Date: 29th July 2020
ASX Announcement (ASX: IHL)

Incannex Healthcare Quarterly Activities Report

and 4C Quarterly Cash Flow Report

Highlights:

- Achieves record quarter of cash sales receipts of $670K for the quarter coinciding with significant ramp up in sales of cannabinoid products
- Receives positive results from pre-clinical animal study for the assessment of IHL-675A against SAARDS and the Company has commenced *in vitro* studies for optimal combination dosing
- Partners with The Alfred Hospital and Novotech on IHL-42X Clinical Program for Obstructive Sleep Apnoea ('OSA')
- Phase 2b clinical trial protocol for OSA in-human clinical trial has been to be submitted to the Alfred Health Ethics Committee for review
- Commences animal study to formally assess the neuroprotective capability of IHL-216A for traumatic brain injury ('TBI') and concussion
- The TBI animal study is being conducted to discern optimal combination dosages for the upcoming in-human clinical trial in MMA fighting athletes
- Company formalises name change to Incannex Healthcare Limited (no change in ASX code).

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 June 2020.

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

Incannex received positive results from its pre-clinical animal study for the assessment of the key constituents of IHL-675A against SAARDS. IHL-675A is hypothesised to limit the progression of infections to sepsis hyperinflammation caused by the "cytokine storm" feedback loop.

The study was designed in this manner to:

1. Demonstrate the ability of Cannabidiol ('CBD') and Hydroxychloroquine ('HCQ') to inhibit inflammatory cytokine production associated with Sepsis and Sepsis Associated ARDS; and,
2. assess the dose responses of CBD and HCQ to the production of cytokine inflammatory markers in rodents after inducing sepsis to benefit the design of the fixed dose combination product.

Compared to baseline mice, CBD reduced 5 key inflammatory cytokine levels by 31-90%, relative to the vehicle. Compared to baseline mice, HCQ reduced 5 key inflammatory cytokine levels by 39-88%, relative to the vehicle. 80% of results were deemed statistically significant.

Incannex has now commenced an *in vitro* study to assess the formulated combinations of CBD and HCQ that provide an optimal inflammation dampening response ratio. Results are expected in approximately 3-5

weeks. The second animal study to test for the optimal fixed dose combination will immediately follow the *in vitro* study.

Subject to success in stage 2 of animal studies, it is the opinion of FDA consultants Camargo Pharmaceutical Services that IHL-675A will be a candidate for FDA Emergency Use Authorisation resulting from the COVID19 pandemic.

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 (drug) treatments available for the condition. Impression has lodged a provisional patent application over IHL-675A for ARDS as it continues development activities.

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

During the quarter, Incannex partnered with The Alfred and Novotech on IHL-42X Clinical Program for Obstructive Sleep Apnoea. Professor Terence O'Brien has been named as Principal Investigator; a world-renowned clinician and highly experienced Principal Investigator of more than 100 clinical trials. Professor O'Brien heads the Neuroscience Clinical Trials Unit at The Alfred Hospital and has an experienced team of study coordinators and research nurses. The primary endpoint of the clinical trial is the improvement in AHI as measured by an overnight polysomnography ('PSG') that will be assessed over multiple weeks.

Secondary outcomes include the following:

- Reduction in oxygen desaturation index (ODI)
- Daytime somnolence measured by the Epworth Sleepiness Scale
- Improvement in mood as measured by the POMS (Profile of Moods State), and well-being as measured by the Short Form 36
- Safety of the IHL-42X combination will be established through adverse event monitoring.

The clinical trial protocol has been to be submitted to the Alfred Health Ethics Committee for review with comments and queries expected back from the ethics committee over a period of 4-5 weeks.

IHL will endeavour to supply IHL-42X for sale in Australia under the Special Access Scheme for unregistered medicinal cannabis products, alongside its existing range of cannabinoid oils and CBD Inhaler. IHL will also proceed to the second Phase 2 'Factorial' clinical trial as it compiles the necessary information for an FDA 505(b)(2) new drug application for exclusive marketability; details of which were released in the announcement on the 25th of March 2020 and entitled, "IHL-42X (OSA) accelerated FDA approval pathway".

OSA is a lethal disease that increases the risk of numerous health complications, affecting approximately 40M adults in the USA alone. Untreated OSA is associated with an increased risk of cardiovascular morbidity. The main current treatment option is the mechanical CPAP device. Patient compliance to CPAP devices is low due to discomfort and claustrophobia.

The current direct global annual market size for OSA detection and treatment using CPAP devices is over US$10B per annum and growing. There is no existing registered pharmacotherapy (drug) treatment option

for sufferers of OSA and IHL anticipates greatly improved patient treatment compliance from a once-nightly oral pharmaceutical product, such as IHL-42X, should it prove successful under clinical assessment.

IHL-216A for Traumatic Brain Injury and Concussion

Subsequent to the end of the quarter, Incannex commenced an animal 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 will be administered components or combinations of IHL-216A at varying doses soon after the trauma. The rodents will then undertake behavioural tests at various intervals to assess their neurocognitive and motor function.

IHL will also monitor secondary injury cascades, assess structural damage to the brain using magnetic resonance imaging and perform micro-scale cellular analysis post-mortem to discern and compare neuronal damage across the cohorts.

The study is being conducted to discern optimal combination dosages for the upcoming in-human clinical trial in MMA fighting athletes 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 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.

The study will contribute to data package FDA 505(b)(2) new drug application for exclusive marketability; details of which were released in the announcement on the 03rd of March 2020 and entitled, "IHL-216A (TBI/Concussion) accelerated FDA approval pathway".

Record Quarter of Cash Sales

IHL achieved a record quarter of cash sales receipts of $671K for June quarter 2020, being an 97% increase over the previous corresponding June 2019 quarter. It represents the largest quarter of sales since the ASX listing of the Company in November of 2016 and coincides with a significant ramp up in the sale of medicinal cannabis products under the Special Access Scheme in Australia.

IHL cannabinoid products are primarily sold under the Company's product supply and distribution relationship with Cannvalate Pty Ltd, which is the largest network of cannabis medicine prescribers in Australia. The CEO of Cannvalate is Dr Sud Agarwal, who is also a Director and Chief Medical Officer of Incannex. Cannvalate and Dr Agarwal are major shareholders of IHL.

Impression has the following cannabinoid products saleable under the medicinal cannabis special access scheme:

- Cannagesia CBD oil
- Releafia 20CBD: 1THC oil
- Nutralesic 10CBD: 1THC oil
- Inflammex 10CBD: 10THC oil
- Incannex CBD Inhaler.

The Company also wound down its non-core activities during the quarter to focus its resources on its medicinal cannabinoid development and sales programs, the key drivers of Company value. Sales of oral devices has concluded; a decision reached at a time when sales of Impression's Incannex branded cannabinoid products continue to gain market share. Additionally, IHL concluded investigations for the manufacture of botanical THC ('Dronabinol') with Resolution Chemicals LLC, in favour of procuring synthetic dronabinol on an ongoing basis, which is more favourable for cGMP replicability of pharmaceutical drugs and FDA/DEA applications.

Corporate Position

Incannex held cash at bank of $3.6M as at close of the June quarter. After the end of the quarter, IHL has received requests to exercise a number of options with ASX ticker code "IHLOB", representing incoming cash of $322K. These options are listed and tradable on the ASX and have an exercise price of $0.04 per share and are exercisable by the 30th September 2020. 252M IHLOB options remain on issue and are a substantial source of funding for the Company's medicinal cannabinoid programs.

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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Investors: investors@incannex.com.au

Date: 29th July 2020
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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 June 2020

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	670	1,389
1.2	Payments for		
	(a) research and development	(1,007)	(1,885)
	(b) product manufacturing and operating costs	(559)	(1,098))
	(c) advertising and marketing	(51)	(585)
	(d) leased assets	-	-
	(e) staff costs	(190)	(938)
	(f) administration and corporate costs	(161)	(700)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	7
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**	**(1,297)**	**(3,810)**

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	-	-
	(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)	-	6,673
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	543	1,077
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(347)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(65)

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)	(18)	(18)
3.10	**Net cash from / (used in) financing activities**	**525**	**7,320**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,375	93
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,297)	(3,810)
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)	525	7,320
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,603**	**3,603**

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	18	23
5.2	Call deposits	3,585	4,352
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)**	**3,603**	**4,375**

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	88
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)	(1,297)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	3,603
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	3,603
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.78

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: .....28 July 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.