ASX / Media Release
12 September 2022

Invex to Present at Virtual ASX Small and Mid-Cap Conference On- Demand Event

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release Exenatide) for neurological conditions relating to raised intracranial pressure, today announces an upcoming on demand presentation by Dr Tom Duthy, Executive Director, as part of the upcoming virtual ASX Small and Mid-Cap Conference to be held on 13 – 14 September 2022.

A copy of the presentation is attached to the release.

In addition, investors wishing to view the on-demand video of the presentation and register for the event can follow this link: https://asx.delegateconnect.co/

The ASX Small and Mid-Cap Conference is a bi-annual event established in 2018 to support and promote ASX-listed companies in their capital market interface. The conference showcases quality ASX-listed companies to our vast network of Australian investors. The conference sees over 20 ASX-listed companies present their vision, strategy, and investment proposition to over 2,000 investors via a 15-minute live stream presentation and 15-minutes of Q&A. Due to significant demand, the ASX has included an 'on-demand' feature in the conference, with Invex Therapeutics invited to participate.

- ENDS -

This release dated 12 September 2022 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

For more information, please contact:

Company/Investors
Dr Thomas Duthy
Executive Director
tduthy@invextherapeutics.com
+61 402 493 727

Media
Margie Livingston
Ignite Communications
margie@ignitecommunications.com.au
+61 438 661 131

To subscribe to Invex email alerts, please visit www.invextherapeutics.com and follow us on Twitter **@InvexThera_ASX**

About Invex Therapeutics Ltd

Invex is a 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, such as Idiopathic Intracranial Hypertension (IIH), acute stroke and traumatic brain injury. Invex has trademarked its repurposed Exenatide as Presendin™. www.invextherapeutics.com.

Invex Therapeutics

ASX Small to Mid Conference On-Demand Event

Dr Tom Duthy, Executive Director

September 2022
ASX Code: IXC

invex
THERAPEUTICS

Disclaimer

This presentation (**Presentation**) is issued by Invex Therapeutics Ltd (ASX:IXC) (the **Company** or **IXC**). The information presented in this Presentation may contain predictions, estimates and other forward-looking statements. Although the company believes that its expectations are based on reasonable assumptions, it can give no assurance that its goals will be achieved. This Presentation is not a disclosure document and is provided to the Recipient for the sole purpose of providing information relating to the investment opportunity described in this Presentation (**Purpose**). The Company will not be liable to compensate the Recipient for any costs or expenses incurred in reviewing, investigating or analysing any information, or in making an offer or otherwise. This Presentation is not to be taken to be an offer by any of the Investors to sell any or all of securities in the Company. This Presentation is provided for information purposes only and does not purport to contain all the information that may be required by each Recipient to evaluate any transaction in relation to the Purpose. In all cases, the Recipient should conduct its own investigation and analysis and should check the accuracy, reliability and completeness of the Information and obtain independent and specific advice from appropriate professional advisers. The information contained in this Presentation has been furnished by the Company and other sources deemed reliable but no assurance can be given by the Parties as to the accuracy or completeness of this information. To the full extent permitted by law: no representation or warranty (express or implied) is given; and no responsibility or liability (including in negligence) is accepted, by the Parties as to the truth, accuracy or completeness of any statement, opinion, forecast, information or other matter (whether express or implied) contained in this Presentation or its appendices or as to any other matter concerning them.

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 (19 Aug-22) [1]	$48.9 million
Enterprise Value (19 Aug-22)	$19.6 million

[1]Based on a closing price of $0.65

Major Shareholders (as at 1 August 2022)	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
JK Nominees Pty Ltd	4.0%
Anthony Grist	3.6%
University of Birmingham	2.7%
Top 20 Shareholders	58.0%

Board of Directors	
Dr Jason Loveridge	Non-Executive 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% p.a.
- 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 - efficacy 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 (SR) 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
- Additional patents pending

Invex Therapeutics - Executive Summary

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

The Disease[1]

- Dysregulation of cerebral spinal fluid secretion in the brain, leading to high intracranial (brain) pressure (ICP)
- >90% of cases overweight women of childbearing age with no known cause
- >90% suffer headaches that are progressively more severe and frequent
- Up to 25% suffer permanent vision loss due to elevated ICP impact on optic nerve

The Impact[2]

- Invasive surgical and/or device interventions to temporarily lower ICP and preserve vision (sig. side effects)
- 40% of patients have repeat hospital admissions, with average stays of 2.7 days
- Sig. 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 (IXC Director, CSO)
- Strong scientific basis for benefit with a well defined mechanism of action
- Patent protection secured: use of Exenatide in IIH & other indications
- Presendin™ - once weekly dosing improves compliance and safety

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)

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.

Recent Highlights / Milestones

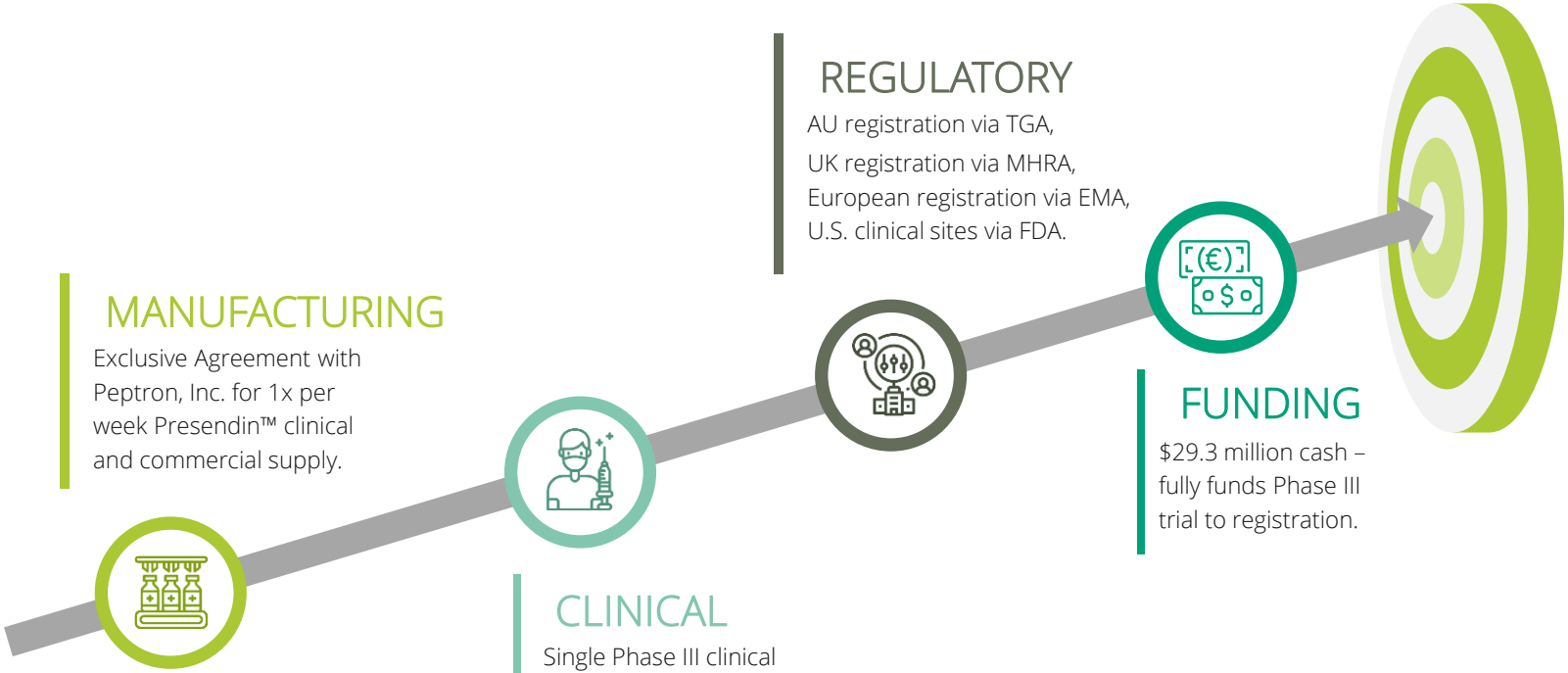
Received Three Regulatory Approvals to Commence Phase III "IIH EVOLVE" Clinical Trial

- 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
- US Food and Drug Administration (FDA) Approval for Investigational New Drug application (IND) – August 2022

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
- 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)

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

AU registration via TGA,
UK registration via MHRA,
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

Established a long-term strategic partner for Invex (Sep 2021)

Listed on South Korean KOSDAQ Exchange (KS:087010)

TIME & RISK REDUCTION

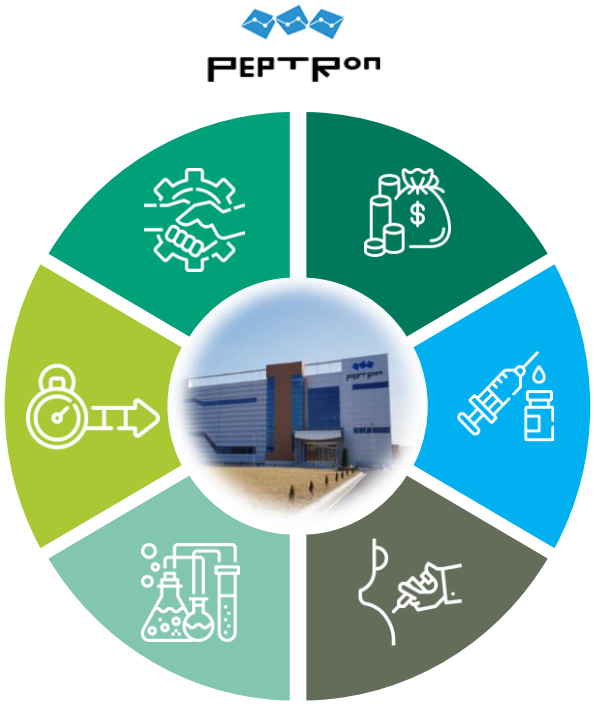
Significant clinical and non-clinical data package provided by Peptron

Significant 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 provides better compliance and convenience

IIH EVOLVE Phase III

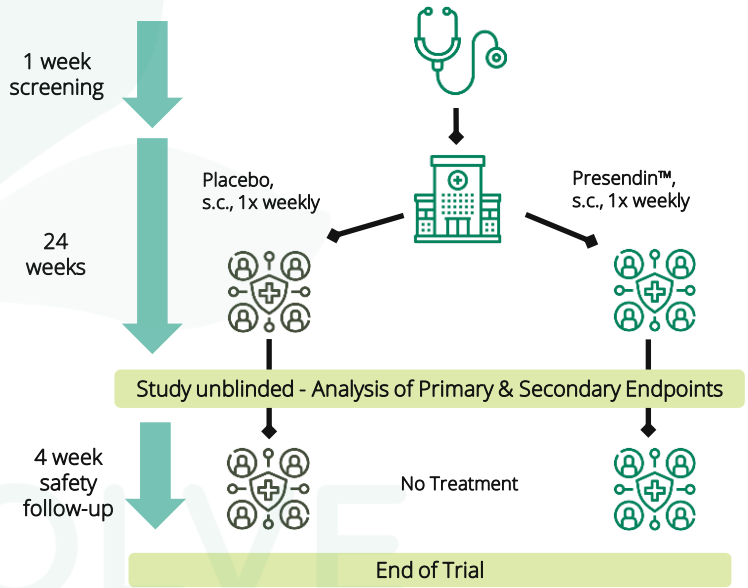
IIH EVOLVE

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 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

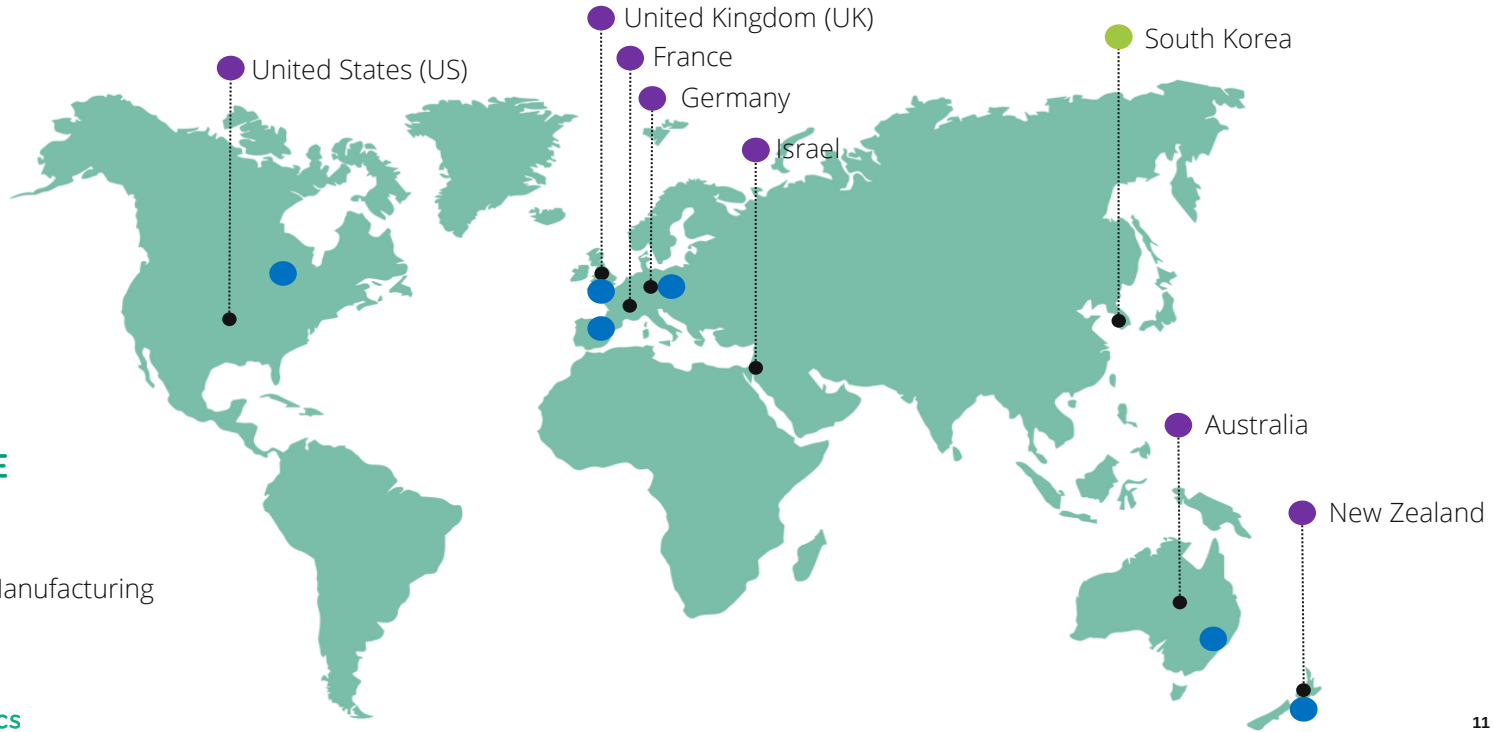
1. OCT – Optical Coherence Tomography is an imaging tool accepted by professional bodies for monitoring papilloedema in IIH by measuring different aspects of the optic nerve. The optic nerve head size and retinal nerve fibre layer (RNFL) are measurements that both reflect swelling of the optic nerve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

IIH EVOLVE Phase III

Manufacturing

Clinical Sites

Trial Steering Committee (TSC)



IIH EVOLVE

- TSC Members
- Presendin™ Manufacturing
- Clinical Sites

Trial Steering Committee – Global Leaders in IIH

Professor Michael Wall – Chair

Professor of Neurology and Ophthalmology at the University of Iowa. Director of the Iowa Visual Field Reading Center.

Associate Professor Clare Fraser – Member

Assoc. Professor Neuro-ophthalmology, University of Sydney. Consultant Visiting Medical Officer at both Sydney Eye Hospital and Liverpool Hospital.

Professor Patricia Pozo-Rosich – Member

Professor Pozo-Rosich is a Head of Section in the Neurology Department at Vall d'Hebron University Hospital in Barcelona and Director of the Migraine Adaptive Brain Centre.

IIH EVOLVE

Professor Susan Mollan – Member

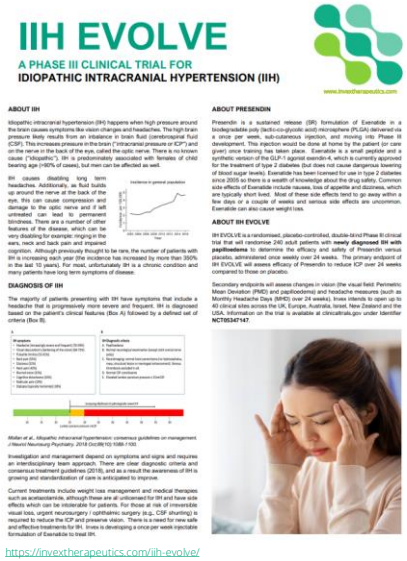
Professor Mollan is Honorary Professor at the University of Birmingham and a Consultant Neuro-ophthalmologist at University Hospitals Birmingham (UHB). Lead author IIH consensus treatment guidelines (2018/9).

Professor Helen Danesh-Meyer– Member

Professor Danesh-Myer is Professor, Faculty of Medical and Health Sciences, Ophthalmology, Sir William and Lady Stevenson Chair in Ophthalmology, Head of Academic Neuro-ophthalmology and Glaucoma, University of Auckland and a Director of the Eye Institute.

Professor Dr Wolf Lagrèze – Member

Professor Lagrèze is Professor of Ophthalmology at the University Medical Center Freiburg, Germany, where he holds the Chair of Neuro-ophthalmology and Pediatric Ophthalmology.



https://invextherapeutics.com/iih-evolve/

Other Committees – Independent Oversight

Data Safety Monitoring Committee (DSMC)

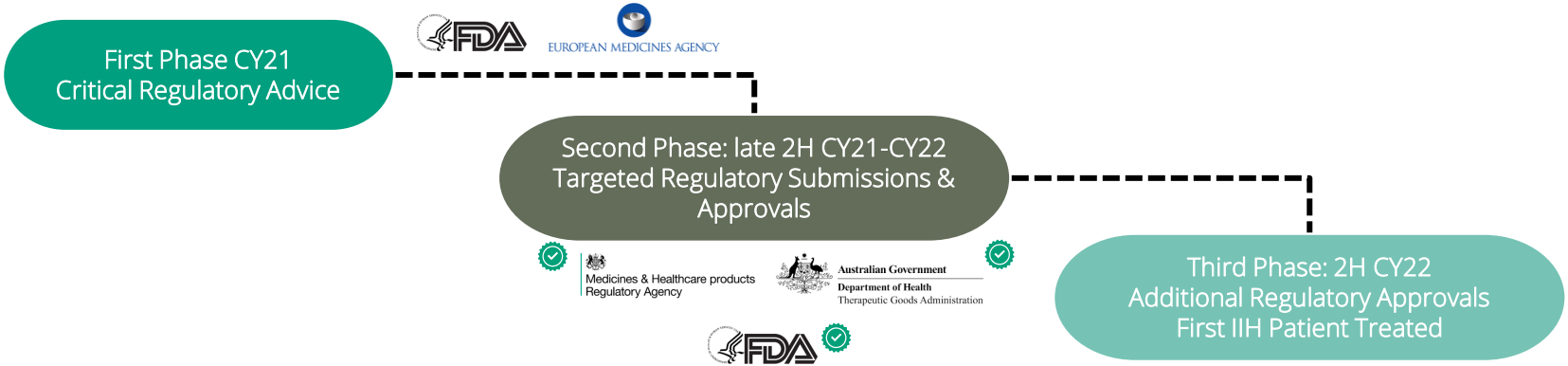
Independent Adjudication Committee (IAC)

- Vision IAC
- Headache IAC

IIH EVOLVE

Regulatory

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



- Efficient
- Cost-Effective
- Clinical Harmonisation

Milestones for 2H CY22

- Completion of additional regulatory filings and/or approvals:
  - Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) – achieved August 2022
  - HREC approval (public hospital) Australia
  - Medsafe - New Zealand
  - Hospital Clearance / Ministry of Health - Israel
  - National Competent Authorities – Europe
- Progressive opening of clinical sites
- First patient recruited and dosed (likely UK or Australia)

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 will inform discussions with FDA to understand regulatory requirements for future clinical trials/approval
- 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

Contacts

INVESTORS

Dr Tom Duthy
Executive Director

+61 402 493 727
tduthy@invextherapeutics.com

MEDIA

Margie Livingston
Ignite Communications

+61 438 661 131
margie@ignitecommunications.com.au

To subscribe to Invex email alerts, please visit www.invextherapeutics.com
Follow us on Twitter **@InvexThera_ASX**