Invex Therapeutics

Investor Presentation

Dr Tom Duthy, Executive Director

July 2022

ASX Code: IXC

invex
THERAPEUTICS

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Company Snapshot

Company	
Repurposed, Proven Drug	Presendin™ (SR-Exenatide)
Clinical Stage	Phase III (Single Trial)
Orphan Disease Focus	Idiopathic Intracranial Hypertension (IIH)
Orphan Designation Granted	USA + EU/UK
Total Addressable Market	$1.6 billion annually (USA/EU/UK)
Valuation Drivers	Clinical, regulatory, patent

Capital	
Shares on Issue	75.2 million
Unlisted Options	4.6 million
Ave. Quarterly Cash Burn (12 mth trailing)	$0.85 million
Cash (30 June-22)	$29.3 million
Market Capitalisation (8 Jul-22) [1]	$37.6 million
Enterprise Value (8 Jul-22)	$8.3 million

[1]Based on a closing price of $0.70

Major Shareholders (as at 1 July 2022)	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
Anthony Grist	4.0%
JK Nominees Pty Ltd	4.0%
University of Birmingham	2.7%
Top 20 Shareholders	58.3%

Board of Directors	
Dr Jason Loveridge	Chairman
Professor Alexandra Sinclair	Executive Director & Chief Scientific Officer
Dr Tom Duthy	Executive Director
Mr David McAuliffe	Non-Executive Director
Dr Megan Baldwin	Non-Executive Director

Invex Therapeutics - Executive Summary

Late-stage drug development Company targeting the orphan disease Idiopathic Intracranial Hypertension (IIH)

Attractive Market Dynamics

- IIH Total Addressable Market (TAM) in the US and EU/UK of **A$1.6 billion** per annum (**~A$1 billion** EU/UK, **~A$0.6 billion** US) and growing at **3.4% per annum**
- Unencumbered drug therapy market – no approved treatments, no new treatments in clinical trials
- Urgent market need, chronic administration required

Supportive Clinical Data

- Strong Phase II clinical data - clear statistical and clinical evidence of efficacy in primary and secondary endpoints demonstrating a strong and sustained drug effect in the IIH population
- No significant safety concerns over 12 weeks of treatment
- Single Phase III clinical trial targeting registration of Presendin™ (sustained-release Exenatide) in the EU, UK and Australia

Significant Barriers to Competition

- Orphan drug designation in US (7 years exclusivity) and Europe (10 years exclusivity)
- Issued patents for use of Exenatide in IIH in US, EU and Japan out to beyond 2035

What is Idiopathic Intracranial Hypertension (IIH)?

The Disease[1]

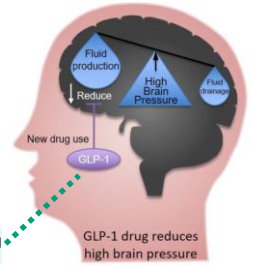
- Dysregulation of cerebral spinal fluid secretion in the brain, leading to increased intracranial (brain) pressure (ICP)
- >90% of cases are overweight women of childbearing age, with no known cause (idiopathic): approx. 4.7 per 100,000
- >90% suffer headaches that are progressively more severe and frequent: major cause of morbidity
- Up to 25% suffer permanent vision loss due to elevated ICP effect on optic nerve function

The Impact[2]

- Invasive surgical and/or device interventions to temporarily lower ICP and preserve vision (significant side effects)
- 40% of patients have repeat hospital admissions, with average stays of 2.7 days
- Significant impact on quality of life and rapidly rising healthcare costs e.g., £462M in UK by 2030 (**5x increase on 2017**)

The Solution

- **Exenatide:** a well know GLP-1 receptor agonist: link to IIH established by Prof. Sinclair
  - Strong scientific basis for benefit
  - Well defined mechanism of action
  - Patents secured: re-purposing opportunity (from T2 diabetes) to improve safety & efficacy → **Presendin™**
- Invex Phase II Pressure Trial in IIH: first clear demonstration of safety & efficacy in IIH with Exenatide



1. Corbett JJ, et al. Arch Neurol. Visual loss in pseudotumor cerebri. Follow-up of 57 patients from five to 41 years and a profile of 14 patients with permanent severe visual loss; Markey et al., Understanding idiopathic intracranial hypertension: mechanisms, management, and future directions (2016).
2. Mollan et al., EYE. The expanding burden of idiopathic intracranial hypertension (2019)

Recent Highlights / Milestones

Major Scientific Dissemination of Phase II "PRESSURE" Trial Data

- The results of the PRESSURE trial have undergone peer review and presented at major, relevant medical conferences:
  - North American Neuro-Ophthalmology Society (NANOS)
  - European Neuro-Ophthalmology Society (EUNOS)
  - Aerospace Medical Association.
- Key Opinion Leader Engagement, Clinical leads for IIH EVOLVE Phase III Trial
- Significant interest in Invex Phase III Trial (lack of approved therapies, urgent market need)

Completed All Necessary Regulatory Documents for Submissions in Key Markets

- Investigational Medicinal Product Dossier (IMPD) for Presendin™
- Investigator's Brochure and Study Protocol

Received Several Regulatory Approvals to Commence Phase III Trial

- Secured Medicines & Healthcare products Regulatory Agency (**MHRA**) approval in the UK & Ethics Approval – late Q2 CY22
- Secured Therapeutics Goods Administration (**TGA**) approval & Human Research Ethics Committee (HREC) approval – early Q3 CY22

Australian Government
Department of Health
Therapeutic Goods Administration

Medicines & Healthcare products
Regulatory Agency

IIH Total Addressable Market (TAM)

Key Inputs[1-5]


~24,000 EU/UK patients


~16,000 US patients


60% Diagnosed


90% Drug Treatable


4.3 year disease duration
~92k active patients


A$1,500 cost per month*
*Example only (ref. drug pricing) – final market price for Presendin™ TBD

Market Size (Annual)[6]


~A$1.0 Billion


~A$0.6 Billion


~A$1.6 Billion


3.4% growth

Market Drivers


Increasing obesity rates


Increasing awareness


10% ↑ in diagnosis rate =
↑ A$300 million in TAM


>A$2.3 Billion market by 2030

invex THERAPEUTICS | INITIAL TARGET MARKETS – EU, UK, AU

1. Mollan et al., EYE. The expanding burden of idiopathic intracranial hypertension (2019) incidence rate of 4.7/100,000 general population, n =23,182 . Targets markets are EU 27(& UK) + USA
2. Mollan SP, et al. Idiopathic intracranial hypertension: consensus guidelines on management (2018) ; Invex estimate re % presenting headache severity
3 Simoens et al., "what price do we pay for repurposing drugs for rare diseases"? (2016) – average 66x & Invex initial pricing analysis => pricing subject to change
4. D. Friesner et al., Idiopathic intracranial hypertension in the USA: the role of obesity in establishing prevalence and healthcare costs (2010)
5. Assumes average of obesity growth rates in UK (https://www.oecd.org/els/health-systems/Obesity-Update-2017.pdf) and historical incidence growth rate
6. Data as at 2020 estimates.

Key Clinician Pathways in the Management of IIH

No Immediate Threat to Vision

Optometrists

- Often patients with vision issues consult an optometrist, who in turn are primary referrers to ophthalmologists
- ~37,000 optometrists in the USA[1]

Ophthalmologists

- ~19,000 ophthalmologists in the USA[1]
- **~260** specialise in neuro-ophthalmology, **specifically treating IIH patients**[2]

Neurologists

- ~19,000 neurologists in the USA who see patients with significant headaches[1]
- **~1,500 to 2,000** sub-specialise as certified headache specialists[2]

~40
~50
~355

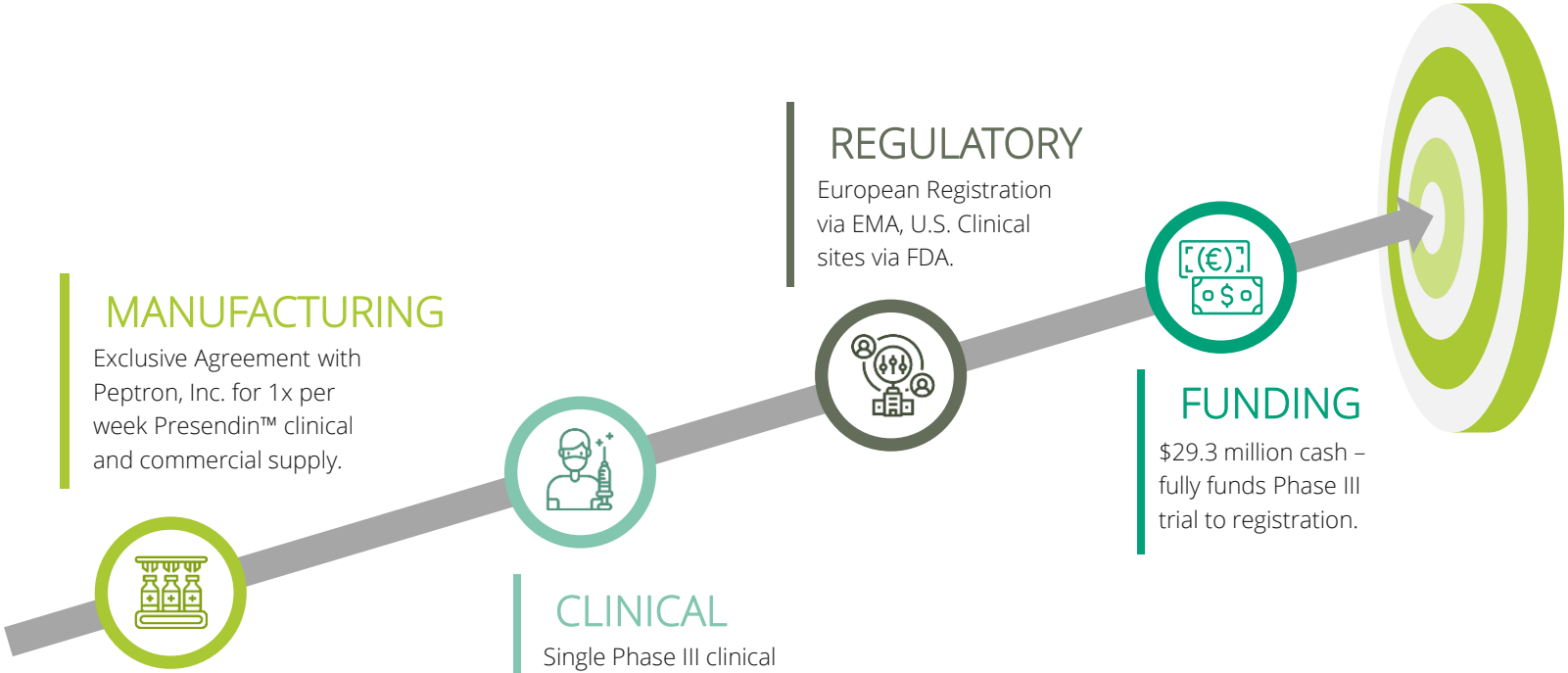
Focussed target market of prescribers following first regulatory approvals for Presendin™ in EU, UK, AU

Threat to Vision

- Hospitalisation and surgical / device intervention
- CSF shunting, ONSF to reduce pressure

1. Optometrist estimates: https://www.bls.gov/oes/2018/may/oes291041.htm; other specialist estimates: https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-largest-specialties-2017.
2. American Migraine Foundation and https://journals.lww.com/jneuro-ophthalmology/Fulltext/2018/03000/A_Profile_of_Neuro_Ophthalmic_Practice_Around_the.11.aspx; RANZCO; EU estimates based on population comparison to US

Critical Components for Success



MANUFACTURING

Exclusive Agreement with Peptron, Inc. for 1x per week Presendin™ clinical and commercial supply.

CLINICAL

Single Phase III clinical trial designed with expert input.

REGULATORY

European Registration via EMA, U.S. Clinical sites via FDA.

FUNDING

$29.3 million cash – fully funds Phase III trial to registration.

Manufacturing

STRATEGIC PARTNER PEPTRON

Establishes a long term strategic partner for Invex (Sep 2021)

Listed on South Korean KOSDAQ Exchange (KS:087010)

TIME & RISK REDUCTION

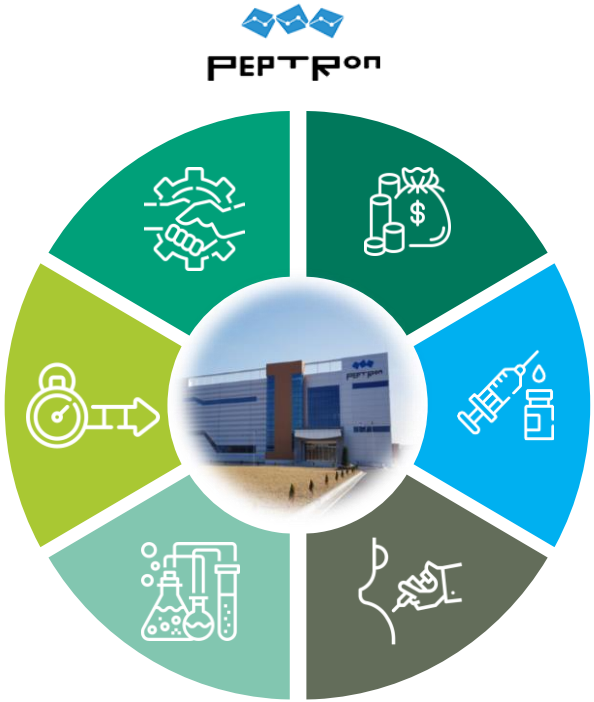
Significant clinical and non-clinical data package provided by Peptron

Significantly de-risking of Invex's development of Presendin™ in IIH

PEPTRON EXPERTISE

Long-Acting Peptide Formulation specialists (SmartDepot™ Technology)

Ongoing product development activities



FINANCIAL

Strong economics

- fixed price per dose
- no royalties
- no milestone payments

MANUFACTURING

Financially robust

Commercial-scale capacity

Established 16,000sqM GMP facility for exenatide formulation

PATIENTS

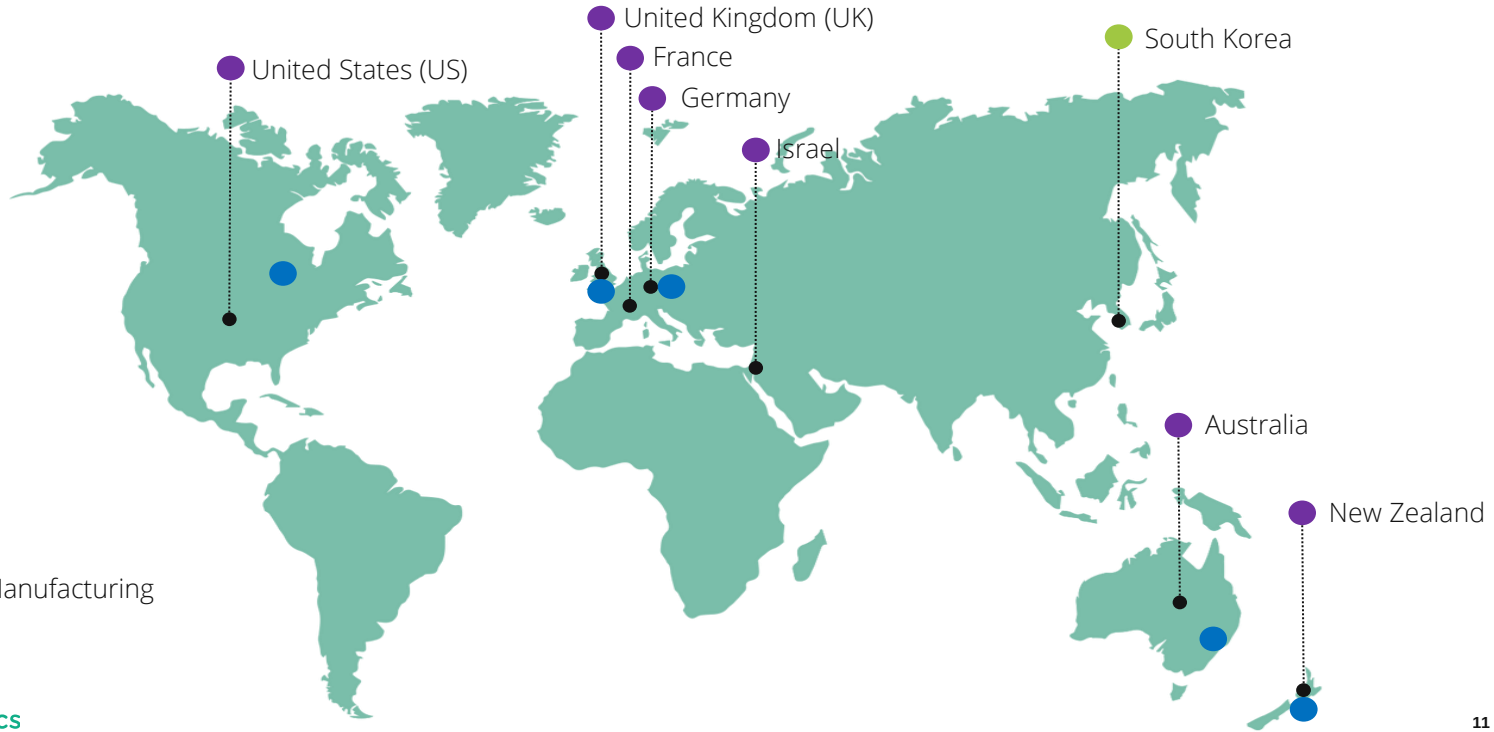
Once weekly dosing

IIH EVOLVE Phase III

Manufacturing

Clinical Sites

Trial Steering Committee (TSC)



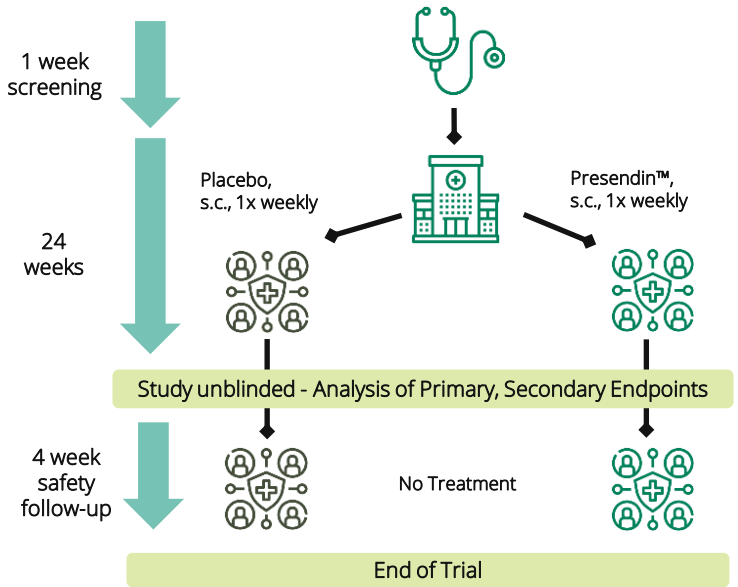
IIH EVOLVE Phase III

Randomised double-blinded, placebo controlled multi-centre clinical trial to determine safety and efficacy of Presendin™ in IIH

40 centres across EU, UK, Australia, NZ, Israel and the US | 240 patients | 24 months recruitment

Primary Endpoint	Change in Intracranial Pressure (ICP) from baseline at 24 weeks
Secondary Endpoint	Change in Perimetric Mean Deviation (PMD) from baseline over 24 weeks
Secondary Endpoint	Papilloedema (optic nerve swelling) by change in OCT[1] measures over 24 weeks
Secondary Endpoint	Change in Monthly Headache Days (MHD) from baseline over 24 weeks
Safety	Adverse events rate, anti-drug antibodies, PK and general lab measures
Quality of Life	Patient reported outcomes (SF-36, ED-5D-5L, VFQ-25), monthly patient diary

Phase III Schematic



Designed to meet registration (approval) requirements in the UK, EU and Australia; data to inform US FDA registration next steps

1. OCT – Optical Coherence Tomography is an imaging tool accepted by professional bodies for monitoring papilloedema in IIH by measuring different aspects of the optic nerve. The optic nerve head size and retinal nerve fibre layer (RNFL) are measurements that both reflect swelling of the optic nerve and hence the extent of papilledema. Optic nerve head measures on OCT correlate with visual field sensitivity loss.
2. s.c. – sub cutaneous

Regulatory

Phase III IIH EVOLVE clinical trial for Presendin™ is intended to initially support: EMA, TGA, MHRA approval for treatment of IIH ($1Bn TAM)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

Medicines & Healthcare products Regulatory Agency

Australian Government
Department of Health
Therapeutic Goods Administration

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

FDA

MINISTRY OF HEALTH
For a healthier life

Initial Phase (CY21)

- Seek Scientific / Protocol Advice from European Medicines Agency (EMA) and FDA
- Assimilate feedback into a complete regulatory package (Study Protocol, IMPD, IB)
- Work with Peptron on Chemistry, Manufacture and Control (CMC) Standards

Second Phase (late 2H CY21 / 1H CY22) – Targeted Regulatory Submissions

- MHRA/REC submission UK & HREC/TGA Australia
- Refine, adapt based on feedback – Both jurisdictions now approved for trial

Third Phase (2H CY22) – Additional Regulatory Filings, Commence Recruitment

- Second HREC (public hospital) Australia
- Submissions/Approval(s): FDA, Competent Authorities (Europe), Israel, NZ
- First IIH patient treated: major milestone

Efficient

Cost-Effective

Clinical Harmonisation

Milestones for 2H CY22

- Completion of additional regulatory approvals:
  - Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA)
  - HREC approval (public hospital) Australia
  - Medsafe Approval New Zealand
  - Hospital Clearance / Ministry of Health Approval Israel
  - National Competent Authorities – Europe
- Progressive opening of clinical sites
- First patient recruited and dosed (likely UK or Australia in the short term)

Summary & Outlook

- Single Phase III trial designed to support Presendin™ market approvals in the EU, UK and Australia - $1 billion+ unencumbered TAM
- Potential for rapid incorporation of Presendin™ into IIH treatment guidelines
- IIH EVOLVE includes an economic evaluation to facilitate the health technology assessment (HTA) process
- Data generated from trial and inclusion of US sites will inform continued dialogue with FDA for future regulatory filings
- Potentially first-ever regulatory approved drug for IIH in any jurisdiction world-wide
- Fully funded Phase III program - **$29.3 million cash (FY22)**, exited FY22 with annualised corporate costs (ex R&D, share-based payments) of **~$1 million** per annum
- Compelling EV & risk/reward opportunity

Contacts

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