
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of June, 2023

Commission File Number: 001-41106

Incannex Healthcare Limited
(Exact name of Registrant as specified in its charter)

not applicable
(Translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Joel Latham
Chief Executive Officer and Managing Director
Level 39, Rialto South Tower
525 Collins Street
Melbourne 3000
Australia
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F Form 40-F

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 16, 2023, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “Principal Investigators Appointed for IHL42X Phase 2/3 Trial”, a copy of which announcement is attached to this Form 6-K as Exhibit 99.1.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Incannex Healthcare Limited

Date: June 16, 2023

By: /s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.

99.1 [ASX Announcement, dated June 16, 2023 – Principal Investigators Appointed for IHL42X Phase 2/3 Trial](#)



Date: June 16, 2023
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Appoints Principal Investigators for IHL-42X Phase 2/3 Clinical Trial

Melbourne, Australia, June 16, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has recruited two highly experienced lead principal investigators (PIs) for the IND opening Phase 2/3 clinical trial investigating IHL-42X for treatment of obstructive sleep apnoea ('OSA'). Dr John D Hudson of FutureSearch Trials of Neurology, Austin, Texas and Dr Russell Rosenberg of Neurotrials Research Inc, Atlanta, Georgia.

Recruiting the lead PIs is a critical step for the IND opening Phase 2/3 study as Dr Hudson and Dr Rosenberg, and their associated facilities, will serve as the first clinical trial sites for submission to the FDA and for ethics approval from Institutional Review Boards. Site recruitment and selection in the US and other jurisdictions is an iterative process and Incannex plans to recruit approximately 45 sites across multiple jurisdictions for this pivotal trial.

Dr John D Hudson, Principal Investigator – FutureSearch Trials of Neurology, Austin, Texas

J. Douglas Hudson, MD, is board certified in Neurology and Sleep Medicine. He serves as the Principal Investigator for FutureSearch Trials of Neurology, Austin, Texas. Dr. Hudson has supervised over 300 clinical trials over the past 20 years mostly related to neurological and sleep disorders and has been a national and international speaker for these disorders.

Dr. Hudson completed his neurology residency at the University of Iowa and was Austin's first board certified sleep specialist. Past activities include founding the Austin Neurological Clinic and Sleep Medicine Consultants. He held the position of President of the Texas Neurological Society, with a Lifetime Achievement Award and President of the Capital Area American Heart Association.

FutureSearch Trials consists of two clinical research facilities in Austin and Dallas, Texas which have been in operation for over 15 years. The Austin site where Dr. Hudson is the Principal Investigator focuses on clinical research studies for treatment of neurological, pain and sleep disorders and features an on-site sleep lab.

Regarding the IHL-42X trial, Dr Hudson said: *"Clinical trials for novel formulations of medication are newsworthy for any specialty and sleep medicine is no exception.*

Obstructive Sleep Apnea, affecting millions of people, remains under treated. This is due in part to patients not being diagnosed, and in part due to poor patient compliance with current therapeutic modalities.

While unheard of a few years ago, oral medications to help reduce the cause of OSA, are now undergoing further investigation. This is more than exciting, it could prove to be life-changing for many patients."

Incannex Healthcare Limited (ABN: 93 096 635 246)
Level 39, Rialto South Tower, 525 Collins Street, Melbourne VIC 3000
P: +61 409 840 786

Russell Rosenberg, PhD, Director and CEO - NeuroTrials Research Inc, Atlanta, Georgia

Dr. Rosenberg is currently Chief Science Officer and CEO of NeuroTrials Research in Atlanta, Georgia. Dr. Rosenberg, a native of St. Louis, obtained his doctorate in clinical and research psychology from The Ohio State University and received specialized training in sleep disorders medicine and research at Rush Presbyterian - St. Luke's Medical Center in Chicago. He has more than 35 years' experience in clinical sleep medicine and research, acting as an investigator in over 300 clinical trials including 14 in OSA and 211 in other sleep related disorders. He is a Board-Certified Sleep Specialist and Fellow of the American Academy of Sleep Medicine. Dr. Rosenberg is former Chair and spokesperson for the National Sleep Foundation (NSF) and has appeared frequently on local and national television news shows including the Today Show, Good Morning America, CNN, and MSNBC.

NeuroTrials Research Inc is a clinical research facility in Atlanta, Georgia that has been in operation for over 25 years. NeuroTrials Research is focused on delivery of trials in neurology/CNS and sleep indications.

Regarding the IHL-42X phase 2/3 clinical trial Dr Rosenberg said: *"Incannex has developed a sound, rational, scientific protocol to determine the efficacy and safety of IHL-42X in subjects with obstructive sleep apnea."*

"Many sleep apnea patients cannot adhere to positive airway pressure therapy, use it for an inadequate period at night or just refuse it. Having a safe, effective pharmacological option for obstructive sleep apnea will be a positive addition to the treatment landscape as it will offer those that struggle to adhere to positive airway pressure therapy an alternative therapy."

CEO and Managing Director, Mr Joel Latham said; "Our Company is delighted to have the endorsement of two leading esteemed research scientists with the relevant experience to advance our IHL-42X drug candidate. Their support is testament to the efficacy of IHL-42X demonstrated in phase 2 proof of concept studies. The multi-site clinical trial being arranged is a pivotal trial, meaning that it can be used for the registration of IHL-42X for regulatory registration and commercial launch, which is an exciting development for Incannex after much hard work and dedication from our broad team of contributors."

This announcement has been approved for release to ASX by the Incannex Board of Directors.

END

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About Incannex Healthcare Limited

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of obstructive sleep apnoea (OSA), traumatic brain injury (TBI) and concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, inflammatory bowel disease, anxiety disorders, addiction disorders, and pain, among other indications.

U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication under investigation currently has no, or limited, existing registered pharmacotherapy (drug) treatments available to the public and represent major global economic opportunities to Incannex and its shareholders.

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. The Company holds 19 granted patents and 30 pending patent applications. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and has American Depository Shares listed on NASDAQ under code "IXHL".

Website: www.incannex.com.au
Investors: investors@incannex.com.au

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

Contact Information:

Incannex Healthcare Limited

Mr Joel Latham
Managing Director and Chief Executive Officer
+61 409 840 786
joel@incannex.com.au

Investor Relations Contact – United States

Alyssa Factor
Edison Group
+1 (860) 573 9637
afactor@edisongroup.com

Incannex Healthcare Limited (ABN: 93 096 635 246)
Level 39, Rialto South Tower, 525 Collins Street, Melbourne VIC 3000
P: +61 409 840 786