

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 February 1, 2024

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

On February 1, 2024, Incannex Healthcare Inc. announced that Clarion Clinics has received approval from the Therapeutic Good Administration to prescribe MDMA for the treatment of PTSD and Psilocybin for Treatment- Resistant Depression at the Melbourne Clinic. 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 February 1, 2024.
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.

Incannex Healthcare Inc.

Date: February 1, 2024

/s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and President



Date: February 1, 2024
Public Announcement (NASDAQ: IXHL)

CLARION CLINICS OPEN FOR PSYCHEDELIC-ASSISTED TREATMENTS

Highlights:

- Clarion's Head of Psychiatry, Professor Suresh Sundram, has been approved by the TGA to prescribe MDMA for Post-traumatic Stress Disorder and psilocybin for Treatment-resistant Depression, alongside extensive psychotherapy.
- Clarion Clinics' built-for-purpose clinic in Melbourne is now open for treatment, and will begin screening patients immediately.
- Clarion Clinics represents Australia's leading track record in psychedelic-assisted therapies, and has developed a best-practice model of care that is substantially longer and more tailored than other psychedelic treatment programs, including those within clinical trials.

February 1, 2024 – 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 Clarion Clinic's co-Founder and Head of Psychiatry, Professor Suresh Sundram, has received Authorised Prescriber approval from the Therapeutic Goods Administration (TGA) to prescribe MDMA in the treatment of Post-traumatic Stress Disorder (PTSD) and psilocybin for Treatment-resistant Depression (TRD) at its first built-for-purpose clinic based in Melbourne, Australia, a city of approximately 5.2M people.

The Australian TGA Authorised Prescriber Scheme is designed to provide access to certain drugs that are not on the Australian Register of Therapeutic Goods (ARTG) by specially authorising experienced medical practitioners to prescribe them for certain indications. On July 1, 2023, following promising clinical trial results, the TGA down-scheduled MDMA and psilocybin for use in the treatment of PTSD and TRD respectively. This change in drug classification, from Schedule 9 (prohibited substances) to Schedule 8 (controlled drug) is the first down-scheduling of any psychedelic drug globally, permitting the use of these drugs in clinical service delivery through the Authorised Prescriber Scheme.

Clarion Clinics is a collaboration between Australia's leading psychedelic-assisted therapy professionals and scientists, and Incannex. Clarion Clinics, Abbotsford, will be the first dedicated psychedelic-assisted therapy clinic in Australia. Located on the Yarra riverfront in Abbotsford, Melbourne, the clinic has been positioned, designed, and fitted out specifically to facilitate an optimal environment for psychedelic-assisted therapy.

"This treatment is potentially life-changing for many people in Australia. Clarion is at the leading edge of mental healthcare, has the right protocols, and an experienced team ready to help people through these challenging conditions," Peter Widdows, Incannex Director responsible for Clarion Clinics, said.

Incannex Healthcare Inc.
Level 39, Rialto South Tower, 525 Collins Street, Melbourne VIC 3000
Email: admin@incannex.com.au



Date: February 1, 2024

Public Announcement (NASDAQ: IXHL)

“Our clinical, support, and leadership teams at Clarion represent Australia’s strongest track record in delivering psychedelic-assisted therapies – I’m looking forward to embarking on the next chapter in our field’s development alongside these brilliant, skilled and compassionate professionals who are all focused on supporting the best possible outcomes for people who access this treatment. Our evidence-informed, extended, and patient-centric treatment model has been designed to harness what we know about how these therapies work towards the highest levels of safety and lasting benefits for the people we treat,” said Dr Paul Liknaitzky, Clarion Clinics co-founder,

“I’m grateful to the TGA for their endorsement of my experience and qualifications to deliver this ground-breaking treatment, which clinical trials have shown to be beneficial to a significant number of people who haven’t responded to, or have ceased to respond to, standard treatments. Clarion has been developed to offer a truly patient centric model of care and I look forward to working with a great team, dedicated to helping people with difficult to treat mental health conditions,” Prof. Suresh Sundram, Clarion co-founder and Head of Psychiatry, said.

“Being early entrants into this field in Australia will position Incannex, via Clarion, at the forefront of psychedelic-assisted therapies, and will facilitate the smooth and safe expansion into more clinics nation-wide, as we roll out the treatment protocols and business model. We believe regulations regarding the use of psychedelic-assisted therapies will change in other countries too, following Australia’s lead and as new drugs receive regulatory approval. Clarion will be well placed contribute to and benefit from progressive changes globally.” Joel Latham, CEO and President of IXHL, said.

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

END

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.

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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.

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