INVEX THERAPEUTICS LIMITED

ASX:IXC

FACT SHEET - SEPTEMBER 2021

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.

21,500 treatable patients
A$1.6bn annual market
EU & USA

3.4%	Estimated growth in incidence per annum
55,000	Estimated annual incidence in 2030
>A$2.3bn	Implied TAM in 2030

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 20 Sept	$0.625
52 Week High/Low	$1.08 / $0.51
Market Capitalisation	$51.5M
Cash (as at 31 Dec 2020)	$32.7M
Enterprise Value	$18.8M
Top 20 Shareholders	58%

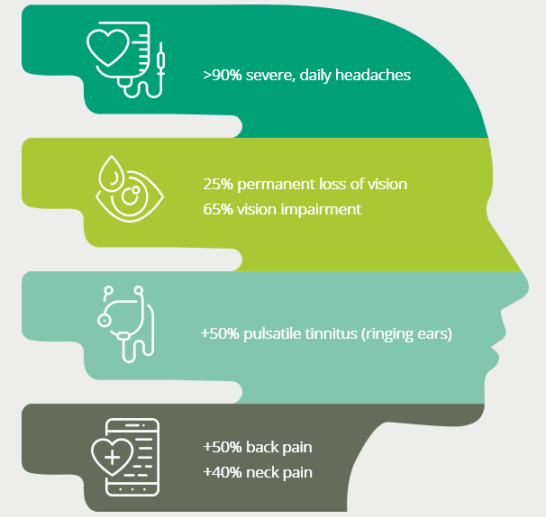
ORPHAN DRUG DESIGNATIONS IN THE US & EUROPE

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.

- Orphan Drug Designation granted in 2017 by EMA (EU) & FDA (USA)
- Single pivotal Phase III registration study required for approval
- 7 years (USA) & 10 years (EU) marketing exclusivity
- Price premium for orphan drugs, greater market access (reimbursement)
- Tax incentives, filing fee waivers & greater regulator access

A SIGNIFICANT & COSTLY BURDEN OF ILLNESS

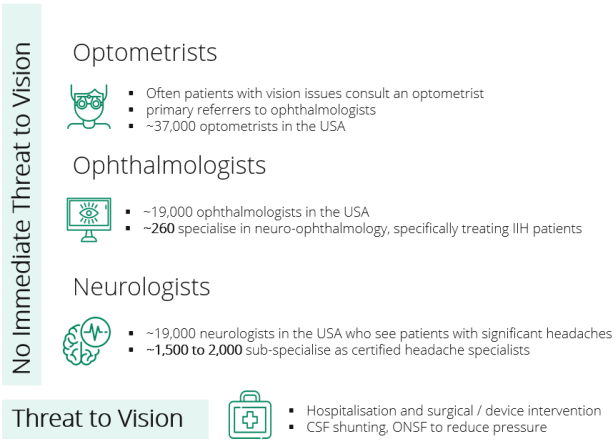
IIH is a rapidly growing orphan indication driven by changing demographics, with incidence CAGR of 5.2% 2002-2016. By 2030 IIH is projected to cost hospitals in England alone +£400m p.a, with a similar trend in USA. A key cost driver is an estimated 40% of IIH patients have repeat hospital admissions 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 purpose of the trial was to obtain first clinical proof of concept for Exenatide in IIH and provide a basis to move into a pivotal Phase III trial by leveraging Invex's orphan drug status in Europe and the United States. 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).

There were no serious adverse events (SAEs) were observed related to the use of Exenatide and overall adverse events (AEs) were relatively low, with nausea the most common seen in >85% of patients treated with Exenatide. This is a known and the most frequent AE of sub-cutaneous administration of Exenatide.

The strength of the outcomes for both primary & key secondary clinical endpoints from the Phase II study implies a clear & strong drug effect in the IIH population & supports progression to a Phase III clinical trial for registration in the USA and Europe.

REGULATORY FEEDBACK AND PHASE III TRIAL DESIGN

In December 2020, Invex concluded its protocol assistance process with the European Medicines Agency (EMA). Invex now has sufficient regulatory input to complete the design of a single Phase III trial to support market approval for Presendin™ in Europe (worth approx. A$1Bn per annum), subject to meeting safety and efficacy requirements.

Further to the FDA response on the proposed Phase III design received in June 2021, and based on expert feedback, Invex continues to investigate and define its regulatory strategy for IIH and Presendin™. The outcome of reviews & Company registration strategy for Presendin™ is expected to be completed in early Q4 CY2021. Commencement of a single-Phase III trial for registration of Presendin™ in 1H CY2022 remains the objective.

SIGNIFICANT MILESTONES IN 2021/2

EVENT	TIMING
Selection of Preferred Formulation Presendin™	**Complete**
Manufacturing Appointment	**Complete**
File with authorities to Commence Phase III	1H CY2022
Phase III Commencement	1H CY2022

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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