Date: 29th October 2021
ASX Announcement (ASX: IHL)

September 2021 Quarterly Activities Report and Appendix 4C

Highlights:

- Phase 2a psilocybin-assisted therapy for Generalised Anxiety Disorder clinical trial has received approval to proceed from the Monash University Human Research Ethics Committee
- The FDA in pre-IND meeting confirmed that the therapeutic strategy for the development of a psilocybin-assisted therapy for Generalised Anxiety Disorder is appropriate
- Incannex received ethics approval to commence an open label extension to the phase 2b clinical trial for IHL-42X in patients with Obstructive Sleep Apnoea
- IHL filed an International Patent Application for the use of IHL-42X for treatment of obstructive sleep apnoea. The International Search Report and Opinion considered key claims to be both novel and inventive.
- IHL commenced a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers
- Incannex announced the public filing of a registration statement on Form F-1 with the US Securities and Exchange Commission as it pursues listing on the Nasdaq
- Incannex completes option exercise program to raise A$17.66M; including A$8.20M from Chief Medical Officer, Dr Sud Agarwal

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

Psi-GAD development program: psilocybin-assisted psychotherapy for Generalised Anxiety Disorder

After the end of 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-Investigational New Drug Application ('pre-IND') meeting with the US Food and Drug Administration ('FDA') regarding the Company's clinical development program comprising psilocybin-assisted psychotherapy for Generalised Anxiety Disorder ('GAD').

Ethics Committee approves Phase 2a Psi-GAD clinical trial

Led by Dr Paul Liknaitzky, Head of Clinical Psychedelic Research at Monash University, the trial is the first in the world to examine the safety and efficacy of psilocybin for any primary anxiety disorder. With 72 participants, this investigator-initiated 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.

Having now received approval from the Monash University Human Research Ethics Committee, the study team will commence the drug importation process, complete the training of trial therapists that is currently underway, and finalise site infrastructure. Participant recruitment is expected to commence early in 2022.

Positive pre-IND meeting with FDA on Psi-GAD development program

The pre-IND meeting package was prepared with assistance from regulatory consultants Camargo Pharmaceutical Services. Included in the meeting package was an overview of the Psi-GAD program, and specific questions Incannex had on the regulatory requirements for opening an investigational new drug ('IND') folder required to conduct human trials in pursuit of FDA marketing approval in the USA.

Both the written responses and the responses provided in the teleconference held recently were positive, constructive, and supportive. The 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 NDA (FDA approval) and marketing authorisation. Specific feedback from the 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.

IHL-42X for Obstructive Sleep Apnoea

During the quarter, IHL announced that it has 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. The International Search Report and Opinion considered key claims to be both novel and inventive.

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. 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 Q1 of 2022.

Incannex has also received ethics approval to commence an open label extension to the phase 2b clinical trial. The open label extension study has recruited people who have experienced a benefit from IHL-42X in the phase 2b trial and will assess the therapeutic benefit and tolerability of IHL-42X in those patients over an extended timeframe.

Incannex has engaged Procaps S.A. to develop and manufacture pharmaceutical grade IHL-42X soft gel capsules, the Company's proprietary combination cannabinoid drug under development for the treatment of obstructive sleep apnoea ('OSA'). The soft gel capsules will be used in pivotal phase 2, phase 3 and open label clinical trials. Procaps is also equipped to provide subsequent commercial manufacture at scale.

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

During the quarter, IHL 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 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.

An International Patent Application entitled "Methods and compositions for treating or preventing an inflammatory condition" was recently filed as part of the IHL-675A development program. This application was filed pursuant to the Patent Cooperation Treaty (PCT), thus providing IHL with an opportunity to pursue patent protection in foreign jurisdictions, including key markets (North America, the EU, Japan, Australia, Israel, among others) with established and developing medicinal cannabis industries.

Pleasingly, the International Examiner considers that claims directed to IHL-675A and methods for the treatment of inflammatory conditions using IHL-675A are novel and inventive and meet the requirements for industrial applicability. Based on the International Search Report and Opinion, IHL is currently considering options to expedite the filing and examination of patent applications in key jurisdictions as part of IHL's intellectual property (IP) strategy.

IHL has completed a pre-IND meeting with the FDA to discuss the regulatory pathway for the development of IHL-675A 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.

Incannex has engaged Procaps S.A., as it has with IHL-42X, to develop the formulation for IHL-675A. Procaps S.A. offers Incannex a complete supply chain solution for a sophisticated, GMP-grade product. Manufacturing at Procaps will support our clinical trial programs and can also quickly ramp up production for commercial supply upon successful clinical trial outcomes.

IHL-216A for Concussion and Traumatic Brain Injury

During the quarter, Incannex continued with the development of the formulation for IHL-216A with Vectura Group plc. 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.

Vectura Group plc 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.

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. This study is ongoing.

Incannex files registration statement with the SEC for proposed initial public offering on Nasdaq in the United States

During the quarter, Incannex announced the public filing of a registration statement on Form F-1 with the US Securities and Exchange Commission (the "SEC"). The filing relates to a proposed US public offering (the "Offering") of American Depositary Shares ("ADSs"), each of which will represent 50 ordinary shares of Incannex. The registration statement on Form F-1 is filed with the SEC by non-US companies seeking to undertake an initial public offering in the United States. It is analogous to a prospectus for an Australian initial public offering but is more comprehensive.

Incannex held an extraordinary general meeting and received shareholder approval for the issuance of ordinary shares under the Offering. The number of securities to be sold and the price per ADS for the Offering have not yet been determined. Concurrent with the proposed US public offering, Incannex would list the ADSs on the Nasdaq. Incannex has applied to list its ADSs on Nasdaq under the ticker symbol "IXHL", which has been reserved for Incannex by Nasdaq.

Incannex completes option exercise program to raise A$17.66M; including A$8.20M from Chief Medical Officer

A total of 118M IHLAH option securities (expired 30 September 2021, ex A$0.08) have been exercised, since being issued, with a significant proportion of option securities being held by Incannex directors or existing shareholders that have a track record of long-term investment in the Company.

40.99M IHLAI non-transferable option securities (expired 30 September 2021, ex A$0.20) held by the Company's Chief Medical Officer and director, Dr Sud Agarwal have been exercised, representing a further investment of A$8.20M by Dr Agarwal into Incannex. Dr Agarwal now has direct and indirect shareholdings representing approximately 8.88% of the Company.

Following the completion of the option exercises, each director of Incannex has executed a 6-month voluntary escrow agreement to satisfy the rules of the US Securities and Exchange Commission as the Company pursues listing on the Nasdaq exchange.

Corporate activities and position

Incannex held cash at bank of $22.45M as at the close of the September 2021 quarter. Net cash outflows were $2.52M. R&D expenditure of $0.94M was the largest expenditure item and most of this expense will be eligible for the Australian Government R&D rebate scheme.

Expenses associated with the Company's SEC application and Nasdaq listing comprise legal, accounting and consulting fees associated with this extensive compliance process and are considered non-recurring.

Item 6.1 of Appendix 4C represents amounts paid to directors and related parties. $0.24M of this expenditure represents a CEO bonus and consultancy payments also associated with work undertaken for the SEC application and proposed Nasdaq listing.

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:

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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	30 September 2021

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	(943)	(943)
	(b) product manufacturing and operating costs	-	
	(c) advertising and marketing	(205)	(205)
	(d) leased assets	-	-
	(e) staff costs	(357)	(357)
	(f) administration and corporate costs	(504)	(504)
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	-	-
1.7	Government grants and tax incentives	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
1.8	Other (provide details if material) - costs associated with SEC application and NASDAQ listing	(511)	(511)
1.9	**Net cash from / (used in) operating activities**	**(2,520)**	**(2,520)**

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 (3 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	15,852	15,852
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**	**15,852**	**15,852**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,124	9,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,520)	(2,520)
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)	15,582	15,582
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**22,446**	**22,446**

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	382	26
5.2	Call deposits	22,064	9,098
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)**	**22,446**	**9,124**

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	384
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)	(2,520)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	22,446
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	22,446
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	8.9

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: .....29th October 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.