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Date: 22nd Oct 2020
ASX Announcement (ASX: IHL)

Incannex Healthcare Quarterly Activities Report

and 4C Quarterly Cash Flow Report

Highlights:

- Ethics approval received for phase 2b clinical trial to investigate IHL-42X oral pharmaceutical in subjects with Obstructive Sleep Apnoea
- Achieves positive results from its *in vivo* and *in vitro* studies for the assessment of the key constituents of IHL-675A against sepsis associated acute respiratory distress syndrome
- Commences *in vivo* study to assess the neuroprotective capability of IHL-216A in preparation for an upcoming in-human clinical trial
- Appointment of Dr Paul Liknaitzky to the Incannex scientific advisory board to advise on the research of novel psychiatric agents and associated therapies
- Achieves second consecutive quarter of record sales receipts of $695K
- Completion of the IHLOB option exercise program to raise in excess of $10M, with closing cash balance of $12.1M as at September 30, 2020.

Clinical stage cannabinoid 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 2020.

IHL-42X for Obstructive Sleep Apnoea ("OSA")

During the quarter, Incannex received ethics approval for its phase 2b clinical trial to investigate IHL-42X in subjects with OSA.

The randomised, double-blind, placebo-controlled dose ranging phase 2b clinical trial will treat patients with OSA to assess the therapeutic benefit of IHL-42X at three different dose levels. The primary endpoint in the trial is the reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels. Participants will also be monitored for improvements in alertness, daytime sleepiness, mood, and quality of life. A positive result in the trial would be a major valuation inflection point for Incannex as the Company pursues FDA registration of IHL-42X under the 505(b)(2) new drug application process.

The study will be performed at the Alfred Hospital under the supervision of experienced principal investigator Professor Terry O'Brien. Patient recruitment is expected to commence in the current December quarter.

OSA is a highly prevalent disease affecting approximately 30M adults in the USA and there is currently no existing registered pharmacotherapy treatment option for sufferers of OSA. It is calculated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately $149.6 billion per

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annum. The estimated costs include $86.9 billion in lost productivity, $26.2 billion in motor vehicle accidents and $6.5 billion in workplace accidents.

IHL-675A for Sepsis Associated Acute Respiratory Distress Syndrome ("SAARDS")

During the quarter, Incannex continued to develop its novel small molecule therapeutic IHL-675A, which comprises hydroxychloroquine ('HCQ') and cannabidiol ('CBD') for the treatment of SAARDS. IHL-675A has been designed to limit the progression of infections to sepsis hyperinflammation caused by the "cytokine storm" feedback loop.

Incannex received both positive *in vivo* and *in vitro* study results to assess the key constituents of IHL-675A against SAARDS. The studies were designed to:

1. Demonstrate the ability of CBD and HCQ to inhibit inflammatory cytokine production associated with Sepsis and SAARDS; and,
2. assess the dose responses of CBD and HCQ to the production of cytokine inflammatory markers to benefit the design of the fixed dose combination product.

in vivo results

Rodent cohorts were dosed with either CBD or HCQ in escalation, introduced to an inflammatory agent to induce sepsis, and then had their blood sampled 2 hours later. Five of the most vital cytokines associated with inflammation were measured.

CBD significantly reduced production of serum cytokine levels after the inflammatory stimulus and with a bell-shaped dose response curve. The maximum level of inhibition ranged from 19-44%, relative to cytokine levels in the vehicle treated mice. The "vehicle" being the delivery fluid that carried the CBD or HCQ. HCQ also significantly reduced the production of serum cytokine levels after the inflammatory stimulus but with a linear dose response curve. The maximum inhibition of cytokine levels ranged from 18-35%, relative to the vehicle treated mice.

The results for both CBD and HCQ compare favourably to IHL's expectation of greater than 15% cytokine inhibition, relative to the vehicle treated mice. Compared to untreated rodents with no induction of sepsis ('baseline'), CBD reduced cytokine levels up to 90%, relative to the vehicle. Compared to the baseline rodents, HCQ reduced cytokine levels up to 88%, relative to the vehicle.

in vitro results

In this assay, human peripheral blood mononuclear cells ('PBMCs') isolated from three different donors were each treated with CBD or HCQ in five different concentrations prior to the induction of an inflammatory response using bacterial lipopolysaccharide ('LPS'). An untreated control where only LPS was added was also included in the experiment.

After 24h incubation in the presence of the study drug and LPS, the culture medium was analysed for levels of key inflammatory cytokines using a Luminex based assay. Both CBD and HCQ displayed linear anti-inflammatory dose response curves. That is, with increasing concentrations of drug, the PBMCs produced less cytokines in response to stimulation with LPS.

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The highest concentrations of CBD (20 μg/mL) and HCQ (50 μg/mL) each completely inhibited cytokine production by PBMCs in response to LPS. These results confirm the Company's expectations on the inflammation dampening effects of the study drugs, as extrapolated from other scientific literature.

Incannex is currently awaiting results for *in vitro* combination drug studies prior that will provide guidance on the optimal fixed dose combination of IHL-675A. Synergistic effect between the two compounds in a fixed dose combination would result in a better therapeutic outcome than the drugs taken singularly.

SAARDS is caused by a hyper-inflammatory response and is the leading cause of mortality associated with severe infections, including the COVID-19 coronavirus infection. There is significant unmet need in the treatment of SAARDS and there are no registered pharmacotherapy treatments available for the condition. Incannex has lodged a provisional patent application over IHL-675A for SAARDS as it continues development activities.

IHL-216A for Traumatic Brain Injury ("TBI") and Concussion

During the quarter, Incannex commenced an *in vivo* study to formally assess the neuroprotective capability of IHL-216A. The trial introduces rodents to head trauma, implemented consistently in a highly controlled environment to inflict a reproducible injury. Eight separate rodent cohorts have been administered components or combinations of IHL-216A at varying doses soon after the trauma.

IHL is monitoring secondary injury cascades, assessing structural damage to the brain using magnetic resonance imaging and performing micro-scale cellular analysis post-mortem to discern and compare neuronal damage across the cohorts. The study is being conducted to discern optimal fixed dose combinations for the upcoming in-human clinical trial and will contribute to the Company's FDA data package.

The drug discovery team hypothesise that there is an optimal fixed dose of APIs within IHL-216A which, given soon after head trauma, will reduce:

- Neuro-excitation
- Neuro-inflammation
- Cerebral blood flow
- Cerebral oxygen consumption,

with the result of providing overall neuroprotection, defined as reduced neuronal cell death or disruption. The consequences of neuroprotection will be improved recovery from the neurocognitive and motor deficits that result from TBI.

IHL-216A is designed to satisfy World Antidoping 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/or hospitalization annually in the world (Schuman et al., 2017). There are currently no pharmaceutical agents approved for the treatment of TBI. Current

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treatment of major TBI is primarily managed through surgical intervention by decompressive craniotomy (Bullock et al., 2006) which involves the removal of skull segments to reduce intracranial pressure.

Appointment of Dr Paul Liknaitzky as a Scientific Officer

During the quarter, Dr Paul Liknaitzky joined the Incannex scientific advisory board. Dr Liknaitzky has been engaged to advise on the research of novel psychiatric agents and associated therapies that are potentially suitable for use in the treatment of anxiety and depression-related illnesses. Incannex expects to provide an update on Dr Liknaitzky's appointment to shareholders soon.

Dr Liknaitzky holds numerous academic research positions, investigating the use of novel psychiatric agents. He has appointments at St Vincent's Hospital in Melbourne, Deakin University, Macquarie University, and Odyssey House Victoria. Dr Liknaitzky earned an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne. His work examines mechanisms of mental illness and treatment development primarily within depression, anxiety, and addiction research.

Quarterly Sales of Medicinal Cannabis Therapeutics

IHL achieved cash sales receipts of $695K for September quarter 2020, which is its second consecutive quarter of record sales. Revenues exclusively comprised the sale of cannabinoid products under the Australian special access scheme ('SAS'). Also, during the quarter, Incannex received an additional 5500 units of its proprietary Cannagesia, Releafia, Nutralesic, Inflammex products, removing limitations on assisting patients seeking relief for a significant range of conditions.

Corporate Position

Incannex held cash at bank of $12.1m as at close of the September quarter following the completion of the IHLOB option exercise program that raised more than $10m with options holders exercising about 99.1% of their holdings.

Item 6.1 of Appendix 4C – amount paid to related parties represents remuneration paid to on-going directors and includes payment of the short-term incentive of $90,000 reported as payable to the group CEO in the FY20 Annual Report as at June 30, 2020.

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 2020

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	695	695
1.2	Payments for		
	(a) research and development	(1,290)	(1,290)
	(b) product manufacturing and operating costs	(530)	(530)
	(c) advertising and marketing	(183)	(183)
	(d) leased assets	-	-
	(e) staff costs	(306)	(306)
	(f) administration and corporate costs	(200)	(200)
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	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,814)**	**(1,814)**

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	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	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	10,326	10,326
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**10,326**	**10,326**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,603	3,603
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,814)	(1,814)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	29	29
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10,326	10,326
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**12,144**	**12,144**

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	35	18
5.2	Call deposits	12,109	3,585
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)**	**12,144**	**3,603**

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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	238
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)	(1,814)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	12,144
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	12,144
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:

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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: .....22 October 2020.....

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.

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