EDISON

# Incannex Healthcare

## Positive Phase I data for IHL-675A

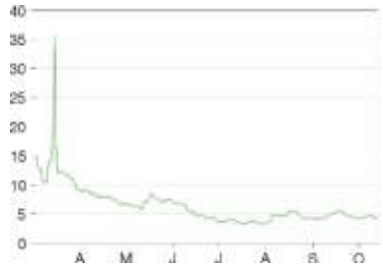
Regulatory update

Pharma and biotech

**14 October 2022**

| | |
|---|---|
| **Price** | **US$4.58** |
| **Market cap** | **US$237m** |
| | ADR/Ord conversion ratio 1:25 |
| Net cash (US$m) at end Q422 | 26.1 |
| ADRs in issue | 60.9m |
| ADR code | IXHL |
| ADR exchange | NASDAQ-GM |
| Underlying exchange | ASX |
| Depository | DBK |

**Share price performance**




**Incannex has announced encouraging safety data from the Australian Phase I trial for its anti-inflammatory drug IHL-675A, having successfully completed patient dosing. The study found that IHL-675A cannabinoid combination therapy (cannabidiol (CBD) and hydroxychloroquine (HCQ)) was well tolerated in healthy volunteers with no serious adverse events reported. Following these positive results, Incannex will continue to progress the development of IHL-675A and is now gearing towards the initiation of a Phase II study, initially focusing on rheumatoid arthritis patients. HCQ (Plaquenil) has already received FDA approval for the treatment of rheumatoid arthritis as a monotherapy, so we view management's decision to prioritise development in this indication as a sensible clinical strategy. Additionally, global sales of rheumatoid arthritis drugs reached c US$30bn (source: EvaluatePharma) in 2021, highlighting the potential opportunity in this target market. We value Incannex at US$714.7m or US$11.74 per ADR.**

| Year end | Revenue (A$m) | PBT* (A$m) | EPS* (c) | DPS (c) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 06/21 | 2.0 | (8.2) | (0.83) | 0.0 | N/A | N/A |
| 06/22 | 0.8 | (14.9) | (1.25) | 0.0 | N/A | N/A |
| 06/23e | 0.0 | (20.6) | (1.38) | 0.0 | N/A | N/A |
| 06/24e | 0.0 | (33.4) | (2.24) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

As a reminder, IHL-675A is a combinational regime being investigated for the treatment of three major indications: rheumatoid arthritis, inflammatory bowel disease and lung inflammation, having previously demonstrated anti-inflammatory activity in preclinical studies. The Phase I trial began patient enrolment in August, recruiting three patient cohorts (n=12 per cohort), with each group being treated with either IHL-675A, CBD or HCQ. Patients will continue to be monitored until the end of October 2022. However, to date, no serious adverse events have been recorded from each of the study arms.

With these results, management intends to open a pre-investigational new drug (IND) meeting with the FDA to discuss the clinical development of IHL-675A. Details of the follow-on Phase II Australian study will be announced following trial commencement. However, the trial will look to recruit up to 100 participants and, in parallel, Incannex intends to open an IND that will allow the initiation of FDA-regulated studies in rheumatoid arthritis. In our view, positive data from the Phase II study will significantly support the application of future FDA trials. The company has also commenced planning for Australian Phase II trials in inflammatory bowel disease and lung inflammation.

This latest announcement marks what has been a period of positive newsflow for Incannex, which has recently released details of a successful pre-IND FDA meeting for its preclinical asset IHL-216A, to treat traumatic brain injury, which we anticipate is nearing entry into the clinic.

**Business description**

Incannex Healthcare is an Australian dual-listed biotech company focused on developing medicinal cannabis pharmaceutical products and psychedelic medicine therapies. These therapies are being designed to target indications with unmet need, including obstructive sleep apnea, generalized anxiety disorder, trauma and inflammatory conditions.

**Analysts**

Soo Romanoff +44 (0)20 3077 5700

Dr Adam McCarter +44 (0)20 3077 5700

healthcare@edisongroup.com

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia