Date: 30th July 2021
ASX Announcement (ASX: IHL)

Incannex Healthcare

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights:

- Incannex completes clinical trial protocol for psilocybin-assisted psychotherapy for Generalised Anxiety Disorder (Psi-GAD)
- Recruitment of therapists for the Psi-GAD program commenced during the quarter and is nearing completion, with the therapist training program to commence in Q3 2021
- IHL is co-ordinating two clinical trials in the Psi-GAD clinical development program aimed at achieving FDA approval for psilocybin-assisted therapy
- Incannex engages the University of Western Australia Centre for Sleep Science as an additional site for the ongoing phase 2b clinical trial assessing IHL-42X in patients with Obstructive Sleep Apnoea
- IHL receives ethics approval to commence an open label extension to the IHL-42X clinical trial - patients that have finished their dosage regimen are immediately eligible to participate
- IHL commences a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers
- Incannex expands IHL-675A development program to assess its potential to become a multi-use pharmaceutical drug applicable to inflammatory lung conditions (COPD, asthma, ARDS, and bronchitis), rheumatoid arthritis and inflammatory bowel disease
- Procaps S.A., a GMP compliant manufacturer has been engaged to produce IHL-675A soft gel capsules and can quickly ramp up production to commercial quantities (registered or unregistered) upon successful clinical trial outcomes
- Incannex engages inhalation drug specialist Vectura Ltd to develop the formulation of IHL-216A and delivery mechanism to be used in clinical trials against traumatic brain injury.

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 30th June 2020. Incannex is undertaking six U.S. Food and Drug Administration ('FDA') programs for cannabinoid pharmaceutical products and psychedelic medicine therapies.

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

The Company's "Psi-GAD" therapy combines psilocybin with psychological support that has been specifically designed for patients diagnosed with generalised anxiety disorder ('GAD'). During the quarter and to date, Incannex, in collaboration with Monash University, has finalised the clinical trial protocol after receiving input from a multi-disciplinary team of experts lead by Principal Investigator Dr Paul Liknaitzky, along with Co-

Investigators Professor Suresh Sundram and Professor Murat Yucel. The wider research team includes national and international experts in psychedelic-assisted therapies, psychometric evaluation, qualitative research, and therapist training.

The Company is now in the process of co-ordinating two clinical trials as part of the clinical development program aimed at achieving FDA approval for Psi-GAD therapy. Recruitment of therapists for these trials commenced during the quarter and is nearly finalised, with the therapist training program to commence in Q3 2021.

This first study is a phase 2 randomised triple-blind active-placebo-controlled trial to assess the safety and efficacy of psilocybin-assisted psychotherapy in patients with GAD. It will include 72 participants that will experience two psilocybin or active-placebo dosing sessions and up to 11 non-drug, specialist psychotherapy sessions over a period of 10 weeks. Primary outcomes are safety, efficacy and tolerability, and secondary outcomes are quality of life, functional impairment, and comorbidities. A preliminary analysis of patient data will be conducted by an independent data safety monitoring board after 30 patients have completed primary endpoint assessment. The preliminary analysis will allow the trial investigators to inform the second part of the trial (n=42) and/or the second phase 2b clinical trial that Incannex is actively planning.

Preparations for this larger, pivotal, multi-site phase 2b clinical trial are continuing and a FDA pre-investigational new drug application ('pre-IND') data package and meeting request has progressed during the quarter. Guidance from FDA at the pre-IND meeting, as well as data and learnings from the initial phase 2 trial being conducted in Australia, will be leveraged to open an investigational new drug application (IND) in the United States in 2022.

IHL-42X for Obstructive Sleep Apnoea

During the quarter, Incannex engaged the University of Western Australia Centre for Sleep Science ('UWA', 'Centre for Sleep Science' or 'CSS') as an additional site for the ongoing phase 2b dose-finding crossover clinical trial investigating the effect of IHL-42X on the Apnoea Hypopnea Index ('AHI') in adults diagnosed with Obstructive Sleep Apnoea ('OSA'). Patient recruitment and dosing at UWA is continuing in parallel with The Alfred Hospital in Melbourne and results of the trial will be available once all subjects have completed treatment and the Clinical Study Report is finalised, which is anticipated to be in Q4 of 2021.

After the quarter, Incannex filed an International Patent Application entitled "Methods for the treatment of obstructive sleep apnoea" as part of the IHL-42X development program. The application was filed pursuant to the Patent Cooperation Treaty (PCT), thus providing IHL with an opportunity to pursue patent protection in foreign jurisdictions, including the key markets of North America, the European Union, Japan and Australia, among others. Specifically, the patent application makes claim that the IHL-42X formulation of acetazolamide, a registered off-patent pharmaceutical, combined with tetrahydrocannabinol (THC) is a method for the treatment of OSA.

Importantly, the filing of the patent application secures the filing date of the application and the claims within it. An interim analysis of the data from IHL's ongoing phase 2b double blind randomised placebo-controlled clinical trial was performed and these results have been included in the patent application to support the claims. Patient dosing is continuing at the University of Western Australia Centre for Sleep Science so whilst interim clinical trial analysis was made available to file the patent application, that data remains confidential and not yet available for publishing to ensure that the trial remains blinded.

Also, after June 30, IHL announced that it has received ethics approval to commence an open label extension to the phase 2b clinical trial. The open label extension study will recruit people who have experienced a benefit from IHL-42X in the phase 2b trial. Some patients have finished their dosage regimen and are eligible to participate in the open label study immediately.

The study comprises daily treatment with IHL-42X for a period of 6 months. The primary endpoint is reduction in Apnoea Hypopnea Index ('AHI') compared to the patient's original, pre-treatment baseline measurement. The main goal of this study is to determine whether the reduction in AHI that was observed for these subjects in the phase 2b study is maintained over an extended period.

IHL-675A for lung inflammation, rheumatoid arthritis, and inflammatory bowel disease

During the quarter, Incannex held its pre-IND with FDA. Following a range of successful pre-clinical studies, and guidance from FDA at the pre-IND meeting, Incannex expanded its development program to assesses the potential for IHL-675A to become a multi-use pharmaceutical drug applicable to inflammatory lung conditions (COPD, asthma, ARDS, and bronchitis), rheumatoid arthritis and inflammatory bowel disease.

IHL has commenced a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers. This study will be conducted at CMAX Clinical Research in South Australia and managed by Australian clinical research organisation 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 will participate in the trial, evenly divided across three arms. The three arms of 12 subjects each will receive one of IHL-675A, CBD, or HCQ. The safety and pharmacokinetic assessments will be identical across the three arms of the trial. IHL anticipates that the first participants will be recruited in Q4 2021.

Subject to clinical success, the results of this clinical trial will form part of three FDA investigational new drug (IND) applications for each of the three indications the Company is pursuing with IHL-675A. Once the IND applications are evaluated and approved, the Company intends to conduct phase 2 and 3 clinical trials partly or wholly in the United States.

The soft gel capsules for the Company's clinical trial programs are being manufactured by Procaps S.A., a GMP compliant manufacturer that can quickly ramp up production to commercial quantities (registered or unregistered) upon successful clinical trial outcomes.

IHL-216A for concussion and traumatic brain injuries

During the quarter, Incannex engaged Vectura Limited ('Vectura') to develop the specific formulation for IHL-216A required for clinical trials. Vectura is a state-of-the-art contract development and manufacturing organisation (CDMO) that specialises in the development and manufacture of inhaled drugs and their associated delivery products. Vectura has contributed to the formulation and development of 13 successful inhaled medical products with partners and licensees that include Sandoz, Novartis and Bayer. In total, these products have cumulatively generated US$11 billion in sales and have been used by 10 million patients since their launch and up until 2020.

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 this 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 development and formulation will occur in parallel with the *in vivo* study to ensure that Incannex is readied with the drug and delivery mechanism required for advancement of pivotal clinical trials once the *in vivo* study is finalised.

IHL-216A is a combination drug that combines CBD with any volatile anaesthetic agent, including isoflurane. It has been designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits. Due to the product's potential therapeutic utility in contact sports, IHL-216A is designed to satisfy the World Anti-doping 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. TBI accounts for approximately 10 million deaths and hospitalizations annually in the world (Schuman et al., 2017) and there are currently no registered pharmaceutical agents approved for the treatment of TBI.

Discontinuation of unregistered cannabinoid products

As previously disclosed in the Company's AGM presentation and as advised in the March quarterly report, the board of directors conducted a review of the business relating to the sale of unregistered products due to overcrowding and discounting particularly in the cannabinoid oils space. In addition, the Company's advice from its US advisors is that US investor interest is focused on IHL's drug development activities and its psychedelic therapy program. These are proprietary programs over which IHL has patent protection or intends to have patent protection over aspects of the drug and or therapy. In the wake of that review, the Board concluded that it would discontinue sales of unregistered generic cannabinoid products to optimise focus on its research and development projects. As a result, the company extinguished the balance of any remaining stock during the quarter and no further expenses related to the sale of generic oil products shall be incurred.

Corporate activities and position

Incannex held cash at bank of $9.124M as at the close of the June 2021 quarter. Net cash outflows were $2.175M, comprising mostly R&D expenditure – part of which expense will be eligible for the Australian Government R&D rebate scheme. The Company achieved $133k of cash inflows associated with the sale of unregistered cannabinoid oils during the quarter. Item 6.1 of Appendix 4C – amount paid to related parties represents remuneration paid to on-going directors.

ENDS

The release of this announcement has been approved for issue by IHL's Board of Directors. For further details on the announcement, interested parties should contact:

Mr Joel Latham, Managing Director and Chief Executive Officer
P: +61 409 840 786
E: joel@incannex.com.au

Investors: investors@incannex.com.au

Date: 30th July 2021
ASX Announcement (ASX: IHL)

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 2021

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	133	2,201
1.2	Payments for		
	research and development	(1,126)	(5,374)
	product manufacturing and operating costs	-	(888)
	advertising and marketing	(225)	(683)
	leased assets	-	-
	staff costs	(225)	(974)
	administration and corporate costs	(599)	(1,191)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,042)**	**(6,908)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
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:		
	(b) entities	-	29
	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**	**-**	29

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	794	12,500
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(100)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
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**	**794**	**12,400**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,372	3,603
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,042)	(4,866)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	29
4.4	Net cash from / (used in) financing activities (item 3.10 above)	794	11,606
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,124**	**10,372**

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	26	12
5.2	Call deposits	9,098	10,360
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)**	**9,124**	**10,372**

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	74
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)	(2,042)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	9,124
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	9,124
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.5

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: .....30th July 2021.....

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.