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

Quarterly Activities Report and Appendix 4C Cash Flow Statement

Highlights:

- Positive phase 2a clinical trial results for IHL-42X with 60% of trial participants experiencing at least a 55% reduction in the Apnoea Hypopnea Index ('AHI')
- 20% of IHL-42X clinical trial participants experienced a reduction in AHI of greater than 80%
- completes comprehensive *in vivo* study on the neuroprotective capability of IHL-216A with results being analysed to be released within 2-3 weeks
- treatment commences in the phase 2a clinical trial to assess psilocybin and specialised psychotherapy for the treatment of generalised anxiety disorder
- initiates a second clinical psychedelic therapy program in a leading-edge academic field of virtual reality (VR) exposure response therapy (ERP) and psychedelics
- executed a term sheet with binding commercial terms to wholly acquire APIRx Pharmaceuticals at fixed price of A$0.573 (equivalent to approximately US$10.45 per ADS), which has 22 active cannabinoid R&D projects underpinned by patents
- patented CanQuit (CBD + nicotine) medicated chewing gum (APIRx product) for smoking cessation has the potential to disrupt the nicotine chewing gum market, which currently exceeds US$5B in sales per annum
- Incannex lists American Depositary Shares (ADSs) on NASDAQ under stock code "IXHL"
- Incannex adequately funded with cash of $40.0M following completion of loyalty option offer to existing shareholders after quarter's end in April 2022.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to provide its quarterly activities report and appendix 4C for the period ended 31st March 2022. Incannex is undertaking a multitude of US 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

During the quarter, Incannex announced successful preliminary results of its phase 2a, proof-of-concept clinical trial investigating novel cannabinoid combination product, IHL-42X, for the treatment of obstructive sleep apnoea ('OSA').

The clinical trial assessed three doses (low, mid and high) of IHL-42X at reducing the apnoea hypopnoea index ('AHI'), the main diagnostic and monitoring criteria for OSA, compared to placebo in patients who suffered from the disease. 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 baseline, the average patient AHI was 42.84. The average AHI was 23.81 after the treatment periods assessing all three doses, which represents a 44.4 % reduction in AHI (p-value 0.0067) compared to baseline AHI. During placebo treatment periods, the average AHI was 40.08, only a 6.4 % reduction (p-value 0.75) compared to baseline.

60% of participants experienced a reduction in AHI of greater than 55% (range: 55.0% to 91.5%) and a resulting AHI of less than 20 during at least one treatment period of one dose strength of IHL-42X. 20% of participants experienced a reduction in AHI of greater than 80% (range: 82.7% to 91.5%) relative to baseline during at least one treatment period of one dose strength of IHL-42X. For all dose strengths used in the clinical trial, IHL-42X was observed to be well tolerated.

After the release of the results, Incannex chief scientific officer, Dr. Mark Bleackley, said; "We are delighted that IHL-42X has demonstrated efficacy and good safety characteristics in our preliminary assessment of data from the proof-of-concept trial. The average reduction in AHI calculated across low, mid, and high-dose IHL-42X has met our expectations for what would constitute a valuable product for the treatment of obstructive sleep apnoea".

Incannex has been granted a pre-IND meeting with FDA on May 11, 2022 (U.S. EST) as planning continues for pivotal clinical trials to commence after opening an IND with FDA.

Patient dose strengths remain blinded by Novotech, the independent research organisation managing the data integrity of the trial, while analysis continues. The final report containing all pertinent trial data, including the superior IHL-42X dose strength, is anticipated to be released in the current June 2022 quarter.

Cannabinoid IHL-216A: neuroprotective cannabinoid combination drug applied 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. Incannex, with the Monash Trauma Group at the Monash University Department of Neuroscience, has recently completed an extensive *in vivo* study on the protective effect of IHL-216A in concussion and TBI. The results of the study are being analysed to be released within 2-3 weeks in the current June 2022 quarter. The model of traumatic brain injury ('TBI') being used in the study was developed in collaboration with the US National Football League (NFL) and is a precursor to pivotal in-human trials required for drug registration.

IHL-216A components, CBD and isoflurane, have previously been observed by Incannex to act synergistically to reduce neuronal damage, neuroinflammation and behavioural deficits that are consequences of TBI. In experiments, IHL-216A outperformed CBD in reducing neuronal damage in post-mortem Nissl staining analysis of brain tissue by 53% for CA1 and 60% for CA2 in the hippocampal region of the brain. IHL-216A reduced the Iba1 neuroinflammation marker by 35% more than CBD alone and 123% more than isoflurane administered alone.

Like with combination cannabinoid products IHL-42X and IHL-675A, an International Patent Application has been filed as part of the IHL-216A development program.

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

During the quarter, Incannex continued preparatory activities to commence recruitment of 36 participants to a 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.

IHL has completed a pre-IND meeting with FDA to discuss the regulatory pathway for the development of IHL-675A for lung inflammation in the United States and plans to open INDs for up to three indications: lung inflammation, rheumatoid arthritis and inflammatory bowel disease. Due to the existence of public data on key pharmaceutical ingredients CBD and HCQ, FDA agreed that marketing applications for IHL-675A should be expedited 505(b)(2) applications.

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 partially disrupt the CBD market. Furthermore, HCQ is currently used as a treatment for rheumatoid arthritis, however, long term use of the drug is associated with adverse side effects.

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

In December quarter 2021, Incannex received approval from the Monash University Human Research Ethics Committee to proceed its phase 2a Psi-GAD clinical trial, led by Dr Paul Liknaitzky.

Therapist training for the specialised treatment has been completed, and participant screening and recruitment commenced in February 2022. The first participants to the trial have been enrolled and treatment has commenced. The trial protocol incorporates a range of treatment innovations currently unseen in the field of psychedelic therapy.

The Psi-GAD study team finalised the trial protocol and commenced the trial after completing a pre-IND meeting with FDA in the December 2021 quarter. Both the written responses and the responses provided in the teleconference with FDA in the pre-IND meeting were positive, constructive, and supportive.

FDA confirmed that the therapeutic strategy for the development of a psilocybin-assisted therapy for GAD is appropriate and conveyed interest in its development. FDA also provided guidance on Incannex's proposed long-term development strategy with regards to what will be required for a successful new drug application (NDA) and marketing authorisation. Specific feedback from FDA on IHL's proposed clinical trial designs will shape a pivotal phase 2b clinical trial, which will be the IND opening study, following either interim or full results from the phase 2a trial.

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 ('Monash'). 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 Liknaizky 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 currently advancing a research agreement for the clinical trials required to develop the new treatment form. The initial clinical trial will assess optimal dose, safety, and tolerability of the treatment method.

Corporate activity: proposed acquisition of APIRx Pharmaceuticals

On March 24, 2022, Incannex announced that it has executed a term sheet with binding commercial terms to wholly acquire APIRx Pharmaceutical USA, LLC ('APIRx'), subject to shareholder approval under ASX listing Rule 7.1.

APIRx is an innovative biotechnology company focused on research, development, and production of prescription pharmaceutical cannabinoid medicines. It has twenty-two (22) active clinical and preclinical research and development projects underpinned by an extensive intellectual property portfolio that includes 19 granted patents and 23 pending patents.

The acquisition of APIRx brings to Incannex a diverse portfolio of promising therapeutic candidates targeted at treating an extensive range of conditions including pain, dementia, Parkinson's Disease,

restless leg syndrome, gastrointestinal diseases, periodontitis, addiction disorders, 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 CBD chewable tablet or chewing gum for the over-the-counter market.

Medchew Dronabinol and Medchew Rx have fast-tracked pathways to drug approval via bridging studies to existing registered products (Marinol and Sativex) that have the same pharmaceutical ingredients. A bridging study is a clinical trial undertaken to demonstrate that an investigational product is sufficiently similar to an approved product to establish a "bridge" to already understood safety and efficacy characteristics.

Proprietary combination cannabinoid medicated chewing gums are well-placed for addiction disorders. The board of directors considers that CanQuit medicated chewing gum has the potential to disrupt the nicotine chewing gum market, which currently exceeds over US$5B in sales per annum. And CanQuitO is an ingenious concept to assist in combatting the opioid addiction crisis in a simple, yet novel way.

The proposed acquisition price of APIRx is US$93.3M in an all scrip (shares) transaction locked in at A$0.573 per share (equivalent to approximately US$10.45 per ADS) and is subject to shareholder approval. An extraordinary general meeting notice and detailed presentation on the APIRx acquisition will be released to ASX in due course.

Corporate activity: Incannex lists American Depositary Shares ('ADSs') on NASDAQ

In February, ADSs representing IHL ordinary shares have commenced trading on the NASDAQ Global Market ('NASDAQ') under the ticker symbol 'IXHL'. Each IXHL ADS represents 25 ordinary shares of the Company. The listing on NASDAQ follows the declaration of effectiveness by the United States Securities and Exchange Commission (SEC) of the Company's registration statement on Form 20-F and formal approval from NASDAQ upon meeting the listing requirements.

Incannex completed the NASDAQ listing without an associated capital raise in the United States. Therefore, initial trading of ADSs may be limited as the Company progressively works to raise its public profile in the United States. Incannex will have a dedicated office managed by Dr George Anastassov, following the successful completion of the APIRx acquisition, to facilitate additional stakeholder

engagement with the investment community, as well as clinical research facilitators and regulatory authorities.

Corporate activity: loyalty option issue raises $A23.6M in capital for R&D

During the March 2022 quarter, Incannex initiated a short-dated entitlement offer of loyalty options, issued for nil consideration to eligible shareholders at a ratio of one (1) free loyalty option for every fifteen (15) shares held on the record date, 23 March 2022.

The loyalty options expired on April 22, 2022. A total of 67.3M new shares are to be issued, resulting in $A23.6M additional capital for the Company's clinical trial endeavours that are now significantly ramping up in 2022 and 2023. The Company's current cash balance is approximately A$40.0M and Incannex has no debt.

For every two (2) shares that are issued, one (1) piggy-back option will be granted to participants under the terms of the entitlement offer. Piggy-back options have an exercise price of A$1.00 (equivalent to approx. US$18.25 per ADS on NASDAQ), expiring 28 April 2023 and will be issued shortly. A total of 33.7M piggy-back options will be issued. Incannex will not seek approval to list the piggy-back options on ASX or NASDAQ as a warrant.

Item 6.1 of Appendix 4C (below) represents amounts paid to directors and related parties.

END

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 2022

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	(845)	(3,745)
	(b) product manufacturing and operating costs	-	
	(c) advertising and marketing	(152)	(676)
	(d) leased assets	-	-
	(e) staff costs	(207)	(867)
	(f) administration and corporate costs	(740)	(1,621)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(29)	731
1.7	Government grants and tax incentives	108	108

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
1.8	Other (provide details if material) - costs associated with SEC application and NASDAQ listing	(1,115)	(2,131)
1.9	**Net cash from / (used in) operating activities**	**(2,980)**	**(8,201)**

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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
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	-	15,869
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**	-	**15,869**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	19,771	9,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,980)	(8,201)
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)	-	15,869
4.5	Effect of movement in exchange rates on cash held	(5)	(6)
4.6	**Cash and cash equivalents at end of period**	**16,786**	**16,786**

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	939	824
5.2	Call deposits	15,847	18,947
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)**	**16,786**	**19,771**

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	(109)
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)	(2,980)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	16,786
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	16,786
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	5.6

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: .....28 April 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.