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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Form 6-K**

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

**For the month of Mar, 2023**

**Commission File Number: 001-41106**

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

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**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)

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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

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**INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

On March 03, 2023, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned "Incannex to Manufacture Psilocybin for Trials & Commercial", 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.

Date: March 03, 2023

### **Incannex Healthcare Limited**

By: /s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and Managing Director

## INDEX TO EXHIBITS

Exhibit No.

99.1 [ASX Announcement, dated March 03, 2023 – Incannex to Manufacture Psilocybin for Trials & Commercial](#)



Date: March 03, 2023  
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

**Incannex Engages Catalent for Development and cGMP Manufacture of Psilocybin Drug Product for Clinical Trials and Commercial Potentiality**

**Highlights:**

- Incannex has engaged Catalent for the development and cGMP manufacture of Incannex's own psilocybin drug product
- The psilocybin is designed for use in Incannex's ongoing psilocybin-assisted psychotherapy "PsiGAD" clinical development program for generalised anxiety disorder
- The psilocybin drug product may also have potential uses in psilocybin-assisted psychotherapy programs in Australia under the new Authorised Prescriber Scheme for psychedelic-assisted psychotherapy recently announced by the TGA in Australia
- Development of the drug product includes generation of the necessary quality and stability data to support future regulatory filings including IND applications.

**Melbourne, Australia, March 03, 2023** – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has engaged Catalent ('Catalent') to develop and manufacture a cGMP-grade psilocybin drug product for: (1) use in Incannex's proprietary psilocybin-assisted psychotherapy drug development program and (2), potential use in the Therapeutic Goods Association ('TGA') Authorised Prescriber Scheme for psychedelic-assisted psychotherapy in Australia.

Commencing development and manufacture of a psilocybin drug product follows an internal analysis of the interim data from the PsiGAD phase 2 clinical trial, giving Incannex confidence to proceed with formulation development and cGMP manufacture of its own psilocybin. Interim results from the PsiGAD trial remain internally confidential to maintain blinding and integrity of the trial, however, interim statistical analysis from the independent data safety monitoring board (DSMB) will be released soon, when available.

Incannex CEO and Managing Director Mr Joel Latham said; "The TGA's decision to down schedule psilocybin for Authorised Prescribers to prescribe psilocybin for treatment-resistant depression has important implications for our long term outlook. Having our own source of pharmaceutical grade psilocybin not only allows our company to freely undertake clinical trials, it also creates a potential opportunity to be a part of providing therapies to patients in Australia in the future, something that the Company is actively assessing."

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



**Date: March 03, 2023**  
**Public Announcement (NASDAQ: IXHL) (ASX: IHL)**

Catalent has been engaged to develop the formulation, generate required quality and stability data for regulatory filings, and establish cGMP manufacture of a drug product to be used in future clinical trials. The proposed manufacturing process will be designed so that it will be scalable to commercial supply levels when appropriate.

Incannex Chief Scientific Officer Dr Mark Bleackley said; “Engaging Catalent for development and cGMP manufacture of Incannex’s psilocybin drug project is an important milestone for the PsiGAD program. The resulting drug product, and supporting data, will form an important component of future regulatory filings and will facilitate Incannex’s development of psilocybin assisted psychotherapy for generalised anxiety disorder. This therapy has the potential to help millions of people whose lives are seriously impacted by generalised anxiety disorder for whom current treatment options have not been effective. We look forward to working with Catalent on the continued development of this exciting drug product.”

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

**END**

Incannex Healthcare Limited (ABN: 93 096 635 246)  
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**Date: March 03, 2023**  
**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 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](http://www.incannex.com.au)**

**Investors: [investors@incannex.com.au](mailto: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**

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