INVEX THERAPEUTICS LIMITED

ASX:IXC

FACT SHEET - January 2023

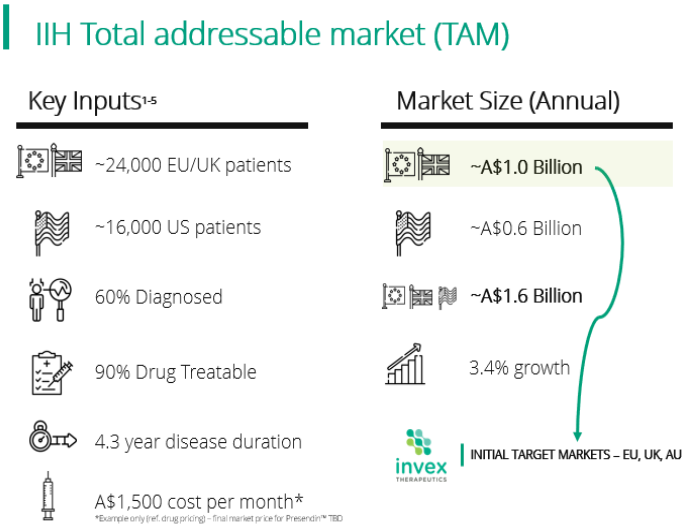
www.invextherapeutics.com

ABOUT INVEX

Invex Therapeutics (Invex) is an Australian Securities Exchange (ASX)-listed biopharmaceutical company focused on the repurposing of an already approved drug, Exenatide, for efficacious treatment of neurological conditions derived from or involving raised intracranial pressure. Our primary focus is on the orphan disease Idiopathic Intracranial Hypertension (IIH), a large and growing market opportunity with no regulatory cleared treatments to date. Invex has trademarked its repurposed Exenatide as Presendin™. Other potential treatable conditions include IIH without papilloedema (IIH-WOP) and other pressure-related conditions.

IIH – A LARGE & GROWING MARKET OPPORTUNITY

IIH is a condition that results pressure inside the brain increasing as a direct result of the increased accumulation of cerebral spinal fluid (CSF), causing vision problems, headaches and other symptoms. 90% of IIH cases are overweight women of childbearing age, with no known cause (idiopathic). Based on published data, the growth in incidence per annum is growing rapidly, commensurate with higher rates of obesity and is expected to show long term annual growth of 3.4%. Invex estimates the annual incidence of IIH in the European Union (EU) and USA to be ~40,000 per annum (60%/40% split). Of those 60% receive a diagnosis and 90% receive treatment for their condition. The annual market is estimated to be worth **A$1.6 billion** for a 1x per day re-formulated Exenatide, chronically administered.



PRESENDIN™ & PEPTRON AGREEMENT

Prof. Alex Sinclair (Invex CSO & Exec. Director) was the first to demonstrate glucagon like peptide 1 (GLP-1) receptor agonists commonly used in diabetes treatment (Exenatide formulated as Byetta® or Bydureon®) act on the choroid plexus in the brain to lower cerebral spinal fluid secretion and consequently, ICP. Exenatide has a well-defined mechanism of action, with Invex securing patents beyond 2035 for use of drugs such as Exenatide to treat pressure related disorders of the brain and patent applications relating to improved formulations, trademarked by Invex as Presendin™.

In September 2021, Invex announced an Exclusive Collaboration, Manufacturing and Supply agreement with Peptron, Inc based in Daejeon, South Korea (KOSDAQ: KS:087010) for a sustained release (SR) formulation of Presendin™ in a biodegradable poly(lactic-co-glycolic acid) microsphere (PLGA). This 1x per week, sub cutaneous formulation has undergone numerous pre-clinical and clinical studies. The agreement is anticipated to save Invex $3M and 12 months of planned lead-in activities (tolerability, human pharmacokinetic studies) ahead of a Phase III trial. Invex can utilise Peptron's extensive preclinical and clinical data package for its own global regulatory submissions. Peptron will provide Presendin™ at a fixed cost per dose for clinical and commercial supply to Invex for IIH. No royalties are payable.

The deal offers significant revenue potential for both Invex and Peptron upon regulatory approvals and numerous benefits to patients, including more convenient dosing and handling.

SNAPSHOT

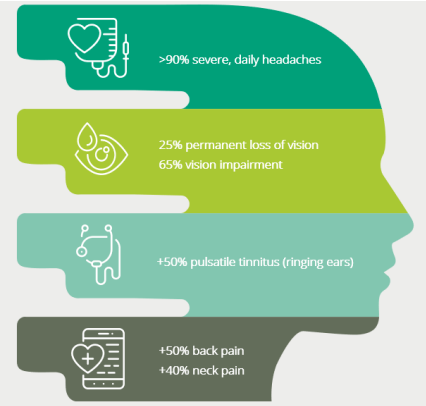
ASX Ticker	IXC
GICS Code	3520
Sector	Pharmaceuticals
Share Price as at 24 January 2023	$0.595
52 Week High/Low	$0.75 / $0.435
Market Capitalisation	$44.7M
Cash (as at 31 December 2022)	$25.4M
Enterprise Value	$19.3M
Top 20 Shareholders	58%
Analyst Coverage	Chris Kallos, MST

ORPHAN DRUG DESIGNATIONS IN THE US & EUROPE

Invex has secured orphan drug designation for Exenatide in both the USA and Europe, which provides a number of advantages shown, including premium pricing, expedited clinical development pathways and regulatory review.

A SIGNIFICANT & COSTLY BURDEN OF ILLNESS

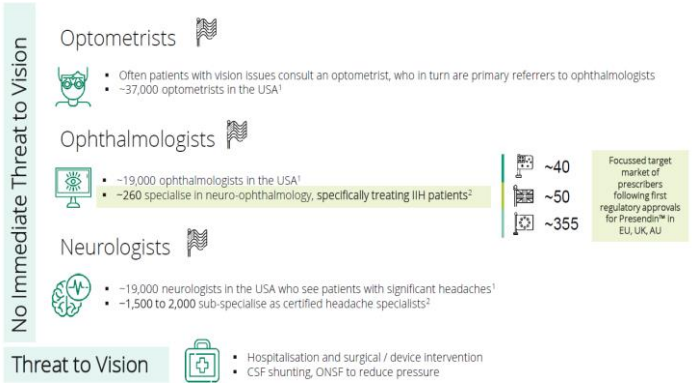
IIH is a rapidly growing orphan indication driven by changing demographics, with incidence CAGR of 5.2% 2002-2016. By 2030 IIH is projected to cost hospitals in England alone +£400m p.a, with a similar trend in USA. A key cost driver is an estimated 40% of IIH patients have repeat hospital admissions and an average length of stay being 2.7 days. >90% of patients suffer headaches that are progressively more severe and frequent: major cause of morbidity and up to 25% suffer permanent vision loss due to the elevated intracranial pressure (ICP) effect on optic nerve function.



NO REGULATORY CLEARED THERAPIES

Despite a large and growing market opportunity, there are currently no approved drug therapies utilized in the treatment of IIH. Importantly, diagnostic criteria for IIH and treatment guidelines are now well-defined. Consensus guidelines co-authored by Prof. Sinclair highlight the urgent need for new therapeutic agents, with current methods of treating more severe cases reliant on medical device/surgical interventions with high failure rates and poor outcomes.

Accordingly, the IIH market is considered an unencumbered drug therapy market with no new treatments in clinical trials except for Invex's Exenatide clinical development. Specialist doctors who treat IIH patients or identify potential cases, is well established.



STRONG AND SUPPPORTIVE PHASE II DATA

In May 2020, Invex released strong Phase II trial results. The design was a double blind, placebo-controlled trial of 16 IIH patients randomised 1:1 to placebo or Exenatide over 12 weeks.

The efficacy results were impressive.

Primary Endpoint (reduction in ICP) Met – 18-21% reduction across three-time points; statistically significant and clinically meaningful.

Secondary Endpoint (Headache) Met – statistically significant & clinically meaningful reduction in headache days (37%/.7.7 day reduction p/m).

Secondary Endpoint (Vision) Met – statistically significant & clinically meaningful improvement in visual acuity (1 line of vision).

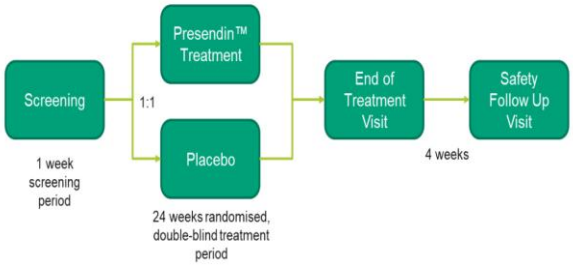
The strength of the outcomes for both primary & key secondary clinical endpoints from the Phase II study implied a clear & strong drug effect in the IIH population & supported progression to a registration-directed single Phase III clinical trial in Europe, Australia, Israel and New Zealand during 2022, with centre participation in the USA under an FDA IND.

REGULATORY/CLINICAL STRATEGY & PHASE III DESIGN

Invex's regulatory and clinical strategy was completed in Q4 2021. A single Phase III clinical trial (IIH EVOLVE) has been designed to meet the requirements for market approval of Presendin™ for the treatment of IIH in the EU, UK and Australia. The trial plans to enrol 240 newly diagnosed IIH patients who will be randomised to receive either once weekly sub-cutaneous injections of Presendin™ or placebo across 40 centres in Europe, UK, Australia, New Zealand, Israel and the USA.

The primary endpoint of IIH EVOLVE will assess the mean difference in Intracranial Pressure (ICP) from baseline at 24 weeks between patients receiving Presendin™ and those on placebo. Secondary endpoints will assess the relative difference in vision (Perimetric Mean Deviation (PMD) and papilloedema) and Monthly Headache Days (MHD) between the two groups over 24 weeks.

Outcomes from IIH EVOLVE clinical trial is expected to facilitate future discussions with the FDA regarding registration of Presendin™ in the US in the future. Recruitment is expected to take 24 months. Invex has received UK MHRA/ethics approval, Australian HREC/TGA approval and US FDA IND approval, allowing Invex to now commence recruitment in these countries.



SIGNIFICANT MILESTONES IN 2022-2023

EVENT	TIMING
Regulatory Approvals (UK, AU, USA, NZ)	**Complete**
Paediatric Investigation Plan (PIP) Approval	**Complete**
First Clinical Sites Activated (UK, AU)	**Complete**
Phase III (First Patient Dosed)	**Complete**
Regulatory Approvals for IIH EVOLVE (EU, IL)	1H CY2023

Based on ASX-listed comparable companies either re-purposing approved therapies, developing orphan drugs or developing therapies within the ophthalmology sector, or Phase III drug therapy assets, Invex's market capitalisation and enterprise value is significantly discounted relative to these peers.

BOARD OF DIRECTORS

Chairman	Dr. Jason Loveridge
Executive Director & CSO	Prof. Alexandra Sinclair
Executive Director	Dr. Tom Duthy
Non-Executive Director	Dr. Megan Baldwin
Non-Executive Director	David McAuliffe

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