ASX / Media Release
18 March 2021

Investor Presentation – March 2021

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 an updated investor presentation to ASX as the Company undertakes a series of investor briefings and presentation to the NWR Small Caps Conference to be held today at 9:35am AEDT.

The NWR event is free and investors can register online to view the presentation here: https://us02web.zoom.us/webinar/register/WN_xEC_ptAISYeEMQjC30Vnxw

Investors are invited to submit questions prior to the event to: matt@nwrcommunications.com.au

- ENDS -

This release dated 18 March 2021 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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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

NWR Small Caps Virtual Conference

March 2021

ASX Code: IXC

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Disclaimer

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Company Snapshot

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

Capital	
Shares on Issue	75.2 million
Unlisted Options	3.9 million
Cash (31 Dec-20)	$33.6 million
Market Capitalisation (12 Mar-20) [1]	$62.0 million
Enterprise Value (12 Mar-20)	$28.4 million

Major Shareholders	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
JK Nominees Pty Ltd	4.0%
University of Birmingham	2.7%
Top 20 Shareholders	**58.0%**

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

* Appointed 17 February 2021

[1] Based on closing price of $0.825

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 file with national health authorities in Europe & commence a Phase III registration trial

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

Q1 2021 Highlights to Date

Dr Megan Baldwin Appointed to the Board of Directors

- Dr Baldwin is CEO and Managing Director of Opthea Limited (ASX:OPT; NASDAQ:OPT)
- Experienced biotechnology executive, having over 20 years' experience working on therapeutic drug development programs for cancer and ophthalmic indications
- Opthea has rapidly advanced its ophthalmology program through Phase I and Phase II clinical development and has initiated two global Phase III clinical trials with lead candidate
- Opthea included into the S&P/ASX 300 in June 2020
- Opthea raised $180 million and listed on NASDAQ Exchange in October 2020

Continued Preparations for Phase III Trial in IIH

- Selection of preferred formulation of Presendin™ for clinical development - **pending**
- Advanced discussions with contract manufacturer for supply of clinical-grade Presendin ™ for Phase III study – **pending**
- Significant expert input into planned study protocol and execution - **ongoing**
- Submission to US FDA for Pre-IND / Type B Meeting in Q1 CY2021 – **on-track**

What is Idiopathic Intracranial Hypertension (IIH)?

The Disease[1]

- >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 intracranial pressure (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**)

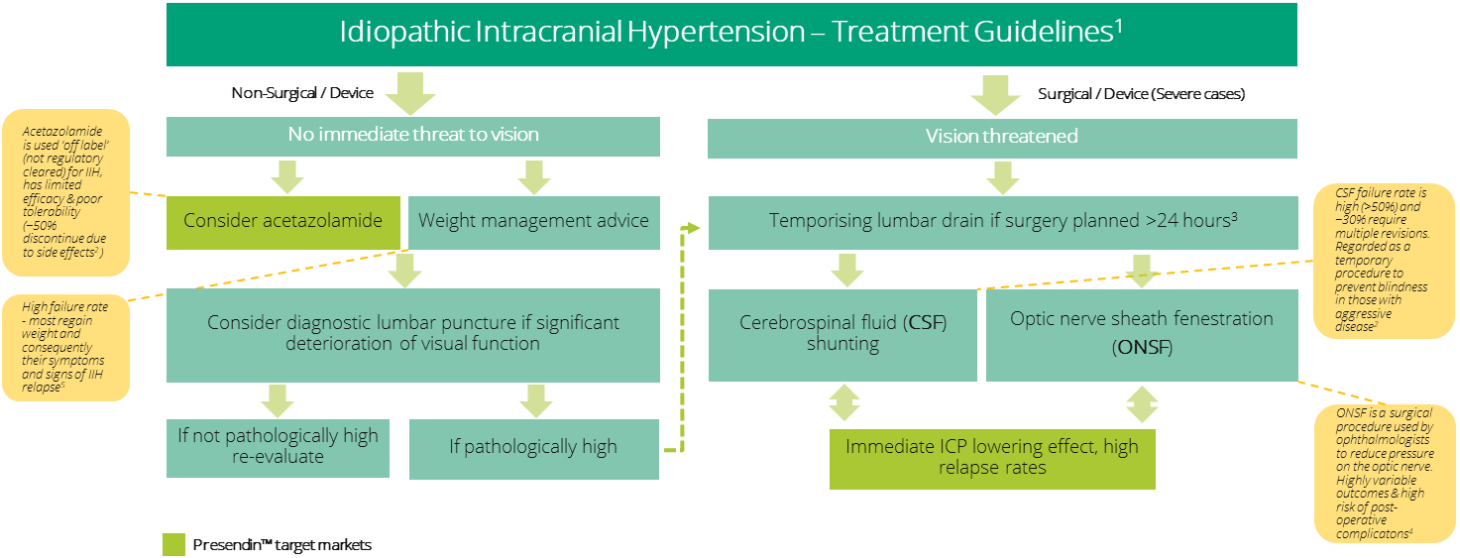
The Solution

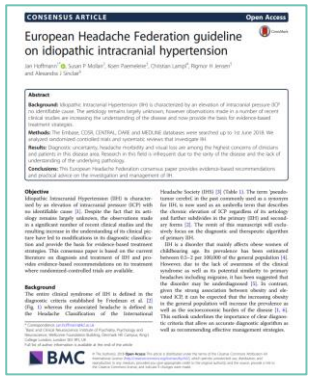
- Prof. Alex Sinclair (Invex CSO & Exec. Director) first to demonstrate glucagon like peptide 1 (GLP-1) receptor agonists commonly used in diabetes treatment (Exenatide formulated as Byetta® or Bydureon®) act on the choroid plexus in the brain to lower cerebral spinal fluid secretion and as a consequence, ICP
- Exenatide - strong scientific basis for benefit, well defined mechanism of action, patents secured - re-purposing opportunity to improve safety & efficacy → Presendin™
- Invex Phase II study in IIH - first clear demonstration of safety & efficacy in IIH

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)

Current treatments for IIH are limited

- Diagnostic criteria (2013) and treatment guidelines (2017/8) now well defined
- IIH consensus guidelines written by Prof. Alex Sinclair & colleagues
- Treatment guidelines highlight the lack of a standard drug therapy in IIH and opportunity for rapid incorporation into treatment guidelines post regulatory clearance
  - Drives clinical use, important for payer coverage

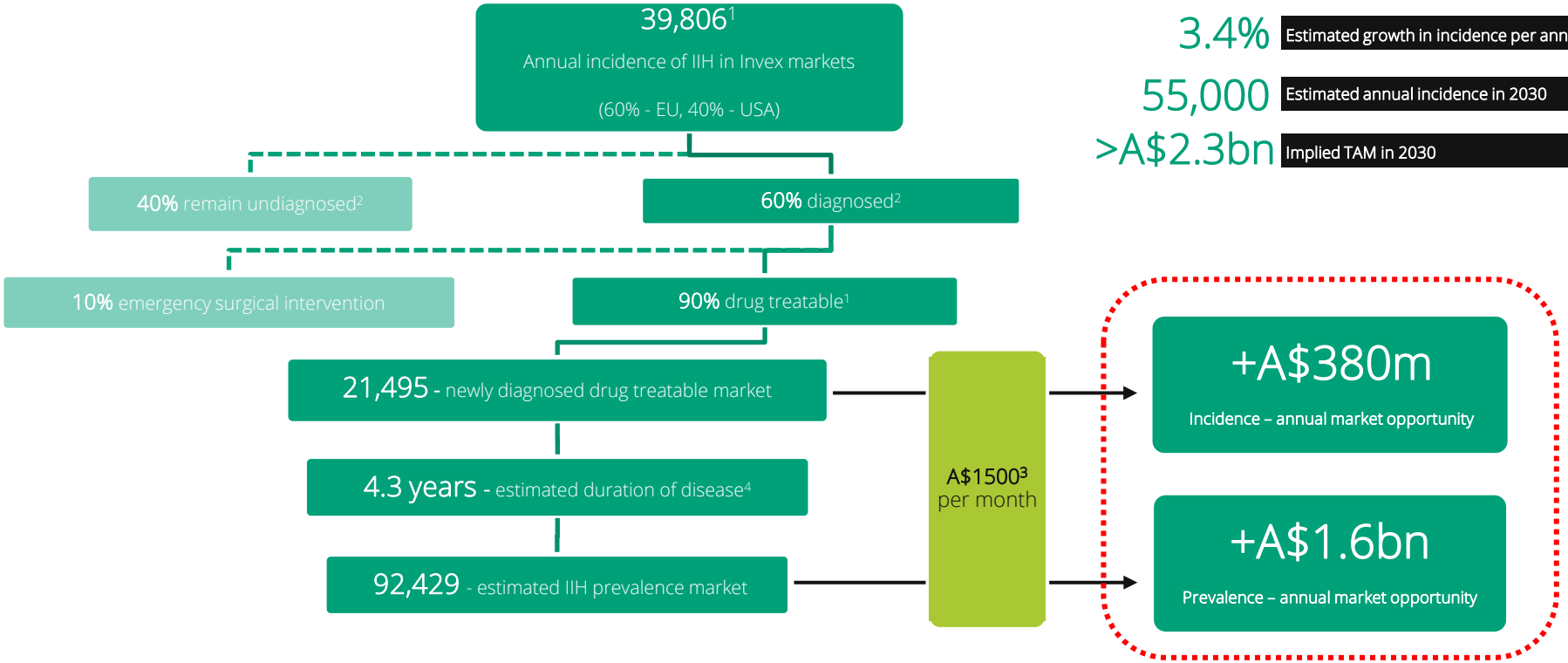




invex therapeutics

1. Mollan SP, et al. Idiopathic intracranial hypertension: consensus guidelines on management (2018); 2. Ball et al., A randomised controlled trial of treatment for IIH (2011), Wall et al, The IIH treatment trial: clinical profile as baseline (2014); 3. Thurtell et al., IIH recognition, treatment and ongoing management (2013); 4. Sergott et al., Optic nerve sheath decompression: a clinical review..(1990); Banta and Farris, Pseudotumor cerebi and optic nerve sheath decompression (2000); 5. Li et al., Meta-analysis: pharmacologic treatment of obesity (2005), Ko et al., Weight gain and recurrence in idiopathic intracranial hypertension (2011)

IIH Total addressable market (TAM)



3.4% Estimated growth in incidence per annum[5]

55,000 Estimated annual incidence in 2030

>A$2.3bn Implied TAM in 2030

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

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]

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

Invex Phase II trial – design & outcomes

Study Purpose

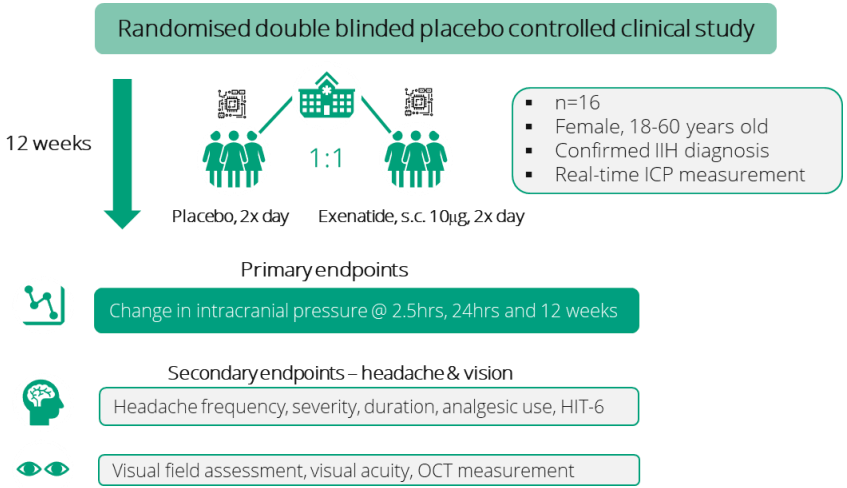
- Obtain first clinical proof of concept for Exenatide in IIH and provide a basis to move into pivotal Phase III trial by leveraging orphan drug status in Europe and the United States

Efficacy Outcomes

- 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 (7.7 days / 37% versus placebo)
- Secondary Endpoint (Vision) Met – statistically significant & clinically meaningful improvement in visual acuity (0.1 logMAR improvement at 12 weeks, equivalent to one line of visual acuity)

Safety Results

- No serious adverse events (SAEs) were observed related to the use of Exenatide
- Overall, adverse events were relatively low, with nausea the most common seen in >85% of patients treated with Exenatide
- Nausea is a known and the most frequent AE of sub-cutaneous administration of this formulation of Exenatide (Byetta®)



Conclusion

- 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.

Lead-In Activities Ahead of Planned Phase III Trial

Reformulation

- Successfully completed a series of animal pharmacokinetic (PK) studies in CY2020 with proprietary formulations
- COVID-19 impacted access to laboratory personnel and testing facilities in Q4 CY2020
- Final formulation candidate for planned clinical studies pending
- Formulations are subject of additional patent filings made by Invex in Q1 CY2020

Tolerability*

- All Presendin™ formulation excipient(s) have been used in already approved drugs and have a well-established safety profile
- Invex only required to undertake one additional safety study to assess local tolerability at the injection site (in animals)
- Study expected to commence in 1H CY2021

Manufacturing

- Require a Contract Manufacturing Organisation (CMO) to manufacture and supply clinical-grade Presendin™ for human clinical trials & perform other activities required by government regulators
- Discussions with globally-recognised manufacturers capable of production and supply are well-advanced
- Final sign off for supply of Good Manufacturing Practice (GMP) Presendin™ pending

Human PK Study*

- As a reformulation of an existing approved drug, a Phase I human pharmacokinetic (PK) study required
- Single and repeated sub-cutaneous doses in healthy (obese) volunteers
- Total amount of bioavailable drug must not exceed that approved for reference Exenatide drug product Byetta®

* Subject to availability of GMP grade Presendin™

Regulatory update

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 EU

European Medicines Agency (EMA)

July 2020: First Response to Protocol Assistance

- One well controlled study providing compelling evidence of safety and efficacy required for marketing authorisation application (MAA) in EU
- CHMP[1] recommended ICP as primary endpoint versus placebo
- Noted headache would also be a clinically meaningful endpoint
- Broad acceptability of Invex's pre-clinical package and human PK study plans

December 2020: Second Protocol Assistance Feedback

- Follow up submission for advice lodged in October 2020
- Successfully concluded process with EMA in December 2020
- Following feedback in late Q4 CY2020, Invex intends to submit a Clinical Trial Application (CTA) within select European countries
- Single pivotal clinical trial for registration of Presendin™ in EU expected to commence thereafter

US Food and Drug Administration (FDA)

July 2020: First Response to Protocol Assistance

- Initial submission asked for advice on either headache or vision as the preferred primary endpoint – reviewed by Division of Ophthalmology
- Requested a complete protocol and statistical analysis plan prior to detailed scientific advice
- Reduction in headache days of moderate to severe headaches a clinically meaningful endpoint
- Broad acceptability of Invex's pre-clinical package

Q1 2021: Submit for Type B / Pre-IND Meeting

- Detailed protocol assistance to be sought following response from EMA and preparation of a full study protocol and statistical analysis plan
- Preferred review by Division of Neurology at FDA
- Over-arching strategy is to align study protocol acceptable to the FDA for a single registration trial that meets requirements of EMA & FDA leveraging orphan drug designations in both jurisdictions

CHMP[1] – Committee for Medicinal Products for Human Use

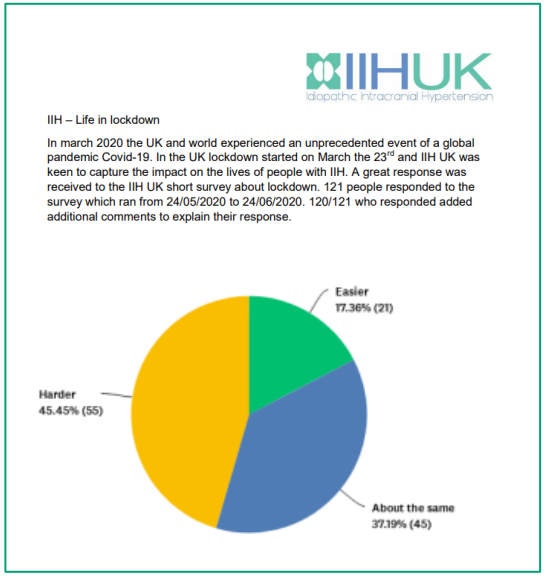
Negative Impact of COVID-19 Lockdown in the UK on IIH

Prospective Evaluation Study Showed 4.7 Fold Increase in Emergency Surgical Interventions to Avoid Permanent Vision Loss

- Study (n=139 over 10 weeks) showed increased risk of disease deterioration and CSF shunting in those with both existing and new IIH
- **367% increase** in surgical rate due to impaired access to emergency care, delayed routine waiting times and lifestyle changes under lockdown
- Increases in anxiety and depression noted, and weight gain

IIH UK Survey[2] Highlights Significant Quality of Life Impacts on IIH Patients

- **45%** felt living with IIH was **harder** under UK lockdown
- Challenges of access to medical care was a common theme with cancelled appointments, unable to get hold of medical teams and a lack of information
- Increase in stress, reduction in activity and increase in weight made IIH condition worse



Multi-City Lockdowns During COVID-19 Have Highlighted the Significant Market Need for New Effective (Non-Surgical) Therapies for IIH Patients Outside of Hospital Setting

1. Thaller M, Tsermoulas G, Sun R, *et al* Negative impact of COVID-19 lockdown on papilloedema and idiopathic intracranial hypertension *Journal of Neurology, Neurosurgery & Psychiatry* Published Online First: 24 December 2020. doi: 10.1136/jnnp-2020-325519
2. https://www.iih.org.uk/images/Life_in_lockdown_result_summary.pdf

Summary & Outlook

- Large, growing market for IIH with no approved medical interventions
- **Orphan Drug Designation in the USA and EU** provides expedited, cost-effective clinical trial recruitment, reporting and approval/registration as well as commercial exclusivity for up to 10 years
- Strong Phase II clinical data established
- **Financial:**
  - **$33.6M** in cash at 31 December 2020 – expected to fully fund completion of a Phase III clinical trial in IIH for registration
  - Very attractive ~**$28M** Enterprise Value (EV) considering stage of development and market attributes
  - Large EV discount to ASX-listed orphan (ASX:CUV, ASX:NEU, ASX:RAC), ophthalmic (ASX:OPT) and re-purposing (ASX:PAR) companies
- **2021 Milestones:**
  - Final Formulation Selection – Near Term
  - Appointment of contract manufacturer – Near Term
  - Pre-IND Submission / Type B Meeting request with FDA – Q1 CY2021
  - Type B Meeting Response from FDA – Q3 CY2021
  - Subject to availability of GMP Presendin™*
    - Human PK study to commence Q3 CY2021
    - Animal tolerability study to commence 1H CY2021
    - Filing of a CTA in Europe for Phase III clinical trial 2H CY2021
    - Commencement of Phase III clinical trial in Europe in late 2H CY2021 to 1H CY2022

* Determined by the contract manufacturer based on available manufacturing slots following formal appointment

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Thank you

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