

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 21, 2023

Incannex Healthcare Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)	001-41106 (Commission File Number)	93-2403210 (IRS Employer Identification No.)
Suite 105, 8 Century Circuit Norwest, NSW 2153 Australia (Address of Principal Executive Offices)		Not applicable (Zip Code)

Registrant's Telephone Number, including Area Code: +61 409 840 786

(Former Name or Former Address, if Changed Since Last Report): Not Applicable

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	IXHL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 21, 2023, Incannex Healthcare Inc.'s Australian subsidiary, Clarion Clinics, received endorsement from the Australian Human Research Ethics Committee for the administration of psychedelic-assisted therapies with respect to Treatment Resistant Depression and Post-Traumatic Stress Disorder. Further information is included in the press release attached as Exhibit 99.1 hereto, which is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Incannex Healthcare Inc., dated December 21, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 hereunto duly authorized.

Date: December 22, 2023

Incannex Healthcare Inc.

/s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and President



Date: December 21, 2023
Public Announcement (NASDAQ: IXHL)

CLARION CLINICS RECEIVES ETHICS BOARD ENDORSMENT FOR THE FIRST DEDICATED PSYCHEDELIC-ASSISTED THERAPY CLINIC IN AUSTRALIA

Highlights:

- Incannex subsidiary, Clarion Clinics, has received Human Research Ethics Committee (HREC) endorsement for administration of psychedelic-assisted therapies for TRD and PTSD in Australia.
- HREC approval is required for the administration of psychedelic drugs in Australia.
- Clarion Clinics is the only dedicated psychedelic-assisted therapy clinic in Australia, with intentions to open more clinics across the country and internationally as legislation permits.
- Clarion Clinics team includes pre-eminent psychedelic researchers, psychologists and psychiatrists whose expertise cannot easily be replicated in Australia.
- The Melbourne clinic fit-out is complete and the clinical and administrative teams in place.

December 21, 2023 – Incannex Healthcare Inc. (Nasdaq: IXHL) ('Incannex' or 'the Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic assisted psychotherapies for unmet needs is pleased to announce that it has received Australian ethics board endorsement for psychedelic assisted therapy at its first clinic based in Melbourne, Australia.

In order to prescribe schedule-8 drugs under the Australian Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme, psychiatrists are required to receive HREC endorsement for their qualifications, experience, the qualifications and experience of the treatment team, and the protocols to be used in the treatment of patients with psychedelic compounds. Clarion is pleased to announce that it has received HREC endorsement for both Psilocybin and MDMA assisted therapy for the treatment of Treatment Resistant Depression (TRD) and Post-Traumatic Stress Disorder respectively (PTSD).

The TGA, which is the Australian equivalent to the FDA in the United States, selectively down-scheduled psilocybin for the treatment of TRD and MDMA for the treatment of PTSD from schedule 9 to schedule 8 in July 2023, which allows authorised psychiatrists to prescribe both drugs under the Authorised Prescriber Scheme.

The Melbourne Clarion Clinic will be the first dedicated Psychedelic-assisted therapy clinic in Australia. Located on the Yarra Riverfront in Abbotsford, Melbourne, this clinic has been designed and fitted out specifically to facilitate an optimal environment for psychedelic-assisted therapy. With seven treatments rooms and a group therapy room, the clinic is a commercial scale prototype and has the capacity to treat approximately 600 people per annum in normal working hours and substantially more in extended hour operations. Future clinics are intended to be significantly larger.



Date: December 21, 2023
Public Announcement (NASDAQ: IXHL)

Clarion Clinics has received a substantial number of expressions of interest in treatment submissions from potential patients since opening its application process earlier this year. It is estimated that 670,000 people suffer from either TRD, PTSD or both in Australia at any given time and many patients do not respond to traditional treatments for both indications, or experience diminishing efficacy. Psychedelic-assisted therapy has been proved through clinical trials to help a substantial proportion of people who do not respond to traditional treatments.

“This treatment is potentially life-changing for hundreds of thousands of people in Australia and tens of millions globally. We believe that Clarion is at the leading edge of mental healthcare, has the right protocols and an experienced team ready in Australia to help people through these challenging conditions.” Peter Widdows, IHL Director responsible for Clarion Clinics, said.

“Being the first entrants into this field in Australia should position Incannex, via Clarion, at the forefront of psychedelic-assisted therapies and should facilitate the smooth expansion into more clinics nation-wide as we roll out the treatment protocols and business model. We believe that regulations regarding the use of psychedelic-assisted therapies will change in other countries too, following Australia’s lead. Clarion should be well placed to take advantage of this.” Joel Latham, CEO and President of IXHL, said.

END



Date: December 21, 2023
Public Announcement (NASDAQ: IXHL)

About Incannex Healthcare Inc.

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 NASDAQ as 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:

Investor Relations Contact – United States

Alyssa Factor
Edison Group
+1 (860) 573 9637