standard and Poor's ("S&P")/ASX 300 Index by S&P Dow Jones. Inclusion was effective on September 19, 2022. Standard and Poor's outlines that the S&P/ASX 300 is designed to provide investors with broader exposure to the Australian equity market. The index is liquid and float-adjusted, and it measures up to 300 of Australia's largest securities by float-adjusted market

capitalization. The S&P/ASX 300 index covers the large-cap, mid-cap, and small-cap components of the S&P/ASX Index Series. This index is designed to address investment managers' needs to benchmark against a broad opportunity set characterized by sufficient size and liquidity. Being listed in the index is a precursory investment condition for many domestic and international investment institutions.

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	30 September 2022

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		
	(a) research and development	(2,256)	(2,256)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(184)	(184)
	(d) leased assets	-	-
	(e) staff costs	(586)	(586)
	(f) administration and corporate costs	(1,221)	(1,221)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	19	19
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	145	145
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(4,083)**	**(4,083)**

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	-	-
	(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)	-	-
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	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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**	-	-

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	37,502	37,502
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,083)	(4,083)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	10	10
4.6	**Cash and cash equivalents at end of period**	**33,429**	**33,429**

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	713	855
5.2	Call deposits	32,716	36,647
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)**	**33,429**	**37,502**

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	(206)
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)	(4,083)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	33,429
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	33,429
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	8.2

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: .....28 October 2022.....

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.