
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 August, 2022

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On August 17, 2022, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “Incannex Appoints Distinguished FDA Expert to Board”, 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: August 17, 2022

By: /s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.

99.1 [ASX Announcement, dated August 17, 2022 – Incannex Appoints Distinguished FDA Expert to Board](#)



Date: August 17, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Appoints FDA Regulatory Affairs Expert Mr Robert B. Clark to the Board of Directors

Highlights:

- Highly experienced pharmaceutical executive with 20+ years at Pfizer and 10+ years at Novo Nordisk
- Secured FDA registration and marketing approval for 12 significant new drugs in the past 10 years at Novo Nordisk in his capacity of Vice President – US Regulatory Affairs
- Personal leadership of more than 15 successful US FDA Advisory Committee Meetings on behalf of Novo Nordisk and Pfizer
- Nationally recognized expert on FDA/EMA liaison interactions and US pharmaceutical advertising and promotional practices
- Documented success with FDA accelerated approval programs including Fast-Track, Orphan Drug, Breakthrough Therapy Designations, and Priority Reviews.

Melbourne, Australia, August 17, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic therapies for unmet medical needs, is pleased to announce the appointment of experienced pharmaceutical executive Mr Robert B. Clark to the Board of Directors.

Mr Clark is a senior-level strategic regulatory affairs expert with over 38 years of US and Global regulatory experience, including >20 years with Pfizer Inc. and >10 years with Novo Nordisk A/S. He is an internationally recognized expert on US Food and Drug Administration ('FDA') and the European Medicines Agency (EMA) liaison interactions, US pharmaceutical advertising practices and regulatory aspects related to healthcare professionals and sales force activities.

Mr Clark is Vice President, US Regulatory Affairs for Novo Nordisk where he provides strategic leadership to a team of over 50 regulatory staff and scientists in the development of new medicines. He advises the global executive team on matters related to drug development programs, FDA liaison strategies, managing FDA-related compliance issues, and monitoring emerging US regulatory trends and opportunities. He and his team manage all interactions with FDA on behalf of Novo Nordisk and have secured FDA approvals for twelve (12) significant new drugs for the company since his tenure began in 2012.

Prior to joining Nova Nordisk, Mr Clark was Vice President of Worldwide Regulatory Strategy and US Regulatory Affairs at Pfizer, leading a team of up to 150 regional regulatory professionals supporting the drug development continuum. During his time at Pfizer, he led or supported FDA approval of many new medicines and represented Pfizer at critical interactions with FDA, and other global health authorities, including key project milestone meetings.

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



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Mr Clark has senior level experience in managing regulatory aspects of large-scale pharmaceutical acquisitions, significant compliance matters and business development due diligence activities. He also has documented success with FDA accelerated approval programs including Fast-Track, Orphan Drug, Breakthrough Therapy Designations, and Priority Reviews, which are areas of interest for Incannex management due to the nature of its drug candidate mix.

“Bob is amongst the best credentialed regulatory affairs experts in the world, and we’re delighted that he has joined our board of directors because it is a strong vote of confidence in our drug candidates and development strategy”, said Mr Joel Latham, CEO and Managing Director of Incannex. “He brings to Incannex deep knowledge of the US regulatory environment and decades of experience at the highest level of large pharmaceutical organisations. His experience will be invaluable to us now that our interactions with FDA have become more frequent whilst we pursue our mission to bring cannabinoid and psychedelic pharmacological solutions to patients with unmet medical needs”.

Non-executive Director, Mr Robert B. Clark said, “I look forward to working with the Board and the management team, and I am excited about the broad Incannex portfolio of products to treat patients who have few or no other available treatments. Cannabinoid and psychedelic pharmacotherapies represent a growing area of research and hold the potential to treat various conditions for which effective options are limited”.

Mr Clark holds a Master’s in Science in Pharmacology from the New York Medical College and formally commences his directorship on August 17, 2022.

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

END



Date: August 17, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

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 29 pending patents. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and also has American Depository Shares listed on NASDAQ under code "IXHL".

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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
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