Date: July 27, 2022
Public Announcement (ASX: IHL) (NASDAQ: IXHL)

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

Melbourne, Australia, July 27, 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 June 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.

Cannabinoid IHL-42X: positive phase 2a clinical trial results in patients with obstructive sleep apnoea

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'). IHL-42X is a proprietary cannabinoid combination drug comprised of tetrahydrocannabinol ('THC') and acetazolamide.

The clinical trial assessed IHL-42X at reducing the apnoea hypopnea index ('AHI') in patients with OSA. Data was also collected for other aspects of sleep quality, THC clearance (relevant to vehicle operation) and safety. Trial participants received each of the three doses of IHL-42X and placebo across four seven-day treatment periods, separated by one week washout periods. At the end of each treatment period, participants attended the clinic for an overnight sleep study where AHI was determined, along with other measures of sleep quality, quality of life and drug safety. The study was conducted at the University of Western Australia Centre for Sleep Science and The Alfred Hospital.

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.

The Company 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, Incannex sought advice from FDA on the Company's long term clinical trial development plan. Following liaison with FDA, the next steps for the development of IHL-42X includes the finalisation of clinical trial designs

and arrangement of operational imperatives necessary to open an investigational new drug application ('IND') with FDA.

Cannabinoid IHL-216A: neuroprotective cannabinoid combination drug inhaled post-concussion or traumatic brain injury ('TBI')

IHL-216A combines cannabidiol ('CBD') with a volatile anaesthetic agent (isoflurane) and has been developed by Incannex to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits. During the quarter, Incannex announced that IHL-216A was observed to have a strong neuroprotective effect in a widely known model of sports concussion.

The pre-clinical study compared IHL-216A to its component drugs, CBD and isoflurane, in a rodent model of sports concussion that was developed in collaboration with the US National Football League (NFL) to accurately represent the type of brain injury that occurs in sports related concussion.

The study compared six groups of twenty-four rodents. Animals were tested in a Y-maze activity, which measures spatial memory by determining the animal's ability to discriminate between a novel (new) and familiar arm. After 24 hours, injured animals treated with IHL-216A were found to have no difference in a discrimination index compared to sham ('uninjured') animals (mean difference= 0.0598, p=0.5855).

In contrast, and after 24 hours, the discrimination index was significantly reduced for injured animals treated with either the vehicle for the active pharmaceutical ingredient or isoflurane alone, compared to uninjured animals (mean diff=0.2704, p=0.0498 and mean diff=0.3095, p=0.0245 respectively). The group treated with CBD alone demonstrated intermediate performance after 24 hours. These findings indicate that the defect in spatial memory observed at 1 day post injury is restored in animals treated with IHL-216A.

The findings from this study further support the protective effect of IHL-216A in concussion and traumatic brain injury and expands upon the initial animal study conducted by Incannex in 2020, the results of which were released on the 15th of December 2020 in the announcement titled, "Positive results from IHL-216A TBI/concussion study".

The Incannex scientific team is targeting a pre-IND meeting with FDA in Q3 2022 to discuss the Company's intention to conduct an expedited clinical trial program required for a new drug application and marketing approval. IHL-216A drug formulation development required for in-human studies is also nearing a conclusion following an extensive research and development process commenced in June 2021.

Due to the product's potential therapeutic utility in contact sports, IHL-216A is designed to satisfy World Antidoping Authority (WADA) and Australian Anti-Doping Authority's (ASADA) specifications for use by athletes at risk of TBI and Chronic Traumatic Encephalopathy, otherwise known as CTE.

Cannabinoid IHL-675A: multi-use drug candidate observed to outperform CBD in multiple preclinical models of inflammation

During the quarter, Incannex continued preparatory activities for its phase 1 clinical trial to assess IHL-675A soft gel capsules. The aims of the study are to demonstrate that there are no, or minimal, additional side effects associated with the combination of CBD and hydroxychloroquine ('HCQ') compared to each drug alone and that the uptake and metabolism (pharmacokinetics) of the two drugs do not materially interfere with one another.

FDA pre-IND guidance was sought and received following six distinct *in vitro* and *in vivo* studies using established disease models relevant to inflammatory disorders. In each of these models, IHL-675A outperformed CBD in supressing inflammation, indicating a wide scope of applications to potentially disrupt the CBD market.

Subsequent to the end of the June quarter, Incannex received approval from the Human Research Ethics Committee (HREC) to commence a phase 1 clinical trial investigating IHL-675A in humans for the first time. Extensive formulation development work to manufacture IHL-675A gel capsules has been completed and the first batch of product has been manufactured for the trial. Subject to clinical success, the results of the phase 1 clinical trial will form part of three FDA IND applications for each of the initial three indications the Company is pursuing for IHL-675A. Patient recruitment is anticipated to begin in August 2022.

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

During the June 2022 quarter, the Psi-GAD phase 2a clinical trial led by Dr Paul Liknaitzky at Monash University ('Monash') continued at pace. 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 has 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.

22 participants are enrolled in the trial and the remaining 8 participants are anticipated to be enrolled during the current quarter.

Principal investigator of the trial, Dr Paul Liknaitzky said; "Operationally, the trial is proceeding as smoothly as we could have hoped for. We're currently, undertaking 3 dosage sessions per week, which is one of the fastest rates of recruitment for a clinical psychedelic trial site".

Psychedelic therapies: virtual reality ('VR') exposure response therapy ('ERP') and psychedelics

During the March 2022 quarter, Incannex executed an exclusive, global license in perpetuity over an immersive therapeutic VR environment in combination with a psychedelic drug treatment. The VR therapy has been established by BrainPark, a state-of-the-art clinical research platform at Monash University's Turner Institute for Brain and Mental Health.

Incannex intends to combine the VR ERP therapy tool with a psychedelic drug to develop a new treatment for severe forms of one or more anxiety disorders. The associated research and development will be led by Dr Paul Liknaitzky at Monash, a highly reputable, globally recognised, and innovative university that ranked #40 in the world in the US News and World Report 2022.

Incannex and Monash are in advanced stages of discussion in relation to a research agreement for the clinical trials required to develop the new treatment form. The initial clinical trial will assess efficacy, safety, tolerability, and optimal dose of the treatment method.

Corporate Activity: Acquisition of APIRx Pharmaceuticals USA, LLC

In May 2022, Incannex announced that it completed a binding share sale and purchase agreement to acquire 100% of the issued share capital in APIRx Pharmaceuticals USA, LLC ('APIRx').

The stakeholders in APIRx ('Sellers') will be issued a total of 218,169,506 new shares at a value of A$0.573 per share to satisfy the purchase of APIRx, which represents the price agreed at the signing of the binding terms sheet announced on March 24, 2022. Approval to issue the shares to the APIRX sellers in consideration for the acquisition of APIRx was sought and approved at a meeting of shareholders on June 9, 2022. 99.27% of voting shareholders approved the issue of shares to the sellers.

Legal transfer of the APIRx group of companies to Incannex is currently being facilitated so that the group of companies sit within a wholly owned subsidiary of Incannex. Thereafter, development plans associated with assets from the APIRx acquisition may be appropriately initiated and formalised by Incannex. The acquisition of APIRx presents Incannex with both long and short-term opportunities for significant value growth.

APIRx has twenty-two (22) active clinical and pre-clinical research and development projects underpinned by an intellectual property portfolio that includes 19 granted patents and 23 pending patents. It holds a diverse portfolio of promising therapeutic candidates targeted at treating an extensive range of conditions including pain disorders, addiction disorders, mental illnesses, gastrointestinal diseases, gum disease, skin conditions and ophthalmic conditions.

The initial priority drug candidates from for Incannex are:

- Medchew Dronabinol for chemotherapy induced nausea and vomiting
- Medchew Rx for pain and spasticity in multiple sclerosis
- CanQuit and CanQuitO – patented chewing gums that combine nicotine and cannabinoids and cannabinoids and opioid antagonists for smoking cessation and opioid addiction respectively
- CheWell – patented high-bioavailability chewable tablet to be implemented in adolescent drug addiction studies among other indications
- CanChew – patented high-bioavailability CBD chewing gum for the over-the-counter market.

Corporate Activity

During the quarter, Incannex completed a short-dated option program to raise a total of A$23.6M at an exercise price of A$0.35 per share. The options expired on April 22, 2022, and a total of 67.3M new shares were issued. For every two (2) new shares that were issued as a result of the program, one (1) piggy-back option was granted to participants. Piggy-back options have an exercise price of A$1.00 (equivalent to approx. US$17.25 per ADR on NASDAQ), expiring April 28, 2023. A total of 33.7M piggy-back options were issued.

At June 30, 2022, Incannex recorded A$37.5M in cash at bank. A$1.83M 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.

Incannex shares trade in Australia 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 June 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,829)	(4,921)
	(b) product manufacturing and operating costs	-	
	(c) advertising and marketing	(207)	(883)
	(d) leased assets	-	-
	(e) staff costs	(200)	(1,067)
	(f) administration and corporate costs	(1,237)	(2,671)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(38)	693
1.7	Government grants and tax incentives	-	108

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.8	Other (provide details if material) - costs associated with SEC application and NASDAQ listing	(404)	(2,349)
1.9	**Net cash from / (used in) operating activities**	**(3,910)**	**(11,085)**

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	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
3.3	Proceeds from exercise of options	23,585	39,454
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**	**23,585**	**39,454**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	17,812	9,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,910)	(11.085)
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)	23,585	39,454
4.5	Effect of movement in exchange rates on cash held	15	9
4.6	**Cash and cash equivalents at end of period**	**37,502**	**37,502**

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	855	1,025
5.2	Call deposits	36,647	16,787
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)**	**37,502**	**17,812**

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	(427)
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)	(3,910)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	37,502
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	37,502
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	9.6

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 July 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.