



## ASX Announcement

28 November 2023

### Chairman's Address to AGM

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**Invex Therapeutics Ltd (Invex, ASX:IXC, or the Company)** a biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release Exenatide) for neurological conditions relating to raised intracranial pressure, today provides the Chairman's address to the 2023 Invex Annual General Meeting (AGM) to be held by way of a virtual meeting today at 11.00am WST (Perth time).

#### **To access the virtual Meeting:**

1. Open your internet browser and go to [investor.automic.com.au](https://investor.automic.com.au)
2. Login with your username and password or click "register" if you haven't already created an account. Shareholders are encouraged to create an account prior to the start of the Meeting to ensure there is no delay in attending the virtual Meeting
3. After logging in, a banner will display at the bottom of your screen to indicate that the Meeting is open for registration, click on "Register" when this appears. Alternatively, click on "Meetings" on the left hand menu bar to access registration.
4. Click on "Register" and follow the steps
5. Click on the URL to join the webcast where you can view and listen to the virtual Meeting
6. Once the Chair of the Meeting has declared the poll open for voting click on "Refresh" to be taken to the voting screen
7. Select your voting direction and click "confirm" to submit your vote. Note that you cannot amend your vote after it has been submitted

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

***This release dated 28 November 2023 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.***



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**For more information, please contact:**

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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. Invex has trademarked its repurposed Exenatide as Presendin™. [www.invextherapeutics.com](http://www.invextherapeutics.com).



**Chairman's Address**  
**Invex Therapeutics Limited**  
**Annual General Meeting**  
**28 November 2023**

Good morning Ladies and Gentlemen, my name is David McAuliffe. I'm a co-founder and the Non-Executive Chairman of Invex Therapeutics Limited and I will Chair today's meeting.

I am pleased that all our directors are present on the webinar today:

- Dr Tom Duthy, Executive Director
- Dr Megan Baldwin, Non-Executive Director and
- Mr David Wheeler, Non-Executive Director who was recently appointed to the Company.

Also in attendance today is Narelle Warren, Invex's Chief Financial Officer and Company Secretary. On behalf of the Board, we are pleased that you have taken the time to attend online and we thank you for your support of the Company over the last 12 months.

The agenda for today's meeting will be as follows. I will start by providing a short Chairman's address, which will be followed by formal matters to be considered at today's AGM, a Q&A session; and closing of the Poll, immediately prior to the Closing of the Meeting.

The Company recorded a net loss after tax of \$7.7 million in FY23 an increase of 80% on the prior corresponding period. This was largely due to higher R&D costs of \$7.4 million, the necessary regulatory and clinical expenditure required to commence the IIH EVOLVE study, along with product manufacturing costs of \$0.7 million associated with the purchase of drug product (Presendin™) and placebo from Peptron. In addition, non-cash share-based payment expenses of \$0.48 million and corporate and administrations costs of \$1.1 million were recorded. Invex has always managed its cash carefully, with the Company in a strong financial position at the end of FY23 with cash and cash equivalents of \$22.5 million.

Operationally, the 2023 financial year started with a great deal of enthusiasm as we received a significant number of regulatory approvals to commence our IIH EVOLVE Phase III clinical trial in patients with Idiopathic Intracranial Hypertension (IIH) within the United States, United Kingdom, Australia and New Zealand during the first half and then recruited our first patient in November 2022 in Adelaide, Australia. The second half reflected the strong regulatory success once more in France, Germany and Israel. In addition, we qualified almost all of the 40 sites we anticipated activating for patient recruitment during the period. Unfortunately, the time difference between



receiving these approvals and qualifying these sites to then activate them for patient recruitment and recruitment itself proved much slower than anticipated.

On 28 June 2023 the Group announced it had engaged a specialised global healthcare intelligence group to undertake an analysis on the potential future risks to the addressable market for Presendin™ for IIH. This independent assessment from DRG/Clarivate was initiated following evidence of the growing use of approved GLP-1 receptor agonists (GLP-1RA) for obesity management, specifically semaglutide, currently sold under the brand names Ozempic®, Wegovy® and Rybelsus®. The Board was concerned about the impact of these drugs on pricing and utilisation of Presendin™, if approved for IIH in Europe and the UK, over the next 3 or more years.

On 21 August 2023, the Company announced the results of the independent assessment, which resulted in immediately moving to close the IIH EVOLVE clinical trial. The analysis undertaken informed Invex, based on feedback from European clinicians and reimbursement groups, that current pricing for GLP-1 receptor agonists (GLP-1RA) like Ozempic® make Presendin™ uneconomic in IIH, and achieving a reimbursement premium for Presendin™ being reflective of its orphan drug status would be challenging, and the continuation of the trial and the necessary expenditure required to complete recruitment under a revised IIH EVOLVE trial was not viable.

The primary principle of IIH management is weight loss, which is considered the disease modifying intervention of choice according to the 2018 IIH Consensus Treatment Guidelines. Put simply, IIH patients are mostly obese, and weight loss is strongly correlated to improvement in IIH symptoms, including reductions in raised intracranial pressure – the target for Presendin™.

Investors should note that the correlation between obesity and IIH does not impact other neurological disorders relating to raised intracranial pressure, such as traumatic brain injury (TBI), hydrocephalus and stroke. On 23 June 2023, Invex announced the granting of orphan drug designation (ODD) from the European Medicines Agency for Exenatide in the treatment of moderate to severe TBI. We also received additional patent coverage with a US patent issued for Exenatide covering TBI on 23 August 2023. More recently, we have undertaken some initial pre-clinical work examining the use of Exenatide in treating elevated eye pressure in the form of glaucoma. Additional patent applications have been submitted.

It is interesting to observe the potential impact of these obesity drugs on large cap healthcare companies such as CSL and Resmed, both of which have suffered substantial deteriorations in their share prices as investors worry about the impact of GLP-1 receptor agonists on their business performance moving forward. In our case, although a difficult decision, it was in the best interests of shareholders to halt IIH EVOLVE and preserve capital. The Board could simply not justify the expenditure required to progress Presendin™ in IIH as the financial returns were simply not there into the future to justify the investment.

On 1 November, we announced a commitment by the Company to return \$14.0 million to shareholders representing approximately 19 cents per share, by way of an equal access capital



return for the purposes of the Corporations Act. The Board has resolved to return this surplus capital in the interests of all shareholders, while allowing us the balance sheet flexibility to continue our existing programs and explore new strategic opportunities to add value to our core intellectual property.

We look forward to a re-start of our strategies in the 2024 calendar year as we continue the development of Presendin™ in neurological disorders associated with raised intracranial pressure including TBI and glaucoma, and carefully manage our cash position following the \$14.0 million return of capital. Shareholders will convene once more to approve the capital return on 5 December 2023. We look forward to speaking with you then.

**David McAuliffe**  
**Chairman**  
**Invex Therapeutics Limited**  
**28 November 2023**