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 3, 2023, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “IHL-675A Phase 1 Results Presentation”, 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 3, 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 3, 2023 – IHL-675A Phase 1 Results Presentation

Incannex

IHL-675A

Phase 1 clinical trial to assess safety and pharmacokinetics as a potential anti-inflammatory drug candidate

ASX Ticker: IHL | NASDAQ Ticker: IXHL

Disclosure and Disclaimer

Not an offer of Securities This document has been independently prepared by Incannex Healthcare Limited (Incannex) and is provided for informational purposes only. This document does not constitute or contain an offer, invitation, solicitation or recommendation with respect to the purchase or sale of any security in Incannex. This document does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in any jurisdiction (in particular, the United States), or a securities recommendation. This document is not a prospectus, product disclosure statement or other offering document under Australian law or any other law, and will not be lodged with the ASIC. 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, options, 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 fault or negligence, for any loss arising from the use of or reliance on information contained in this document including representations or warranties or in relation to the accuracy or completeness of the information, statements, opinions, forecasts, reports or other matters, express or implied, contained in, arising out of or derived from, or for omissions from, this document including, without limitation, any financial information, any estimates or projections and 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 it constitute financial product advice or take into account 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. Information in this Document is Confidential This document and the information contained within it are strictly confidential and are intended for the exclusive benefit of the persons to whom it is given. It may not be reproduced, disseminated, quoted or referred to, in whole or in part, without the express consent of Incannex. By receiving this document, you agree to keep the information confidential, not to disclose any of the information contained in this document to any other person and not to copy, use, publish, record or reproduce the information in this document without the prior written consent of Incannex, which may be withheld in its absolute discretion. Acceptance By attending an investor presentation or briefing, or accepting, accessing or reviewing this document you acknowledge and agree to the "Disclaimer" as set any information in this document or to inform any recipient of any new or more accurate information or any errors or mis-descriptions of which Incannex and any of its affiliates or advisers may become aware. Forward Looking Statements Certain information in this document refers to the intentions of Incannex, but these are not intended to be forecasts, forward looking statements or statements about the future matters for the purposes of the Corporations Act or any other applicable law. The occurrence of the events in the future are subject to risk, uncertainties and other actions that may cause Incannex's actual results, performance or achievements to differ from those referred to in this document. Accordingly Incannex and its affiliates and their directors, officers, employees and agents do not give any assurance or guarantee that the occurrence of these events referred to in the document will actually occur as contemplated. Statements contained in this document, including but not limited to those regarding the possible or assumed future costs, performance, dividends, returns, revenue, exchange rates, potential growth of Incannex, industry growth or other projections and any estimated company earnings are or may be forward looking statements. Forward-looking statements can generally be identified by the use of words such as 'project', 'foresee', 'plan', 'expect', 'aim', 'intend', 'anticipate', 'believe', 'estimate', 'may', 'should', 'will' or similar expressions. These statements relate to future events and expectations and as such involve known and unknown risks and significant uncertainties, many of which are outside the control of Incannex. Actual results, performance, actions and developments of Incannex may differ materially from those expressed or implied by the forward-looking statements in this document. Such forward-looking statements speak only as of the date of this document. There can be no assurance that actual outcomes will not differ materially from these statements. To the maximum extent permitted by law, Incannex and any of its affiliates and their directors, officers, employees, agents, associates and advisers: • disclaim any obligations or undertaking to release any updates or revisions to the information to reflect any change in expectations or assumptions; • do not make any representation or warranty, express or implied, as to the accuracy, reliability or completeness of the information in this document, or likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement; and • disclaim all responsibility and liability for these forward- looking statements (including, without limitation, liability for negligence).

Results Summary

IHL-675A Phase 1 clinical trial

The 36 patient clinical trial demonstrates IHL-675A to be well tolerated, with no serious adverse events of concern.

About

IHL-675A

IHL-675A is a cannabinoid combination drug comprising hydroxychloroquine sulphate ('HCQ') and cannabidiol ('CBD').

HCQ is a disease-modifying anti-rheumatic drug (DMARD) that works by calming a person's immune system.

CBD is a non-psychoactive phytocannabinoid derived from the cannabis plant, associated with anti-inflammatory and analgesic activity.

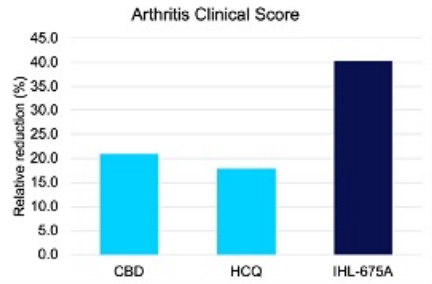
Incannex has demonstrated that IHL-675A components, HCQ and CBD act synergistically to inhibit production of inflammatory cytokines and reduce disease severity in animal models of:

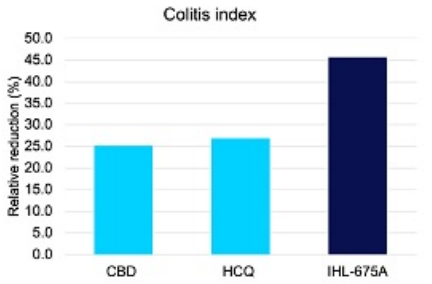
- Rheumatoid arthritis
- Inflammatory lung conditions
- Inflammatory bowel diseases

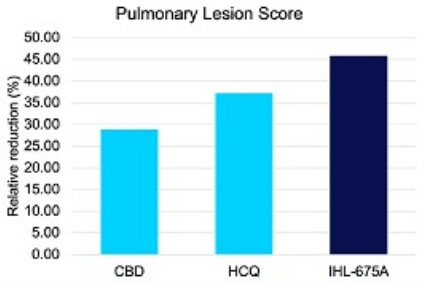
Performance Results

IHL-675A
Reducing disease severity in animal models

IHL-675A outperformed HCQ and CBD administered alone at reducing inflammatory disease scores – a strong efficacy signal demanding clinical assessment.







Clinical development

IHL-675A

- Animal disease model results were a major commercial signal: targeting the disruption of incumbent multi-billion dollar markets for diseases of inflammation.
- The addressable target markets exceed $125B per annum globally and include rheumatoid arthritis, COPD, asthma, bronchitis, colitis and Crohn's disease.
- IHL-675A Phase 2 clinical trial launched for patients with rheumatoid arthritis.
- Phase 2 trials for inflammatory lung conditions and inflammatory bowel disease are currently in planning.

Addressable Market

A$125B

per annum globally

Including; Rheumatoid arthritis, COPD, Asthma, Bronchitis, Colitis and Crohn's disease

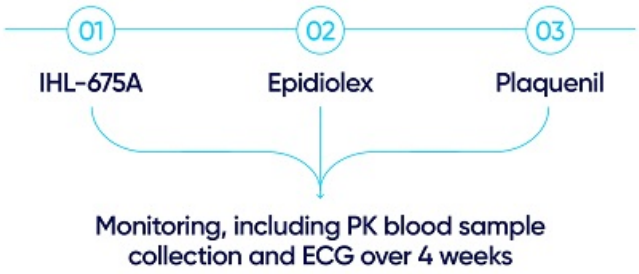
Phase 1 clinical trial

IHL-675A
First assessment in humans

Aim

To assess the safety, tolerability and pharmacokinetics of IHL-675A compared to reference listed drugs for CBD and HCQ, marketed as Epidiolex and Plaquenil respectively, in healthy volunteers.

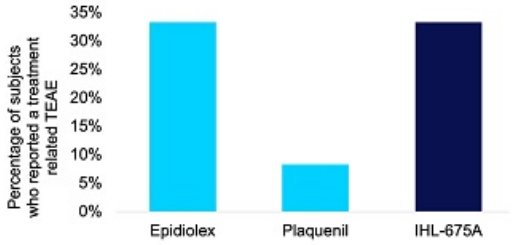
Three-armed study with twelve patients per arm



Monitoring, including PK blood sample collection and ECG over 4 weeks

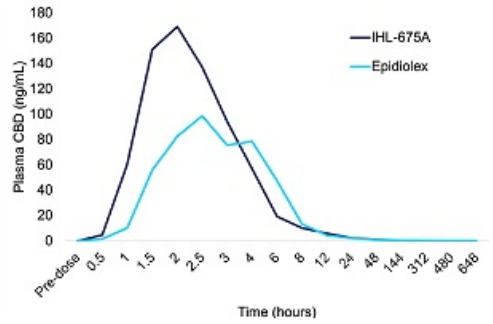
IHL-675A ⟶
Safety/tolerability results

- No adverse events of concern.
- Adverse events were consistent with public reports for Epidiolex and Plaquenil.
- Treatment-related treatment emergent adverse events (TEAEs) included abdominal pain, dizziness, fatigue, frequent bowel movements, headache and somnolence.
- The number of TEAEs for IHL-675A was the same as Epidiolex.
- All TEAEs were mild in severity with the exception of one incident of abdominal cramps of moderate severity in the IHL-675A group, which resolved soon after onset.
- No cardiac related TEAEs were reported.



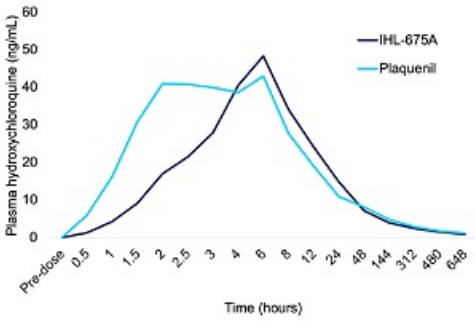
Pharmacokinetics: CBD ⟶

- Compared to Epidiolex, CBD dosed in IHL-675A:
  - Reached a greater maximum concentration (C_{max}), 1.57 times higher
  - Was taken up more rapidly (T_{max}), 26 % faster
  - Was cleared more quickly ($T_{1/2}$), 13 % faster
  - Had a similar level of total exposure (AUC_{inf})
- These differences are only trends at this point (p>0.05).
- Similar patterns were observed for major CBD metabolites 7-COOH-CBD and 7-OH-CBD.



Pharmacokinetics: HCQ ⟶

- Compared to Plaquenil, HCQ from IHL-675A was:
  - Taken up more slowly (T_{max}), 46% slower
  - Reached a similar maximum concentration (C_{max})
  - Had a similar rate of clearance ($T_{1/2}$)
  - Had a similar total exposure (AUC_{inf})
- These differences are only trends at this point (p>0.05).
- Only low (average < 2 ng/mL) concentrations of HCQ metabolites desethylhydroxychloroquine, bisdesethylhydroxychloroquine and desethylchloroquine were detected at all points in the study.



Conclusions

01.
IHL-675A is well tolerated in healthy volunteers.

02.
Adverse events for IHL-675A were consistent with what was observed, and has been publicly reported for Epidiolex and Plaquenil.

03.
Both active pharmaceutical ingredients, CBD and HCQ, are absorbed from IHL-675A.

04.
Trends in PK profiles indicate that the uptake of CBD may be more rapid for IHL-675A than Epidiolex and the uptake of HCQ may be slower for IHL-675A than Plaquenil.

05.
This could be advantageous for IHL-675A. CBD provides immediate relief for inflammation and pain whereas HCQ is a slower acting molecule and provides extended relief.

Next Steps

Phase 2 Clinical Trials

01 **Commencement**

Incannex has commenced a phase 2, blinded, placebo controlled clinical trial to determine the safety and effect on pain and function of IHL-675A in patients with rheumatoid arthritis.

02 **Engagement**

The trial is engaging up to 10 trial sites and recruiting 120 patients in total.

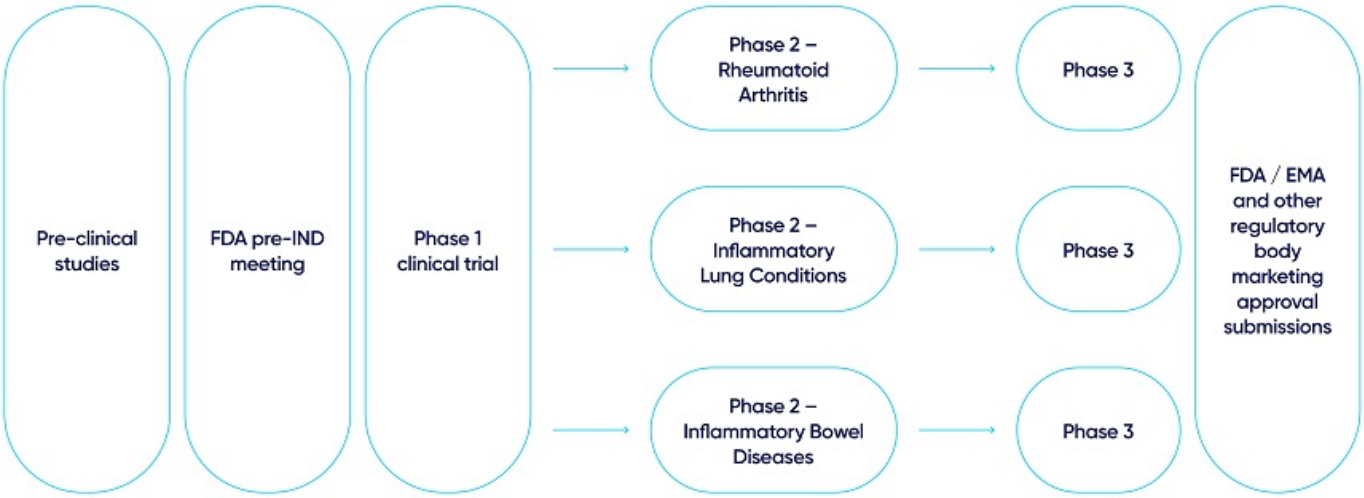
03 **Planning**

Planning of Phase 2 studies in patients with inflammatory bowel disease and lung inflammation is underway.

04 **Treatment**

The treatment of these three indications has a combined global addressable annual market size exceeding US$125B per annum.

Clinical and Regulatory Progression



CBD and metabolite PK results

		IHL-675A				Epidiolex			
		C_{max}	T_{max}	AUC_{inf}	$T_{1/2}$	C_{max}	T_{max}	AUC_{inf}	$T_{1/2}$
		(ng/mL)	(hr)	(hr*ng/mL)	(hr)	(ng/mL)	(hr)	(hr*ng/mL)	(hr)
CBD	Mean	207.04	2.13	841.08	220.17	131.89	2.88	725.9	231.22
	SD	117.44	0.91	358.63	53.85	61.92	1.21	223.98	56.45
	Min	72.6	1.02	391	113.84	45.6	1.5	355	144.41
	Max	472	4	1699	301.17	241	6	1121	305.88
7-OH-CBD	Mean	55.24	2.17	389.18	40.54	21.06	3	262.27	21.15
	SD	34.58	0.94	214.49	52.79	9.15	1.22	103.95	10.05
	Min	14.9	1.02	220	10.78	7.7	1.5	149	10.54
	Max	116	4	950	202.58	38.4	6	448	49.36
7-COOH-CBD	Mean	479.75	2.83	18753.9	167.87	362.17	4.97	16268	153.68
	SD	218.74	1.2	8979.02	95.47	299.63	1.3	11069.2	92.41
	Min	209	1.5	11445	46.03	116	2.5	4475	18.47
	Max	921	6	43714	332.65	1180	6.05	42018	317.68

HCQ and metabolite PK results

NA - metabolite not detected at levels sufficient to calculate PK parameter

		IHL-675A				Epidiolex			
		C_{max}	T_{max}	AUC_{inf}	$T_{1/2}$	C_{max}	T_{max}	AUC_{inf}	$T_{1/2}$
		(ng/mL)	(hr)	(hr*ng/mL)	(hr)	(ng/mL)	(hr)	(hr*ng/mL)	(hr)
HCQ	Mean	54.71	5.59	2986	182.62	55.52	3.46	3430.8	251.6
	SD	23.85	2.51	1244.46	93.7	24.81	1.94	1104.38	73.65
	Min	22	2	800	35.68	26.1	1	2073	163.92
	Max	105	12.03	4217	311.57	124	6	5888	421.51
DESETHYL-HYDROXY-CHLOROQUINE	Mean	1.38	81.08	NA	NA	1.29	17.46	NA	NA
	SD	1.24	183.01	NA	NA	1.04	35.04	NA	NA
	Min	0	0	0	0	0	0	0	0
	Max	4.4	673.83	0	0	3.3	123.93	0	0
THYL-CHLOROQUINE	Mean	0.8	7.77	NA	NA	0.42	5.59	NA	NA
	SD	0.72	13.03	NA	NA	0.84	13.58	NA	NA
	Min	0	0	0	0	0	0	0	0
	Max	2	49.05	0	0	2.9	49.07	0	0
BISDESETHYL-HYDROXY-CHLOROQUINE	Mean	0	0	NA	NA	0	0	NA	NA
	SD	0	0	NA	NA	0	0	NA	NA
	Min	0	0	0	0	0	0	0	0
	Max	0	0	0	0	0	0	0	0

Incannex

incannex.com.au

Media Enquiries

For media related enquiries please contact:

Joel Latham
joel@incannex.com.au

Investor Enquiries

For investor related enquiries please contact:

Brad Dilkes
investors@incannex.com.au

Partnership Enquiries

For partnership related enquiries please contact:

admin@incannex.com.au