
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 May, 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

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 May 16, 2023, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned "Psychennex Pty Ltd – Company Update", 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: May 18, 2023

By: /s/ Joel Latham

Name: Joel Latham

Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.

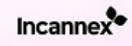
99.1 [ASX Announcement, dated May 16, 2023 – Psychennex Pty Ltd – Company Update](#)

Psychennex Pty Ltd

Company Update

Market Update
May 2023

Psychennex Pty Ltd
A Division of Incannex Healthcare Ltd
(IHL-ASX) (XHL-NASDAQ)



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Summary Information: This document contains a summary of information about Incannex and its activities that is current as at the date of this document. The information in this document is general in nature and does not purport to be complete or to contain all the information which a prospective investor may require in evaluating a possible investment in Incannex or that would be required in a prospectus or a product disclosure statement prepared in accordance with the Corporations Act 2001 (Cth) (Corporations Act). No Liability: The information contained in this document has been prepared in good faith by Incannex, however no guarantee representation or warranty expressed or implied is or will be made by any person (including Incannex and its affiliates and their directors, officers, employees, associates, advisers and agents) as to the accuracy, reliability, correctness, completeness or adequacy of any statements, estimates, opinions, conclusions or other information contained in this document. To the maximum extent permitted by law, Incannex and its affiliates and their directors, officers, employees, associates, advisers and agents each expressly disclaims any and all liability, including, without limitation, any liability arising out of or derived from, or for omissions from, this document including, without limitation, any financial information, any estimates or projections any other financial information derived therefrom. Statements in this document are made only as of the date of this document unless otherwise stated and the information in this document remains subject to change without notice. No responsibility or liability is assumed by Incannex or any of its affiliates for updating. Not Financial Product Advice: This document does not constitute financial product advice or consider your investment objectives, taxation situation, financial situation or needs. This document consists purely of factual information and does not involve or imply a recommendation of a statement of opinion in respect of whether to buy, sell or hold a financial product. An investment in Incannex is considered to be speculative in nature. Before making any investment decision in connection with any acquisition of securities, investors should consult their own legal, tax and/or financial advisers in relation to the information in, and action taken on the basis of, this document.

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Mental unwellness is the defining health crisis of our time. It affects millions of people in many ways. Traditional treatments successfully enable a number of those affected to manage their symptoms but many are left behind, their illness unresponsive to those treatments.

Psychennex Pty Ltd

Psychedelic-assisted psychotherapy offers the hope of sustained improvement to the significant proportion of people for whom traditional treatment has not worked.

Psychennex is pioneering the Australian psychedelics sector via its clinical research programs and its move into service delivery through its Clarion Clinics Group.

Psychennex Pty Ltd

All of IHL's psychedelic assets in one place.

Improving the quality of life for people who suffer debilitating and intractable mental health conditions.

Psychennex Pty Ltd is the holding company for:

• INTELLECTUAL PROPERTY FROM:

PsIGAD Clinical Trials

MOVER License

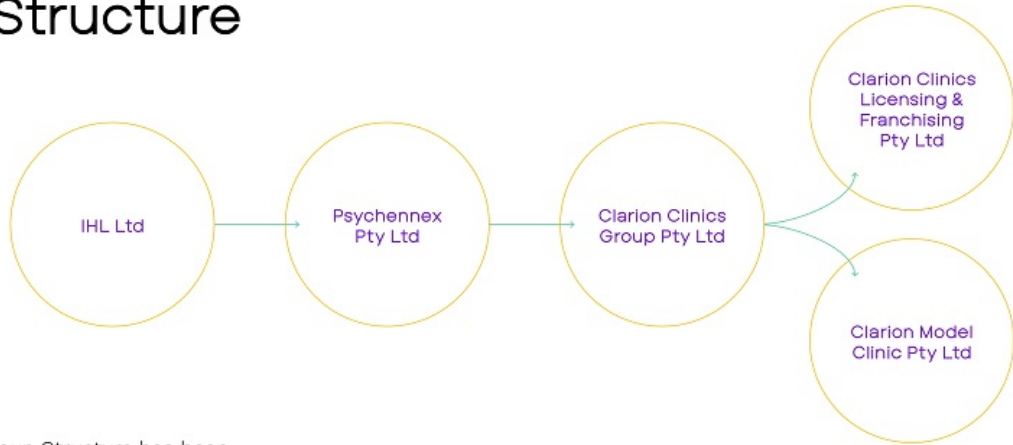
All future psychedelic clinical trails

• PSYCHEDELIC PRODUCT DEVELOPMENT

• DISTRIBUTION CONTRACTS FOR PSYCHEDELIC DRUGS

• PSYCHEDELIC CLINIC SUBSIDIARIES

Psychennex Group Structure



The Psychennex Group Structure has been designed to hold all IHL's psychedelic assets to facilitate coordinated management and potential future exit.

Experienced Business Leadership

Peter Widdows

Peter, a long time IHL director, is leading the Psychennex businesses.

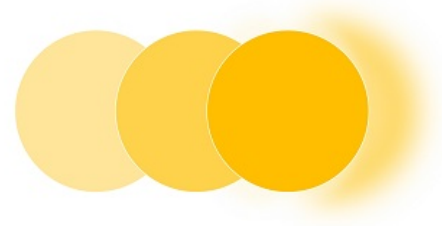
"Being entrusted to deliver something which has the potential to materially improve the health of so many people is a privilege I take stock of everyday. It reinforces my drive to make this venture successful."

30 Years of Senior Business Leadership

- HJ Heinz – CEO covering:
 - Australasia & large part of Asia, 18,500 employees & Multi-billion dollar revenues
- Director: Youi insurance
- Chairman: Sunny Queen Australia
- Extensive international business leadership experience
- Chartered Accountant



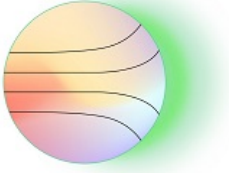
Three Distinct Asset Groups



Multiple Revenue Streams

Strong revenue streams

Within each of its asset platforms are multiple near term revenue stream plans.



PSYCHENEX PTY LTD

STREAM ONE

Intellectual Property from Clinical Trials

- Global licensing fees

STREAM TWO

cGMP Psilocybin

- Sale to IHL Clinics
- Sale to IHL Franchisees & Licensees
- External sale to other clinics

STREAM THREE

Clarion Clinics Group

- Operation and ownership of clinics
- Training of psychotherapists
- Franchising & licensing

Clinical Trials & IP Assets

Potential Market for IP Assets

A\$1.5B

01

PsiGAD

02

Virtual Reality Augmented
Psychedelic-Assisted
Psychotherapy

03

Clinics as Trial Sites

PsiGAD-Phase 2 Clinical Trial

Psychedelic-Assisted Psychotherapy for
Generalised Anxiety Disorder.

Psychennex is completing a phase 2 clinical trial
at the Monash University BrainPark, under the
supervision of Prof. Suresh Sundram, Dr. Paul
Liknaitzky and Prof. Murat Yucel.

01

PsiGAD

55 of 72 Patients completed trial so far – No patients have dropped out

Power analysis of interim results shows strong probability
(85%* with 95% CI) of statistically significant benefit at end of trial

Mid point DSMB reported no safety or trial design concerns

Trial completion due Q4 2023

Virtual Reality (VR)

Psychedelic-Assisted Psychotherapy
Augmented by Virtual Reality.

Psychennex has an exclusive, perpetual, global
license over ground-breaking virtual reality technology
developed at the BrainPark in Monash University.

02

Virtual Reality Augmented Psychedelic-Assisted Psychotherapy

Exclusive global license over immersive virtual reality technology
developed at BrainPark Monash university

To be used in conjunction with psychedelic-assisted psychotherapy
by providing triggering stimuli in a controlled manner

Potential to treat multiple anxiety disorders

Clinical Trial Sites

We will conduct clinical trials as a commercial provider and continue to gather clinical data.

Psychennex clinics will provide clinical trial services where capacity allows on a commercial basis to 3rd parties. It will also continue to collect clinical data from treatments to support efforts in regulatory approval and Medicare approval.

03

Clinics as Trial Sites

Commercial Provider of Clinical Trials

Continued Data Collection from Patients

Health Economics and Clinical Results to Support Regulatory Approval

Ongoing Data Driven Protocol Development

cGMP Psilocybin

SUPPLY TO

Psychennex Licensed
and Franchised

External Clinics

Clinical Trials

SCALING

Manufacturing Agreement

Psychennex has entered a manufacturing agreement with Catalent, which will deliver its own cGMP psilocybin product.

While sales in early years will be modest, they are expected to grow as the treatment becomes more mainstream.

INTRODUCING

CLARION
Clinics

The Clarion Clinics Group

The world's leading Psychedelic-
Assisted Psychotherapy Clinics





The company's move into clinical service delivery is the natural next step in its efforts to reduce the mental health burden society faces. Giving us the capability to treat many more patients than we could in a trial setting.

Own and operate

Established to own and operate a chain of psychedelic-assisted psychotherapy clinics, nationally and internationally.

World class

Partly owned and clinically directed by 3 world class mental health professionals with incomparable experience in Australia.

Rapid expansion

Designed for rapid expansion capability through ownership and license/franchise options.

Effective treatment

Goal to deliver ethical and effective treatment to over 1 million people.



World Class Clinical Leadership

Clinical Experts

Experience with psychedelic drugs in conjunction with psychotherapy is rare in Australia. Psychennex has partnered with Australia's most experienced and able clinical experts in this field, creating a strong competitive advantage.

Dr Paul Liknaitzky

Co-Founder, Director, Chief Strategy and Scientific Officer

Professor Suresh Sundram

Co-Founder, Director and Head Of Psychiatry

Sean O'Carroll

Co-Founder, Director and Head Of Psychotherapy

Dr Paul Liknaitzky



"The safe, useful, and ethical translation of clinical psychedelic research into practice has been at the forefront of my mind for some years, as we conduct trials and learn first-hand about the potential and the complexity of providing psychedelic therapies.

I feel motivated now to contribute to a community-based service where we can draw on our substantial experience in coordinating and delivering this treatment, alongside a wealth of treatment and training resources, and an extensive network of mentors and collaborators from around the world."

Co-Founder, Director, Chief Strategy and Scientific Officer

Paul Liknaitzky is Head of the Clinical Psychedelic Lab at Monash University, and Chief Principal Investigator on a program of psychedelic trials. He is a Senior Research Fellow within both the Dept of Psychiatry and the Turner Institute at Monash University, and earned an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne.

In Australia, Liknaitzky has played a central role in establishing the field of psychedelic research, is an Investigator on several of the country's initial psychedelic trials across multiple institutions, has coordinated a number of psychedelic therapist training and supervision programs, and leads the first clinical psychedelic lab.

He has been invited to deliver numerous academic, professional, and public talks on psychedelic science, and has been interviewed on the topic for television, documentaries, print media, radio, and podcasts.

Liknaitzky supervises a team of over 40 researchers, clinicians and students, co-convenes the Australasian Research Group for Psychedelic Science, and is a member of a number of Scientific Advisory Boards.

He has Adjunct or Honorary appointments at St Vincent's Hospital, the University of Melbourne, Swinburne University, and Deakin University.

His work is focused on a rigorous program of research in clinical psychedelics that seeks to innovate on treatment design, evaluate therapeutic effects, mitigate known risks, explore potential drawbacks, and understand therapeutic mechanisms.

Professor Suresh Sundram



"The down-scheduling of certain psychedelic treatments for certain conditions is an important transition point to establish the utility and role of psychedelic-assisted psychotherapy in mental illness. Providing a custom-tailored environment in order to deliver the best possible therapeutic experience is critical. To enable this, and to evaluate and deliver outcomes, is a rare opportunity."

CLARION CLINICS

Co-Founder, Director and Head Of Psychiatry

Professor Sundram (MBBS, MMed, FRANZCP, PhD) is a psychiatrist and neuroscientist committed to understanding the biological foundations of schizophrenia and related disorders in order to improve the lives of affected patients and families through the development of relevant biomarkers and ultimately disease modifying treatments.

He is Chair and Head, Department of Psychiatry, School of Clinical Sciences, Monash University; Director of Research, Mental Health Program, Monash Health; and Clinical Director, Cabrini Outreach. He is co-Chair of the Monash Partners Neuroscience and Mental Health Theme.

At Monash University and Monash Health, he established and leads the Translational Molecular Psychiatry program with over 25 staff and students which uses a recursive bedside to bench and back philosophy to discover new molecules and genes of relevance to the major psychiatric disorders. Prior to these roles he established and led a molecular laboratory at the Mental Health Research Institute in conjunction with a

clinical research laboratory at the Northern Hospital which transferred to the Florey Institute of Neuroscience and Mental Health where he also was appointed as Head of the Statewide Psychotropic Drug Advisory Service.

Professor Sundram has conducted in excess of 40 phase II, IIIA, IIIB and IV industry sponsored and investigator initiated clinical trials with multiple pharmaceutical companies. Currently, he co-supervises the Clinical Psychedelic Laboratory at Monash University conducting cutting edge clinical research using psychedelic agents in mental disorders.

He has held a number of international roles including: current President-elect, Asian College of Neuropsychopharmacology; expert consultant, United Nations High Commissioner for Refugees; Member, Joint Advisory Committee to the Governments of Australia and Nauru on Nauruan Regional Processing; Co-Chair, Asian Schizophrenia Network; Executive Committee Member and Member, Section on Developing Countries, World Psychiatric Association.

Sean O'Carroll



"There are very few experienced psychedelic-assisted psychotherapists in Australia, and the team we are assembling includes many of the most experienced practitioners in the country. We take this responsibility seriously and are uniquely placed to support the emergence of psychedelic-assisted psychotherapy as a safe and efficacious new treatment modality."

Co-Founder, Director and Head Of Psychotherapy

Sean is the Lead Psychotherapist and Trainer with the Clinical Psychedelics Lab at Monash University. He has conducted training for numerous other psychedelic research teams and individuals, including teams from Swinburne University and Curtin University. He works as a psychedelic-assisted psychotherapy consultant within the industry - both academic and commercial - with an emphasis on psychotherapy training and protocol development.

Sean has a background in academic philosophy, earning his Honours in Philosophy from the University of Western Australia in 2004, before going on to study psychotherapy and experiential therapy. He opened his private psychotherapy practice in Melbourne in 2011, and works as an integrative psychotherapist, trainer, and academic. He is a qualified Dancing Freedom instructor (ecstatic dance), and has a longstanding interest in the use of "non-ordinary states" in healing and ceremony. He completed his Masters by Research in Experiential Therapy in 2017. He completed the MDMA Training Program with MAPS (Multidisciplinary Association for Psychedelic Studies) in 2021.

Sean is the director of the Wild Mind Institute, which he founded in 2014. Through the institute, he has trained hundreds of mental health practitioners in psychedelic-assisted psychotherapy, "bad trip" integration, and eco-psychotherapy. Since 2019, Sean's primary focus has been on supporting the emergence of psychedelic-assisted psychotherapy in Australia as a safe, efficacious, and affordable treatment.

Clarion Clinics Group Pty Ltd

Clarion Clinics Group Pty Ltd is the home of Psychennex's clinics business.



CLARION CLINICS

15.5% owned by its clinical leaders and 84.5% by Psychennex Pty Ltd.

Wholly owns and operates all company owned clinics, except 'model' clinic

Owens 100% of Clarion Clinics Licensing and Franchising Pty Ltd



Leading Edge Treatments

The transfer of psychedelic-assisted psychotherapy from a clinical trial setting to a treatment setting will create commercially scalable treatment protocols and valuable intellectual capital.

01.

MDMA Assisted
Psychotherapy
for PTSD

02.

Psilocybin Assisted
Psychotherapy
for TRD

03.

Psilocybin Assisted
Psychotherapy
for Generalised
Anxiety Disorder
(Post Approval)



Post-traumatic Stress Disorder

Post-traumatic stress disorder (PTSD) is a disorder that develops in some people who have experienced a shocking, scary, or dangerous event.

It is natural to feel afraid during and after a traumatic situation. Fear triggers many split-second changes in the body to help defend against danger or to avoid it.

This "fight-or-flight" response is a typical reaction meant to protect a person from harm. Nearly everyone will experience a range of reactions after trauma, yet most people recover from initial symptoms naturally.

Those who continue to experience problems may be diagnosed with PTSD. People who have PTSD may feel stressed or frightened, even when they are not in danger.

According to the 2007 National Survey of Mental Health and Wellbeing, an estimated 12% of Australians experience PTSD in their life (lifetime prevalence), with women being at almost twice the risk of men (15.7% and 8.6% respectively) (ABS 2008).

According to the 2017-18 National Health Survey, an estimated 1.7% of women and 1.3% of men reported that they had been told by a doctor, nurse, or health professional that they have PTSD (point prevalence estimate) (ABS 2019).

12% of Australians experience PTSD in their lifetime

1.5% of Australians suffer from PTSD at any given time



Treatment Resistant Depression (TRD)

Depression is considered treatment resistant when the patient has failed to respond to two types of intervention.

The Australian Department of Health and Aged Care estimates that, of the 4.1% of the population who suffer from depression, 26.5% experience treatment resistant depression.

Other supporting data studies show similar results:

"Our results suggest that between 29% and 46% of depressed patients fail to respond fully with antidepressant treatment of adequate dose and duration. In particular, although partial response appears to occur in 12% to 15% of the depressed patients studied, nonresponse is observed in 19% to 34% of this population."

"From an epidemiologic point of view, because the prevalence of depression has been estimated to vary from 2.6% to 5.5% in men and from 6.0% to 11.8% in women, one must conclude that treatment-resistant depression is a very common clinical problem that is likely to affect more than one third of depressed patients."

4.1% of Australians suffer from depression

26.5% of them experience TRD

*Fava M, Davidson KG. Definition and epidemiology of treatment-resistant depression

CLARION CLINICS

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Addressable Market

TRD and PTSD are highly prevalent in society, with PTSD affecting 1.5% of the population at any given time and TRD affecting 1.1% of the population.

	Australia	Advanced Nations
Population	26,100,000	1,200,000,000
PTSD		
Lifetime prevalence of PTSD (12%)**	3,132,000	144,000,000
Point Prevalence (1.5%)**	391,500	18,000,000
TRD		
Prevalence of Depression***	10,700,000	49,200,000
Prevalence of TRD (26.5% of above)***	2,835,777	13,038,000
Addressable Market (People)	675,077	31,038,000
Total Addressable Market (\$)	13,501,530,000	620,760,000,000
Psychedelic-Assisted Psychotherapy Penetration		
PTSD****	20%	20%
TRD****	15%	15%
Annual Patient Demand Estimate - PTSD	78,300	3,600,000
Annual Patient Demand Estimate - TRD	42,536	1,955,700
Total Annual Target Market (People)	120,836	5,555,700
Total Annual Target Market (\$)	2,416,729,500	111,114,000,000

*Source: Australian Institute of Health & Welfare (Aus Gov)

**The number of people suffering PTSD at any given time. Source: Australian Institute of Health and Welfare (Aus Gov)

***Source: Australian Gov Department of Health and Aged Care

****Estimate is based on a number of factors: affordability of treatment, willingness to be treated, etc. This percentage will grow significantly as treatment becomes more widely accepted and government funding is available.

Domestic Expansion Plans

Clarion has plans to expand rapidly and help as many patients as possible. However, the market is expected to be under-supplied into the foreseeable future.

	PATIENT CAPACITY					
	2023	2024	2025	2026	2027	2028
Model Clinic	400	600	800	900	980	980
Sydney Clinic		1,500	3,428	3,428	3,428	3,428
Melbourne Clinic		1,000	3,428	3,428	3,428	3,428
Brisbane Clinic			1,500	3,428	3,428	3,428
Sydney 2 Clinic				1,500	3,428	3,428
Perth Clinic				1,000	2,000	2,000
Adelaide Clinic				1,000	2,000	2,000
Gold Coast Clinic				750	1,500	1,500
Canberra Clinic				750	1,500	1,500
Other Regional Clinics					2,000	4,000
Planned Capacity	400	3,000	9,156	15,184	23,692	25,692
Market Size	120,836	123,253	128,183	141,001	155,101	170,611
% of Market Treated by Clarion Group*	0.33%	2.52%	7.14%	11.48%	15.28%	15.06%

*This is not market share as we believe the available capacity will not meet the market for some time, so people who want treatment will go untreated



Helping Provide More Accessible Treatment

Clarion Group is committed to making psychedelic-assisted psychotherapy accessible to everybody who will benefit from it. The group is actively working on numerous patient funding opportunities.

Funding options

Medicare Mental Health Plan and Private Insurance Subsidy.

Work With Medicare and Department of Health for Full Patient Funding.

Veterans and First Responder Associations Funding.

Charitable Contributions.

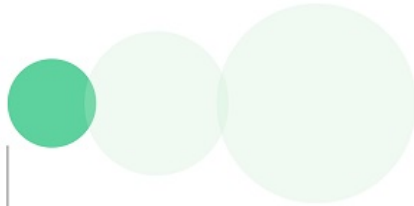
Psychennex Pro-Bono Treatments.



Model Clinic

The first Clarion Clinic will open in Melbourne's inner-north later this year.

The Model clinic will serve as a prototype for the Company's planned rapid roll-out of further clinics. While being a prototype, the clinic will be run at a commercial scale and is a significant business in its own right.



Stage One

CLARION CLINICS

Opening

Q3 2023

Location

Abbotsford Riverfront, Melbourne

Capacity

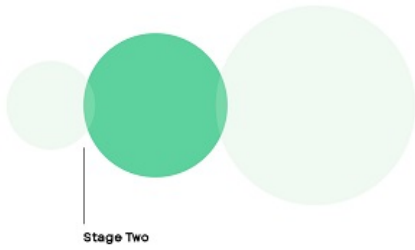
Patient Capacity

- 600 in normal working hours
- 1,000 in extended operating hours



Franchised and Licensed Clinics

At each step, the company will decide whether owning or licensing/franchising the clinics is the better option, based on speed to market, financial returns and management capability.



CLARION CLINICS

Commencing

2024

Existing & New Operators

Target 80+ Clinics

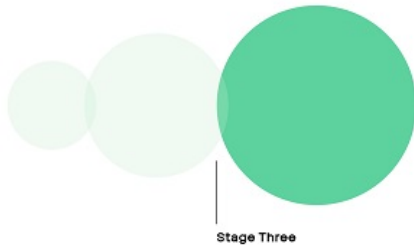
License/Franchise Revenue

Based on a percentage of clinic revenue



International Expansion

International expansion will be dictated by the regulatory and competitive environment of target geographies.



CLARION CLINICS

Seek Licensing and Franchising Partners

All geographies where legislation allows

Open Owned Clinics

Major populations centres where legislation allows

Targets

To be determined as opportunity arises



Competition

A number of providers, motivated by the down-scheduling of MDMA and psilocybin, have said they will enter the market for psychedelic-assisted psychotherapy. We believe that ethical and competent competition will be good for the industry.

It will offer the patients a choice of providers and also help to meet what is expected to be a surplus of demand over capacity for the foreseeable future.

At Clarion Group we believe that we have strong advantages over most other providers in that:

01.

We are clinically led by a world class team of psychedelic-assisted psychotherapy experts, with extensive experience in the application.

02.

We have a team of dedicated therapists who understand and have hands on experience in psychedelic-assisted psychotherapy.

03.

Our services will be solely dedicated to the provision of psychedelic assisted psychotherapy and our knowledge in this specific treatment.



Exit Options

IHL will continually evaluate its options regarding the exit of Psychennex Pty Ltd based on what is most beneficial to IHL shareholders.



Investor & Media Enquiries

For investor related enquiries please contact:

Peter Widdows

peterwiddows@clarionclinics.com

Market Update
May 2023

Psychennex Pty Ltd
A Division of Incannex Healthcare Ltd
(IHL-ASX) (IXHL-NASDAQ)

Incannex 