Date: 31st January 2022
ASX Announcement (ASX: IHL)

December 2022 Quarterly Activities Report and Appendix 4C

Highlights:

- Completes dosing of participants in the phase 2a clinical trial investigating IHL-42X in patients with Obstructive Sleep Apnoea; results due Q1 2022
- commences preparation of US FDA pre-IND meeting package for IHL-42X
- prepares for recruitment of patients to a phase 1 clinical trial to assess multi-use drug candidate IHL-675A in healthy volunteers following US FDA pre-IND advice
- extensive *in vivo* study on the protective effect of IHL-216A in traumatic brain injury and concussion nears conclusion
- advancement of the IHL-216A inhaled formulation for use in clinical trials
- phase 2a clinical trial using psilocybin-assisted therapy for Generalised Anxiety Disorder has received approval to proceed from the Monash University Human Research Ethics Committee
- pre-IND meeting with FDA confirmed that the therapeutic strategy for the development of psilocybin-assisted therapy for Generalised Anxiety Disorder is appropriate
- therapist training for the phase 2a trial assessing psilocybin-assisted therapy for Generalised Anxiety Disorder is completed; patient recruitment to commence imminently
- Incannex files Form 20-F registration statement with the SEC for listing on Nasdaq in the United States
- Incannex adequately funded with cash of $19.77M at 31st December 2021.

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 December 2021. Incannex is undertaking six US Food and Drug Administration ('FDA') programs for cannabinoid pharmaceutical products and psychedelic medicine therapies.

IHL-42X for Obstructive Sleep Apnoea

During the quarter, IHL completed dosing of participants in the 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 of IHL-42X at reducing the apnoea hypopnoea index ('AHI'), the main diagnostic criteria for OSA, compared to placebo in patients with the disease. The study was conducted at the University of Western Australia Centre for Sleep Science and The Alfred Hospital. 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, they 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 trial data is being analysed by Novotech, the contract research organization ('CRO') engaged by Incannex to manage the study and resulting data. Delivery of the final clinical study report is expected in Q1 2022 and is anticipated to coincide with IHL's listing on the Nasdaq exchange in the United States.

During the quarter, Incannex also announced that it has commenced preparation of a pre–investigational new drug (pre-IND) meeting package. Guidance from FDA is being sought for a larger, pivotal phase 2 clinical trial under an investigational new drug ('IND') application. We expect this meeting to occur in the first quarter of 2022.

OSA is a serious medical condition affecting approximately 30 million adults in the United States alone. The decrease in the level of blood oxygen, that occurs during OSA, increases blood pressure, and strains the cardiovascular system. Many people with OSA develop high blood pressure (hypertension), which can increase the risk of heart disease. The more severe the OSA, the greater the risk of coronary artery disease, heart attacks, heart failure and stroke. Incannex has filed an international patent application entitled "Methods for the treatment of obstructive sleep apnoea" as part of the IHL-42X development program.

IHL-675A multi-use drug candidate for Lung Inflammation, Rheumatoid Arthritis, and Inflammatory Bowel Disease

During the quarter, Incannex commenced a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers. The study is being conducted at CMAX Clinical Research in South Australia and managed by Australian CRO Avance Clinical. The aims of the study are to demonstrate that there are no, or minimal, additional side effects associated with the combination of cannabidiol ('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.

A total of 36 subjects are participating in the trial, evenly divided across three arms. The three arms of 12 subjects will each receive one of IHL-675A, CBD, or HCQ. The safety and pharmacokinetic assessments will be identical across the three arms of the trial. Recruitment is anticipated to commence in the current quarter.

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 plan to open INDs for each of the three indications. 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 different *in vitro* and *in vivo* studies using established disease models relevant to inflammatory disorders. In each of these models, IHL-675A outperformed both CBD and HCQ in supressing inflammation.

Incannex has engaged Procaps S.A. ('Procaps') to develop the formulation for IHL-675A. Procaps offers IHL a complete supply chain solution for a sophisticated, GMP-grade product. Manufacturing at Procaps will support the IHL-675A clinical trial programs and can also quickly ramp up production for commercial supply upon successful clinical trial outcomes.

An international patent application entitled "Methods and compositions for treating or preventing an inflammatory condition" was filed recently as part of the IHL-675A development program.

IHL-216A for Concussion and Traumatic Brain Injury

IHL-216A combines 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, is conducting an extensive *in vivo* study on the protective effect of IHL-216A in sports concussion. 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. This study is ongoing and is expected to conclude in the current quarter.

During the quarter, Vectura Group, a state-of-the-art contract development and manufacturing organisation (CDMO), has continued development of the IHL-216A inhaled formulation for use in clinical trials planned to follow *in vivo* studies.

Psilocybin-assisted psychotherapy for Generalised Anxiety Disorder ("Psi-GAD")

During the quarter, IHL announced that:

1. the phase 2a Psi-GAD clinical trial, led by Dr Paul Liknaitzky at Monash University, has received approval to proceed from the Monash University Human Research Ethics Committee (MUHREC); and
2. the completion of its pre-IND meeting with FDA regarding the Company's Psi-GAD clinical development program.

With 72 participants, the Psi-GAD phase 2a trial is the largest psychedelic trial in Australia to date. The trial is well controlled (triple-blind, active placebo), and includes a range of treatment innovations alongside the development of a specialised therapist training program. The Psi-GAD study team has commenced the drug importation process, completed the training of trial therapists and finalised trial site infrastructure. Participant recruitment is expected to commence in the current 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 IHL'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.

Incannex files Form 20-F registration statement with the SEC for listing on Nasdaq in the United States

After the end of the quarter, and as outlined during the Company's AGM on the 20th of January, Incannex decided to complete a "compliance listing", which is a regular US listing but without an associated capital raise, so that many variables associated with listing on Nasdaq are under the Company's control.

This decision was taken due to recent weakened conditions within the Nasdaq Biotech Index and also because Incannex has adequate cash reserves of $19.77M, at 31st December 2021, to fund its clinical trial programs and research ambitions for the foreseeable future.

After listing on Nasdaq with ticker "IXHL", shareholders may commence trading on Nasdaq after packaging their IHL ordinary shares into American Depositary Shares. The Company reserves the right to raise capital at an appropriate time and to the appropriate suite of investors, as guided by our US financial partners EAS Advisors and Roth Capital.

The Incannex Board of Director's believes that deferring any US capital raise will allow the Company to strategically time any initiative to take advantage of improved market conditions. Additionally, IHL will have the opportunity to announce further developments regarding its clinical programs and potentially new research programs in the psychedelic therapy field as its relationships within that space mature.

To strengthen the Company's presence in the United States, Incannex is establishing an office in the US to undertake strategic stakeholder engagement with the investment community, as well as clinical research facilitators and regulatory authorities.

Corporate activities

Net cash outflows were $2.96M. R&D expenditure of $1.96M was the largest expenditure item and most of this expense will again be eligible for the Australian Government R&D rebate.

Expenses associated with the Company's US Securities and Exchange Commission ('SEC') application and Nasdaq listing comprise legal, accounting and consulting fees associated with this extensive compliance process and are considered non-recurring. Incannex has lodged a Form 20-F registration statement with the SEC. The information contained within Form 20-F is facsimile to the Form F-1 registration statement previously reviewed by SEC.

Finally, the Board of Directors is also currently contemplating a free bonus option entitlement to reward our loyal shareholders. At this point no definitive decision has been made as to the terms of the bonus issue but the Company will provide an update to market once the Board has finalised this initiative.

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

Date: 31st January 2022
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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 2021

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		
	(a) research and development	(1,957)	(2,900)
	(b) product manufacturing and operating costs	-	
	(c) advertising and marketing	(319)	(524)
	(d) leased assets	-	-
	(e) staff costs	(403)	(760)
	(f) administration and corporate costs	(537)	(1,041)
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	760	760
1.7	Government grants and tax incentives	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
1.8	Other (provide details if material) - costs associated with SEC application and NASDAQ listing	(505)	(1,016)
1.9	**Net cash from / (used in) operating activities**	**(2,961)**	**(5,481)**

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 (6 months) $A'000
3.3	Proceeds from exercise of options	287	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**	**287**	**15,869**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	22,446	9,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,961)	(5,481)
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)	287	15,869
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	**Cash and cash equivalents at end of period**	**19,771**	**19,771**

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	824	382
5.2	Call deposits	18,947	22,064
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)**	**19,771**	**22,446**

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	235
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)	(2,961)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	19,771
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	19,771
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	6.7

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: n/a

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: n/a

3.	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: n/a

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: .....31 January 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.