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

Incannex Healthcare Quarterly Activities Report

and 4C Quarterly Cash Flow Report

Highlights:

- Psi-GAD-1 psilocybin-assisted psychotherapy for generalised anxiety disorder phase 2 clinical trial protocol and US FDA pre-IND meeting package advancing
- IHL expands target indications for IHL-675A to lung inflammation, IBD and rheumatoid arthritis following pre-IND meeting with US FDA; initiates clinical trial program for a multi-use drug as IHL-675A performs better than CBD for inflammatory conditions in animal studies
- Incannex continues recruitment and has initiated dosing IHL-42X to patients with Obstructive Sleep Apnoea in its phase 2 clinical trial
- IHL-216A being assessed in a model of traumatic brain injury developed by US NFL as a precursor to pivotal in-human trials required for drug registration
- IHL continues to work with its advisors on a potential US listing, given increasing investor interest in both cannabinoid-based pharmaceuticals and psychedelic therapeutic endeavours in North America.

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 2020. Incannex has six US Food and Drug Administration ('FDA') programs for medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies.

Psilocybin-assisted psychotherapy for Generalised Anxiety Disorder

During the quarter, Incannex advanced its phase 2 randomised double-blind active-placebo-controlled clinical trial to assess the safety and efficacy of psilocybin-assisted psychotherapy in the treatment of Generalised Anxiety Disorder ('Psi-GAD-1').

IHL executed a partnership agreement with Monash University ('Monash') in December 2020 to conduct Psi-GAD-1. It is a world-first clinical trial led by Dr Paul Liknaitzky, who is the chief investigator of the trial and a member of the Incannex medical advisory board. Psi-GAD-1 clinical trial will recruit at least 72 patients and will include major innovations in treatment approach and study design. Davies Collison Cave are IHL's patent attorney in relation to the development program.

In February, IHL formally engaged Camargo Pharmaceuticals LLC ('Camargo') to work with Incannex and Monash to advise upon and compile the pre-Investigational New Drug ('PIND') information package necessary to call a PIND meeting with FDA. It is anticipated that the meeting will provide Incannex with regulatory clarity and confidence as Incannex develops its Psi-GAD-1 clinical trial protocol. Following FDA feedback, the protocol will be adjusted as required so that the trial may become one of the pivotal trials necessary for registration and marketing approval in the US.

Currently, two psilocybin research programs for depression have received Breakthrough Designation from the US Food and Drug Administration. A second psychedelic medicine trial to investigate another indication has been largely advanced with further details to be released to market when relevant contracting is finalised.

IHL-675A multi-use pharmaceutical drug progressing to clinical trial post FDA PIND meeting

Following a successful PIND meeting with US FDA, IHL has expanded its development program to assesses the potential for IHL-675A, which combines cannabidiol ('CBD') and Hydroxychloroquine ('HCQ') to become a multi-use pharmaceutical drug. applicable to the treatment of patients with lung inflammation, inflammatory bowel disease (IBD) and rheumatoid arthritis.

During the quarter, IHL received multiple sets of results from distinct *in vivo* studies using animal models that are applicable to a range of conditions. The indications prioritised for clinical assessment are:

- Lung inflammation – including acute respiratory distress syndrome (ARDS) and sepsis associated ARDS (SAARDS), COPD, asthma, and bronchitis,
- inflammatory bowel disease, and
- rheumatoid arthritis.

Incannex has commenced the process of designing a phase 1 clinical trial necessary to assess these conditions in-human with the purpose to form part of three distinct investigational new drug applications ('INDs') and their associated studies required for registration and marketing authority. The combined global market size of the indications being targeted by Incannex with IHL-675A is over US$125B per annum.

Results from an *in vivo* model of rheumatoid arthritis indicated that IHL-675A has a benefit in the treatment of rheumatoid arthritis greater than that of CBD or HCQ alone. HCQ is currently approved and widely used for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate; marketed as Plaquenil. In an animal model, low dose IHL-675A was 1.06 to 3.52x more effective at reducing arthritis across multiple assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels versus the standard dose of HCQ. The results demonstrate that IHL-675A has the potential to permit a ten-fold reduction in HCQ dose, without sacrificing efficacy, in treatment of arthritis. If replicated in human studies, IHL-675A could result in a lower side effect profile for patients currently being treated with HCQ.

IHL-42X Phase 2 Clinical Trial to treat Obstructive Sleep Apnoea Continues

Incannex has continued recruitment and has initiated dosing IHL-42X to patients with Obstructive Sleep Apnoea in its phase 2 clinical trial during the March quarter. The primary endpoint under observation is the reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels and the trial is being performed at the Alfred Hospital under the supervision of experienced principal investigator Professor Terry O'Brien.

Incannex proprietary formulation IHL-42X is a combination drug that includes dronabinol and other pharmaceutical ingredients specifically formulated to improve upon results achieved in academic studies concerning dronabinol, when administered prior to nocturnal sleep, and OSA.

A clinical trial involving dronabinol for the treatment of OSA completed at Northwestern University (United States) in 2005 demonstrated that dronabinol significantly improves patient measure of AHI.

That trial was a fully blinded, Phase 2, randomized placebo-controlled trial of dronabinol in 56 adult patients with moderate to severe OSA. By random assignment, 56 adult subjects AHI between 15 and 50 received either placebo (N=17), 2.5mg (N=19) or 10.0mg (N=20) of dronabinol daily, one hour before bedtime for 6 weeks.

Overall, baseline AHI was 26.0±11.6 (SD). In comparison to placebo, statistically significant end of treatment declines in AHI were observed for both the 2.5 and 10 mg doses (-9.7±4.1, p=0.02 (or -37.3%), and -13.2±4.0, p=0.001 (or -50.8%), respectively).

The trial undertaken by Northwestern University demonstrates that dronabinol alone is effective in lowering AHI in patients with moderate obstructive sleep apnoea. There is a growing recognition that mild to moderate OSA is a very prevalent condition and may affect not only quality of life but also long-term cardiovascular and cerebrovascular health. OSA is a major health burden to individuals and has a significant impact on public health with limited tolerable treatment options available to patients. It effects approximately 30M people and has a total economic burden of US$149.6 billion per annum in the USA alone. There is currently no pharmacological product available for its treatment. Therefore, the board of directors considers that positive results from the trial will be a major value driver for the Company.

IHL-216A being assessed in a model of traumatic brain injury developed by US NFL

In March, Incannex partnered with the Monash University Trauma Group at the Department of Neuroscience to conduct an extensive *in vivo* study in relation to the neuroprotective capability of IHL216A; the Company's proprietary combination pharmacotherapy (drug) comprising CBD and isoflurane.

The study utilises a unique model of traumatic brain injury ('TBI') 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. In this model, concussions experienced by NFL players have been scaled to Sprague Dawley rats, according to known biological relationships, to mimic the collision mechanics including high velocity impact and head acceleration.

The study is a precursor to pivotal in-human trials required for drug registration, negating the previous requirement to complete an in-human proof-of-concept study; saving time and expense to the development program.

IHL-216A components, CBD and isoflurane, have previously been found 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.

An International Patent Application entitled "Compositions and methods for the treatment or prevention of traumatic brain injury" has been filed as part of the IHL-216A development program.

Appointment of EAS Advisors and Dual US listing

In February, Incannex appointed US-based EAS Advisors LLC ("EAS") in response to increasing investor interest in both cannabinoid-based pharmaceuticals and psychedelic therapeutic endeavours in North America.

Amongst other matters, EAS are to facilitate introductions to US banks and institutions with the intention to list on a US main market, whilst simultaneously retaining its ASX listing. EAS is also mandated to generate global investor awareness of Incannex's pharmaceutical development programs in the USA, Europe, Asia, and Australia.

As foreshadowed in the ASX announcement dated 11th February 2021, the Company continues to progress a potential listing on a major US stock exchange. The company looks forward to updating the market when it is in a position to do so.

Corporate Activities and Position

Incannex held cash at bank of $10.4m as at the close of the March 2021 quarter. Net cash outflows were $1.98M, comprising mostly R&D expenditure – part of which expense will be eligible for the Australian Government R&D rebate scheme.

The Company achieved $638k of cash inflows associated with the sale of unregistered cannabinoid oils during the quarter with revenue largely remaining steady and consistent with the previous two quarters. However, as previously disclosed in the Company's AGM presentation, the board of directors has noticed substantial and increasing margin compression in a space that is becoming overcrowded. This has resulted in significant product discounting throughout the sector.

In addition, the Company's initial advice from its US advisors is that US investor interest is likely focused on IHL's drug development activities and its psychedelic 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. This is particularly relevant following FDA pre-IND guidance relating to IHL-675A having the potential to be a multi-purpose drug.

The Board will take this corporate advice into consideration and assess resource allocation to optimise high-value projects versus generic unregistered products as it continues to assess the ongoing desirability of generic product sales, which are limited to only the Australian market via the special access scheme. Incannex will decide on this matter as it continues to explore its options in relation to a main board US listing.

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:

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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 2020

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	638	2,068
1.2	Payments for		
	(a) research and development	(1,903)	(4,248)
	(b) product manufacturing and operating costs	(129)	(888)
	(c) advertising and marketing	(166)	(458)
	(d) leased assets	-	-
	(e) staff costs	(219)	(749)
	(f) administration and corporate costs	(201)	(592)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	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**	**(1,979)**	**(4,866)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
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	-	29
	(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**	**-**	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	505	11,706
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 (9 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**	**505**	**11,606**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	11,846	3,603
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,979)	(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)	505	11,606
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**10,372**	**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	12	483
5.2	Call deposits	10,360	11,363
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)**	**10,372**	**11,846**

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	180
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)	(1,979)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	10,372
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	10,372
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	5.2

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: .....29 April 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.