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

# Incannex Healthcare Quarterly Activities Report

# and 4C Quarterly Cash Flow Report

**Highlights:**

- First patients recruited into IHL-42X phase 2b obstructive sleep apnoea clinical trial following receipt of human research ethics approval from the Alfred Hospital Ethics Committee
- Positive results from its *in vivo* and *in vitro* studies for the assessment of the anti-inflammatory activity of IHL-675A, which confirmed the drug's potential in prevention of sepsis associated acute respiratory distress syndrome; in the process of submitting a FDA pre-IND meeting request
- Positive results from *in vivo* study assessing proprietary IHL-216A; which outperformed cannabidiol for neuroprotective qualities including lessening of neuronal damage; development pathways being evaluated
- Commenced the design of the first psychedelic-assisted psychotherapy clinical trial; assessing psilocybin and psychotherapy combined for the treatment of Generalised Anxiety Disorder at Monash University; considering other opportunities in the psychedelic medicines sector
- Achieves fifth consecutive quarter of record sales receipts of $735K in the December quarter.

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. The Company has continued to advance its US Food and Drug Administration ('FDA') programs for its medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies.

***First patients recruited into IHL-42X phase 2b obstructive sleep apnoea clinical trial***

During the quarter, Incannex recruited the first patients to its phase 2b clinical trial to assess the safety and efficacy of IHL-42X in the treatment of obstructive sleep apnoea ('OSA'). Patient recruitment follows the receipt of Human Research and Ethics Committee ('HREC') approval to commence the trial. 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.

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, has a total

economic burden of US$149.6 billion per annum in the USA alone and there is currently no pharmacological product available for its treatment.

***Positive in vivo results confirm strong synergistic activity of IHL-675A constituents to inhibit inflammation; engages Camargo Pharmaceutical Services to call a pre-IND meeting with the FDA***

During the quarter, IHL-675A components, cannabidiol and hydroxychloroquine, were demonstrated to act synergistically to inhibit production of key inflammatory cytokines in both *in vitro and in vivo* experiments. Specifically, IHL-675A outperformed predicted cytokine inhibition, based on the activity of each drug alone, by 26% to 81% *in vivo* across the five analysed cytokines after 2 hours.

Due to these results, Incannex has expanded its provisional patent protection to cover the treatment of a range of other inflammatory diseases, additional to sepsis associated acute respiratory distress syndrome ('SAARDS'), that represent additional potential applications and for IHL-675A that the Company is evaluating.

IHL is also in the process of arranging a pre-IND meeting with the FDA to formulate the best path forward for clinical testing considering the compound's applicability to SAARDS, which is the leading cause of mortality from COVID-19. During the pre-IND process, Incannex will propose that IHL-675A be considered for an Emergency Use Authorisation if the drug proves to be effective at reducing the occurrence of SAARDS in a Phase 2 clinical trial. If successful, the Company will be given the opportunity to have its proprietary drug administered to COVID-19 patients in the US.

***Positive results from IHL-216A in Traumatic Brain Injury in vivo study***

During December, Incannex received results from its extensive *in vivo* study of IHL-216A, which has been developed to lessen secondary brain injuries resulting from head knocks and concussion.

The Company reported that IHL-216A components, cannabidiol ('CBD') and isoflurane, act synergistically to reduce neuronal damage, neuroinflammation and behavioural deficits that are consequences of traumatic brain injury ('TBI'). 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. IHL-216A also reduced the Iba1 neuroinflammation marker by 35% more than CBD alone and 123% more than isoflurane alone.

An International Patent Application entitled "Compositions and methods for the treatment or prevention of traumatic brain injury" was recently filed as part of the IHL-216A development program, with the International Examiner indicating that claims directed to IHL-216A and methods for the treatment of TBI using IHL-216A are novel, inventive and satisfy the industrial applicability requirements.

IHL-216A has been designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits. Secondary brain injuries evolve over minutes, days and months

after the primary insult and result from biochemical, metabolic, and cellular changes initiated by the primary event. Due to the product's potential therapeutic utility in contact sports, 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.

Incannex is currently assessing the most efficient clinical trial program to follow the successful *in vivo* studies so that it may pursue an FDA new drug application, subject to further clinical success. TBI accounts for approximately 10 million deaths and/or hospitalisations throughout the world annually (Schuman et al., 2017) and there are currently no registered pharmaceutical agents approved for the treatment of TBI.

***Psilocybin-assisted psychotherapy for the treatment of Generalised Anxiety Disorder***

Also, in December, IHL initiated a psilocybin-assisted psychotherapy trial to treat Generalised Anxiety Disorder ('GAD'). The trial will recruit at least 72 patients to make it the largest psychedelic R&D project in Australia and is anticipated to have a substantial impact on the field globally.

The treatment will be delivered within BrainPark, a state-of-the-art research platform at Monash University's Turner Institute for Brain and Mental Health. Treatment will include psilocybin dosing sessions alongside a program of specialised psychotherapy. The trial is planned to be FDA compliant, with the Company calling a pre-IND meeting as soon as practicable to discuss the clinical trial protocol.

Currently, two psilocybin research programs for depression have received Breakthrough Designation from the FDA. GAD is a relatively common disorder with about 6-9% lifetime prevalence, and about 3% 12-month prevalence in countries like Australia and the United States.

Chief Principal Investigator of the trial, Dr Paul Liknaitzky, works as a Research Fellow at Monash University, and has Adjunct or Honorary appointments at St Vincent's Hospital, Macquarie University, Deakin University, and the University of Melbourne. He earned an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne and is a leader in the field of psychedelic medicines in Australia. Dr Liknaitzky is also a member of the Incannex medical advisory board.

In addition to the GAD psilocybin trial, IHL continues to evaluate psychedelic medicine opportunities as the Company believes that the revival of these compounds has great potential to change the lives of patients with long standing mental health conditions.

***Corporate Activities and Position***

IHL achieved cash sales receipts of $735K for December quarter 2020, which is its fifth consecutive quarter of record sales. Revenues comprised the sale of cannabinoid products under the Australian special access scheme ('SAS'). Incannex held cash at bank of $11.8m as at close of the December quarter.

In November, Incannex signed a corporate advisory mandate with Canary Capital Pty Ltd ("Canary Capital"), a boutique investment management and corporate advisory firm headquartered in Sydney. Canary Capital prides itself on creating value for its clients through long-term strategic investments in micro and small cap companies which it believes have the potential to become leaders in their field and are globally scalable.

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 (6 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 735 | 1,430 |
| 1.2 | Payments for | | |
| | (a) research and development | (1,056) | (2,346) |
| | (b) product manufacturing and operating costs | (229) | (759) |
| | (c) advertising and marketing | (109) | (292) |
| | (d) leased assets | - | - |
| | (e) staff costs | (224) | (530) |
| | (f) administration and corporate costs | (191) | (391) |
| 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** | **(1,073)** | **(2,887)** |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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 | 875 | 11,201 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (100) | (100) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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** | **775** | **11,101** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 12,144 | 3,603 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,073) | (2,887) |
| 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) | 775 | 11,101 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **11,846** | **11,846** |

| **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 | 483 | 35 |
| 5.2 | Call deposits | 11,363 | 12,109 |
| 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)** | **11,846** | **12,144** |

| 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 | 156 |
| 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<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | (1,073) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 11,846 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 11,846 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | 11.0 |

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 January 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.