Date: 28 July 2023
Public Announcement (ASX: IHL) (Nasdaq: IXHL)

Incannex Healthcare June 2023 Quarterly Activities Report and Appendix 4C Cash Flow Statement

Melbourne, Australia, July 28, 2023 - Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL) (NASDAQ: IXHL), ('Incannex' or the 'Company'), is pleased to provide its quarterly activities report and appendix 4C for the period ended 30 June 2023. Incannex is undertaking a multitude of U.S. Food and Drug Administration ('FDA') research and development ('R&D') programs for cannabinoid pharmaceutical products and psychedelic medicine therapies administered by health professionals.

Incannex Receives Ethics Approval for Bioequivalence/Bioavailability Clinical Trial for IHL-42X

During the quarter, Incannex received approval from the Bellberry human research ethics committee ('HREC') to commence a bioavailability/bioequivalence ('BA/BE') clinical trial to assess the pharmacokinetics and tolerability of IHL-42X, which is the Company's proprietary drug for treatment of Obstructive Sleep Apnoea ('OSA').

The BA/BE clinical trial will assess the pharmacokinetics and tolerability of the two active pharmaceutical ingredients ('APIs') in IHL-42X, dronabinol ('THC') and acetazolamide, compared to the respective FDA reference listed drugs, as well as the effect of food on pharmacokinetics of the two APIs. The study will include 116 participants who will each complete four (4) single dose treatment periods, being dosed with IHL-42X, dronabinol and acetazolamide under fasted conditions as well as IHL-42X under fed conditions. Blood samples will be collected over 48 hours and the concentrations of the APIs and their major metabolites in the samples will be analysed. The clinical trial will be conducted at CMAX Clinical Research in Adelaide, South Australia and managed by Novotech.

The design of the BA/BE trial is consistent with US Food and Drug Administration ('FDA') recommendations and specific advice received by Incannex in its pre-IND with the FDA regarding the development of IHL-42X for treatment of OSA. The results of the BA/BE trial will form a critical component of a future new drug application ('NDA'), providing the necessary bridge to the reference listed drugs, thereby facilitating the use of historic safety data via the FDA505(b)2 regulatory pathway.

The BA/BE study will run in parallel to the pivotal Phase 2/3 trial that will commence after the Company opens an IND with the FDA.

Incannex Submits IND Application to the US FDA for IHL-42X for Obstructive Sleep Apnoea

Subsequent to the end of the quarter, Incannex successfully submitted an Investigational New Drug ('IND') application to the US Food and Drug Administration ('FDA') for IHL-42X for treatment of

obstructive sleep apnoea. The IND dossier compiled by the Incannex team includes comprehensive modules on the safety and efficacy of IHL-42X and its component active pharmaceutical ingredients. It also includes detailed information on the development, manufacturing, quality and stability of the IHL-42X drug product, as well as the clinical protocol and investigator information for the Phase 2/3 IND opening clinical trial.

Submitting an IND to the FDA is crucial for companies to gain regulatory approval, conduct clinical trials, and engage in scientific dialogue with FDA whilst they progress investigational drugs through the stages of development in the United States. The FDA review process for an IND application involves evaluation of the scientific, clinical, and safety aspects to ensure that the proposed clinical trial meets regulatory requirements. The IND application details the clinical trial protocol for the IND opening clinical trial, which is a multisite phase 2/3 clinical trial investigating IHL-42X for the treatment of OSA.

Incannex engages Fortrea to Manage its FDA IND Opening Phase 2/3 Clinical Trial Investigating IHL-42X for Treatment of OSA

Incannex has engaged Fortrea as the contract research organisation ('CRO') to manage the IND opening Phase 2/3 clinical trial investigating IHL-42X for treatment of OSA. The Phase 2/3 clinical trial will assess the safety and efficacy of IHL-42X in people with OSA who are intolerant, non-compliant, or naïve to continuous positive airway pressure ('CPAP'). This extensive trial will be conducted across 45 sites, including many in the United States. Fortrea will implement its technology enabled clinical trial solutions designed to increase drug development efficiency, reduce timelines, and improve compliance.

At the time, CEO and Managing Director of Incannex, Mr Joel Latham said, "The initial Phase 2 proof of concept clinical trial over IHL-42X demonstrated an average reduction in our primary end point, AHI of 50.7%, with 25% of subjects having a reduced AHI of >80%. Importantly, we also observed a reduction in average patient oxygen desaturation index of 59.7%, markedly improved sleep quality and a reduction in cardiovascular stress. These results were truly remarkable and now allows for this Phase 2/3 trial to be a genuine long-term safety and efficacy trial. If we again observe such remarkable drug efficacy, safely administered over the 52 weeks, Incannex is confident that our product will be marketable."

There are no registered pharmacotherapy (drug) treatments available to people with OSA, representing a major economic opportunity to Incannex with IHL-42X, should the study achieve its endpoints as in the proof-of-concept trial.

Incannex enters a lease for first psychedelic-assisted psychotherapy clinic Melbourne, Australia

During the quarter, Incannex subsidiary company, Clarion Clinics Group Pty Ltd, entered a lease for riverfront premises in Abbottsford, Melbourne. The premises will be used to provide psychedelic-assisted psychotherapy. Fit out and commissioning of these premises is expected to be complete in August 2023, facilitating the opening of the first clinic shortly thereafter. The clinic is designed as a

commercial scale prototype, which can be scaled up and replicated to other locations. It will have capacity to treat over 600 patients per year in normal working hours and substantially more in extended hour operations.

Director for Incannex's psychedelic clinics business, Mr Peter Widdows said; "The initial clinic is a pioneering venture that will implement best practice in psychedelic treatment and aims to positively impact the lives of many people suffering with intractable mental health conditions. It alone is a substantial business opportunity and has the potential to expand into a very sizable venture with the subsequent planned roll-out of numerous clinics. The estimated Australian market for psychedelic-assisted psychotherapy is anticipated to be more than $2bn per annum and the global market closer to $60bn. Clarion Clinics Group is uniquely placed to be a significant player in this market by entering early, having the treatment model, business model and the best qualified people in place."

Incannex Announces Final Results from Phase 1 Clinical Trial Assessing Safety and Pharmacokinetics of IHL-675A

In May, Incannex released the final results from the Phase 1 clinical trial undertaken to assess pharmacokinetics and safety of the anti-inflammatory drug IHL-675A. IHL-675A is a combination cannabinoid drug comprising cannabidiol ('CBD') and hydroxychloroquine ('HCQ') in a fixed dose combination. IHL-675A was observed to outperform either CBD and HCQ in various pre-clinical models of inflammation, including in vivo models of rheumatoid arthritis, inflammatory bowel disease and lung inflammation. Synergistic anti-inflammatory activity of CBD and HCQ was observed in these distinct pre-clinical studies and was evidence to support the Company's international patent application over the drug.

The Phase 1 trial measured the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ). Three cohorts of 12 participants (n = 36) received either IHL-675A, CBD or HCQ and the clinical assessments were identical across the three arms of the trial. Participants were monitored for adverse events and had blood samples collected for pharmacokinetic analysis over a four-week period.

IHL-675A is well tolerated in healthy volunteers. Adverse events for IHL-675A were consistent with what was observed, and has been publicly reported, for Epidiolex and Plaquenil. Both active pharmaceutical ingredients, CBD and HCQ, are absorbed from IHL-675A. Trends in PK profiles indicate that the uptake of CBD may be more rapid for IHL-675A than Epidiolex and uptake of HCQ may be slower for IHL-675A than Plaquenil. This could be advantageous for IHL-675A. CBD provides immediate relief for inflammation and pain whereas HCQ is a slower acting molecule and provides extended relief.

Incannex Receives HREC Approval for Phase 2 Clinical Trial Assessing IHL-675A for use in Treatment of Pain and Function in Rheumatoid Arthritis

Incannex has received approval from the Human Research Ethics Committee ('HREC') for the lead site, Emeritus Research, Camberwell, VIC for the Phase 2, Blinded, Placebo Controlled Clinical Trial to Determine the Safety and Effect on Pain and Function of IHL-675A in Patients with Rheumatoid Arthritis.

Prior to commencing clinical trials, Incannex observed positive results from an animal model of RA. IHL-675A was observed to be more effective at reducing arthritis across multiple assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels than the rodent equivalent of the standard dose of HCQ or equivalent doses of CBD. The reduction in disease assessments achieved by IHL-675A was 1.06-3.52 times that observed for HCQ alone at the standard dose.

These promising observations led the company to prioritise rapid clinical assessment, particularly given that HCQ, marketed as Plaquenil and generic equivalents, is a common long-standing treatment prescribed for RA with a considerable market profile. The Phase 2 study, that has now been approved by HREC at the lead site Emeritus Research, Camberwell, Victoria, will assess the efficacy, safety and tolerability of IHL-675A compared to the respective component Active Pharmaceutical Ingredients (APIs), CBD and HCQ, and placebo.

The trial will be managed by Avance Clinical, an Australian and US CRO, who will engage 8-10 clinical trial sites across Australia and New Zealand, recruiting 128 patients in total. The trial will aim to assess the effect of IHL-675A on pain and function by utilising patient reported outcomes, disease scores and inflammatory biomarker analysis over a 24-week period. The results of the trial will establish the safety and efficacy of IHL-675A in rheumatoid arthritis patients and contribute to the combination rule assessment in a 505(b)2 new drug application dossier with FDA.

Incannex Appoints QPS to Advance CannQuit-N™ (Nicotine), CannQuitO™ (Opioid) and Renecann™ Products in the USA and EU

In April, Incannex appointed Quest Pharmaceutical Services ('QPS') to provide regulatory advice and manage clinical trials for the development of CannQuit™ and ReneCann™ products for addiction and immune-disordered skin diseases. QPS was founded in 1995 to provide high-quality bioanalytical LC-MS/MS contract services. Since then, QPS has grown from a small molecule bioanalysis shop of three people to more than 1,250+ employees in the United States, Europe, India, and Asia. Over the years, QPS has adopted additional services, including Neuropharmacology, DMPK, Toxicology, Translational Medicine, Early Phase Clinical Research and Phase II – IV Clinical Research.

QPS is currently drafting pre-investigational new drug (pre-IND) submissions for both the European Union's European Medicines Agency ('EMA') and the US Food and Drug Administration ('FDA') for the CannQuit™ and ReneCann™ Products. Once advice is received from the regulators over the proposed research and development programs, QPS will retain a leading role in the management of clinical trials, which will be undertaken to provide relevant evidence of safety and efficacy.

The CannQuit™ and ReneCann™ products are patent protected and were acquired as part of the acquisition of APIRx Pharmaceuticals ('APIRx'), completed in 2022. These products are being developed and manufactured by Eurofin's Scientific (Eurofins). Data collected by Eurofins on the quality and stability of the products will be key components of future regulatory packages.

CannQuit-Nicotine (N)™ A functional, controlled-release, pharmaceutical-grade (cGMP) medicated chewing gum formulation comprising cannabidiol (CBD) and nicotine. Drug product development and testing is underway at Eurofins. Nicotine chewing gum is already an effective and accepted treatment and maintenance product throughout the globe with annual sales amounting to $US5.2B in 2020, however, the progression to complete smoking cessation is limited. By adding CBD in a patented combination, CannQuit-N™ is hypothesised by Incannex to improve upon the therapeutic outcomes of nicotine only gum. The patented technology of controlled and sustained release of the active ingredients also is believed to improve the therapeutic value of this novel drug candidate.

CannQuit-Opiod (O)™ A functional, controlled-release, pharmaceutical-grade medicated chewing gum formulation that combines CBD and an opioid antagonist/agonist in a proprietary water-soluble chewable tablet for the treatment of opioid addiction. The water-soluble chewable tablet, known as CheWell, is uniquely loaded with a high CBD dose and in addition the unique polymer composition that ensures faster onset and higher bioavailability as shown in preliminary PK/PD studies. At present, stability evaluation is being done for the pharmaceutical ingredients within CannQuit-O™.

Renecann™ ReneCann™ is Incannex's proprietary topical cannabinoid formulation for treatment of dermatological conditions caused by disorders of the immune system, including vitiligo, psoriasis, and atopic dermatitis, otherwise known as eczema. The unique formulation combines Cannabigerol ('CBG') and CBD. CBG is a non-psychoactive cannabinoid with potent anti-inflammatory properties. Analytical characterization of the APIs, including validation of the assay methods have been completed and formulation development of the Renecann drug product, including placebo, have commenced.

Incannex Intention to Redomicile to United States, List all Shares on Nasdaq, Delist from ASX

Subsequent to the end of the quarter, Incannex announced its intention to redomicile to the United States via a Scheme of Arrangement pursuant to Australian law. A newly formed Delaware corporation (Incannex Healthcare Inc.) will become the ultimate parent company of the group, following implementation of the Scheme of Arrangement. The shares of common stock issued by Incannex Healthcare Inc. in exchange for all outstanding ordinary shares of Incannex, pursuant to the Scheme of Arrangement, will be listed on Nasdaq.

Incannex anticipates that it will have greater access to a capital market more cognisant of IHL's value proposition with peer comparison companies trading at significantly higher market valuations.

Incannex shareholders will be given the opportunity to vote on redomiciling to the US in October 2023 and, if approved, the change in nature of the shares and options in Incannex can be implemented

rapidly. Incannex will assist shareholders to seamlessly transfer their holdings to US shares tradable on Australia broking platforms to ensure little to no disruption to shareholders. The Board also believes that the re-domiciliation may deliver certain additional benefits to Incannex and its shareholders, including:

- improved access to lower-cost equity capital in the U.S. markets, which are larger and more diverse than Australian capital markets, thus enabling future growth to be financed at a lower cost;
- increased alignment with other prominent pharmaceutical companies that are already listed on Nasdaq which can enhance the group's visibility and reputation within the industry, making it more attractive to potential investors, strategic partners, and other stakeholders;
- a simplified corporate structure for potential future merger, sale or acquisition transactions, which may increase Incannex US's attractiveness to potential merger partners, sellers or acquirers.
- increased attractiveness of Incannex US to a broader U.S. investor pool who previously could not invest in non-U.S. or packaged ADR securities;
- enhanced regulatory pathway for Incannex's pharmaceutical products through direct access to FDA resources, guidance, and expertise; and
- better collaborative opportunities with FDA.

Redomiciling Incannex to the US is not intended to coincide with any capital raise as the Company already has significant cash reserves for development activities.

Corporate Activities

At June 30, 2023, Incannex recorded A$33.4M in cash at bank. A$3.6M was recorded as cash outflows associated with R&D activities. Incannex is eligible to receive an annual cash rebate equivalent to approximately 43.5% of all monies spent on research and development in Australia. Eligible R&D expenditures typically include costs associated with pre-clinical and clinical trial activities in Australia and internal and external research consultancy personnel. The Company's expansive pipeline of clinical development programs remains fully funded into 2025.

Incannex shares trade on the ASX under stock code "IHL". Incannex American Depository Shares (ADSs) also trade on the NASDAQ under code "IXHL". Each IXHL ADS represents 25 ordinary shares of the Company. Item 6.1 of Appendix 4C (below) represents amounts paid to directors and related parties.

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 2023

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	-	-
1.2	Payments for		
	(a) research and development	(1,458)	(10,283)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(69)	(702)
	(d) leased assets	(196)	(196)
	(e) staff costs	(268)	(1,194)
	(f) administration and corporate costs	(1,732)	(5,356)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	124	302
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	6	1,338
1.7	Government grants and tax incentives	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,593)**	**(16,091)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(295)	(295)
	(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)	109	12,253
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
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**	**109**	**12,253**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	37,141	37,502
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,593)	(16,091)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(295)	(295)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	109	12,253
4.5	Effect of movement in exchange rates on cash held	1	(6)
4.6	**Cash and cash equivalents at end of period**	**33,363**	**33,363**

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	290	14
5.2	Call deposits	33,073	37,127
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)**	**33,363**	**37,141**

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	(343)
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)	(3,593)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	33,363
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	33,363
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	9.3

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 2023.....

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.