



## ASX Announcement

18 November 2020

# Chairman's Address to AGM and Presentation

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**Invex Therapeutics Ltd (Invex, ASX:IXC, or the Company)** a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (Exenatide) for neurological conditions relating to raised intracranial pressure, today provides the Chairman's address to the 2020 Invex Annual General Meeting (AGM) and accompanying investor presentation, to be held by way of a virtual webcast today at 3.30pm WST (Perth time).

Investors are reminded that pre-registration is a requirement of attendance at the virtual AGM, via the following link: [https://us02web.zoom.us/webinar/register/WN\\_2z0RDi\\_nRxqf2IirQP4Fg](https://us02web.zoom.us/webinar/register/WN_2z0RDi_nRxqf2IirQP4Fg)

A webcast of the AGM will be available at <https://invextherapeutics.com/presentations/> shortly after the conclusion of the meeting.

***This release dated 18 November 2020 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.***

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## About Invex Therapeutics Ltd

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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](http://www.invextherapeutics.com).



**Chairman's Address**  
**Invex Therapeutics Limited**  
**Annual General Meeting**  
**18 November 2020**

Good afternoon Ladies and Gentlemen, my name is Dr Jason Loveridge and I am a Founder and the Chairman of Invex Therapeutics Limited and will Chair today's meeting.

Online we have our directors:

- Professor Alexandra Sinclair, Executive Director, Chief Scientific Officer and co-Founder
- David McAuliffe, Non-Executive Director
- Dr Tom Duthy, Executive Director, and
- Narelle Warren, Company Secretary

On behalf of the Board, we are pleased that you have taken the time to attend online and thank you for your support of the Company.

Given the significant health concerns attributed to the COVID-19 pandemic, in addition to guidelines and restrictions issued by the respective Australian state and federal governments, the Company considers that it is appropriate to hold the 2020 AGM as a virtual meeting, in a manner that is consistent with the temporary modifications to the Corporations Act 2001 introduced by the Commonwealth Treasurer.

The agenda for today's meeting will be as follows:

I will start by providing a short Chairman's address with accompanying presentation which will be followed by formal matters to be considered at today's AGM, a Q&A session; and closing of the Poll, before the final Closing of the Meeting.

I will now provide an overview of the significant progress the Company has made over the last 12 months, starting with a successful listing on the Australian Securities Exchange (ASX) raising an initial \$12 million.

Invex is focused on research and development centred around understanding the mechanisms that regulate pressure in the brain and in particular the potential to repurpose an already approved drug, Exenatide, to reduce intracranial pressure, which we believe is a significant unmet



medical need. This re-purposed, re-formulated Exenatide has been trademarked by the Company as Presendin™.

Our first target indication is an orphan disease called Idiopathic Intracranial Hypertension - or IIH - which we believe represents a significant commercial opportunity as defined by a potential annual market size in the region of \$1.6 billion in the European Union and the United States, with little competition given there are no approved treatments for the disease on the market. IIH patients have severely raised intracranial pressure which causes disabling daily headaches and in a minority of patients can compress the optic nerve and causing serious vision impairment.

During the year, the Company completed recruitment and reported the results of a Phase II, double-blind, randomised placebo controlled clinical trial of Exenatide in IIH. The trial hit its primary endpoint and demonstrated a statistically significant reduction in Intracranial Pressure in IIH patients receiving Exenatide at all timepoints out to completion of the study at 12 weeks. This was the first ever clinical study to demonstrate the pressure lowering effects of Exenatide and the first in patients with IIH patients. This excellent outcome validated both the scientific thesis proposed by Professor Alex Sinclair for the utility of GLP-1 agonists to reduce pressure in the brain and the scientific basis for our Company.

In addition to meeting the primary outcome of the study a number of other important clinical outcome measures were achieved, defined as secondary endpoints, where Exenatide was shown to provide statistically significant & clinically meaningful benefit to patients. With respect to headache, Exenatide use resulted in a 7.7 day (or 37%) reduction in the number of monthly headache days experienced by IIH patients. And in terms of vision, Exenatide use demonstrated an improvement in visual acuity equating to one line on a LogMAR eye chart – which is a significant and clinically meaningful improvement.

On the back of this strong Phase II clinical trial results, the Company undertook a transformational capital raise of \$26 million by way of a share placement to sophisticated, professional and institutional investors from Australia and overseas. The Company received cornerstone commitments totalling \$10.5 million from existing investors, including \$5.0 million from Tattarang (formerly Minderoo Group). The capital raised will be progressively deployed by the Company to fund the planned Phase III Presendin™ registration study for IIH and lead-in activities such as manufacturing of GMP grade drug product.

During the past year our intellectual property portfolio has been significantly strengthened with a notice of allowance from both the US and Japanese patent offices covering the use of Exenatide in indications of elevated intracranial pressure, such as IIH. These patents could potentially provide protection in these jurisdictions until at least August 2035. In the case of our US patent, I am pleased to report that of today, that patent has been formally issued by the US patent and trademark office. In addition, Invex has filed additional patent applications covering its novel formulations of Exenatide which are currently under examination in a range of jurisdictions including the US, Europe and Australia. Finally, with respect to intellectual property, we have also



submitted a number of trademark applications for Presendin™ and were granted this trademark in the UK.

In combination with our US and EU orphan drug designations for Exenatide in IIH, which themselves provide 7 and 10 years market exclusivity, respectively, Invex is constructing a solid and extensive barrier to entry for competition that increases the overall attractiveness of our Exenatide asset.

Moving to regulatory and importantly as we exited the 2020 financial year, we received regulatory feedback known as protocol assistance or scientific advice from the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) on the Invex's proposed Phase III design and preclinical package for Presendin™.

EMA indicated a single pivotal study of Presendin™ against placebo would be sufficient to support a filing for regulatory approval in IIH in Europe. EMA suggested intracranial pressure as the most appropriate primary endpoint, but also acknowledged that a reduction in headache frequency would also constitute an acceptable primary endpoint.

The FDA stated they would need more information in order to evaluate the Invex's proposed design but did guide that two well controlled studies would be required to support registration in the US. Both regulatory agencies agreed that Invex's proposed pre-clinical and human pharmacokinetic approach was broadly acceptable for the proposed Phase III study.

Since receiving this initial feedback, we have made a subsequent submission to the EMA relating to the acceptability of headache as a primary endpoint in IIH and expect to make a submission to the FDA for a pre-IND / Type B meeting to discuss our plans following receipt of EMA feedback, which is expected late in the fourth quarter this calendar year. We look forward to updating investors further at that time.

I would like to express our gratitude to the clinicians and patients who have given their time in the pursuit of finding new, effective treatments for IIH, where currently no such approved treatments exist in the market today. And finally, to our shareholders, I thank you for your continuing support. Drug development pathways are complex, but I have confidence we have the right team in terms of staff and expert clinical and regulatory consultants to move Presendin into a first registration study in 2021.

Invex remains in a solid financial position with approximately \$34 million in cash as at 30 September 2020 and we look forward to a prosperous 2021.

**Jason Loveridge, Ph.D**  
**Chairman**  
**Invex Therapeutics Limited**  
**18 November 2020**



# Invex Therapeutics

2020 Annual General Meeting

Dr Jason Loveridge, Chairman

18 November 2020

ASX Code: IXC

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# Invex Therapeutics - Executive Summary

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

## Attractive Market Dynamics



- IIH Total Addressable Market (TAM) in the US and Europe of **A\$1.6 billion** per annum 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
- Plan to commence Phase III registration trial in 1H CY2021

## Significant Barriers to Competition



- Orphan drug designation in US (7 years exclusivity) and Europe (10 years exclusivity)
- Issued and pending patents for use of Exenatide in IIH. Formulation patents filed Q1 2020

# Summary & Outlook

- 12 Month Milestones:
  - Response from EMA expected late Q4 CY2020
  - Final Formulation Q4 CY2020
  - Appointment of contract manufacturer Q4 CY2020
  - Pre-IND Submission / Type B Meeting with FDA expected Q1 CY2021
  - Subject to availability of GMP Presendin™
    - Human PK study to commence 1H CY2021
    - Animal tolerability study to commence 1H CY2021
    - Filing of a CTA in Europe for Phase III clinical trial 1H CY2021





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