Invex Therapeutics

Repurposing An Approved Drug

Successfully raises $A12 million and lists on the Australian Stock Exchange

ASX Code: IXC

5 July 2019

FORREST CAPITAL

CPSCapital
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invex
THERAPEUTICS

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Invex Therapeutics - ASX:IXC

- Invex Therapeutics (Invex or the Company) was established March 2019
- Focused on repurposing Exenatide for neurological conditions involving raised intracranial pressure such as idiopathic intracranial hypertension(IIH)
- Assignment of intellectual property from University of Birmingham, United Kingdom
- Prof Alexandra Sinclair is a founder of Invex, CSO and Executive Director
  - clinician and global leader in the pathophysiology of idiopathic intracranial hypertension and headache, with over 10 years research in this field
- Successful Initial Public Offering (IPO) raised the maximum of $A12 million to fund the proposed later stage research and development programme
- Directors and founding shareholders have committed more than $A2.5 million in seed capital and investment at IPO

Capital Structure & Major Shareholders

Capital Structure

- Shares on Issue 55 mil
- Unlisted Options* 3 mil @ 60c
- Cash ~$A11.3 mil
- Market Cap $A 22 mil

Major Shareholders

- Directors / Management 20%
- Minderoo Pty Ltd 9.1%
- Kim Hogan 7.3%
- Tony Grist 7.3%
- Tom Henderson 7.3%
- Jason Peterson 4.5%
- University of Birmingham 3.6%

Top 20 80%

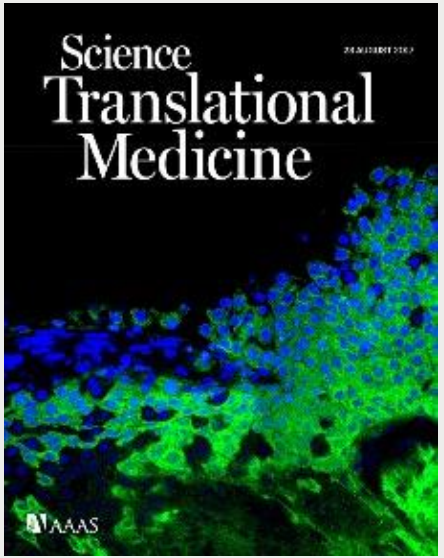
* To be issued within three months of admission to ASX

Board and Management Team

- **Dr Jason Loveridge, Chairman**
  - Experienced life science investor & CEO
- **Prof Alexandra Sinclair, Executive Director and Chief Scientific Officer**
  - Global scientific & clinical leader in IIH
- **Mr David McAuliffe, Non Executive Director**
  - Founder of numerous life science companies
- **Ms Narelle Warren, Non Executive Director and Company Secretary**
  - Expertise in finance and compliance

IPO Investment Highlights

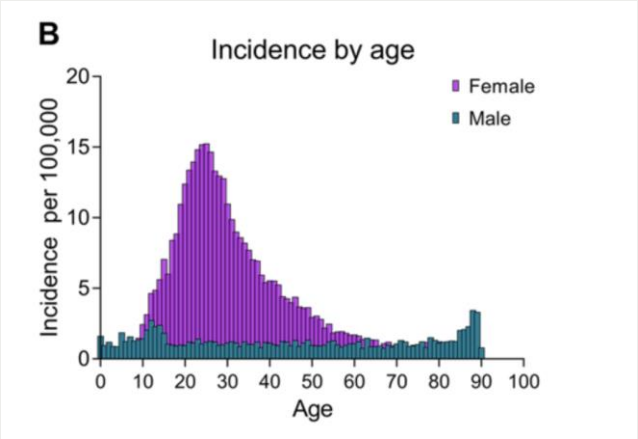
- Completed proof-of-concept preclinical *in-vitro* and *in-vivo* studies
  - data published in world leading scientific journal
- Orphan Drug Designations granted for IIH in Europe (EMA) and in the US (FDA)
- Phase II proof of concept clinical study initiated in IIH
- Lower development risk
- Faster commercialisation strategy
  - an established lower cost business model
- World-class scientific and management team
- Key patent applications filed in 2014 (UK, US, EU)
  - assigned to Invex from University of Birmingham, UK @ IPO



Botfield et al., Sci. Transl. Med. 9 (2017)

Idiopathic Intracranial Hypertension (IIH)

- Disease characterised by raised intracranial pressure & papilloedema
- Symptoms
  - severe headaches
  - visual impairment, with ~25% of patients experiencing permanent loss of vision
- 90% of IIH patients are obese women of childbearing age



IIH peaks between years 20-30

The expanding burden of idiopathic intracranial hypertension, Susan P. Mollan, Magda Aguiar, Felicity Evison, Emma Frew & Alexandra J. Sinclair, Nature Eye volume 33, pages 478–485 (2019)

Ongoing Phase II Study in IIH

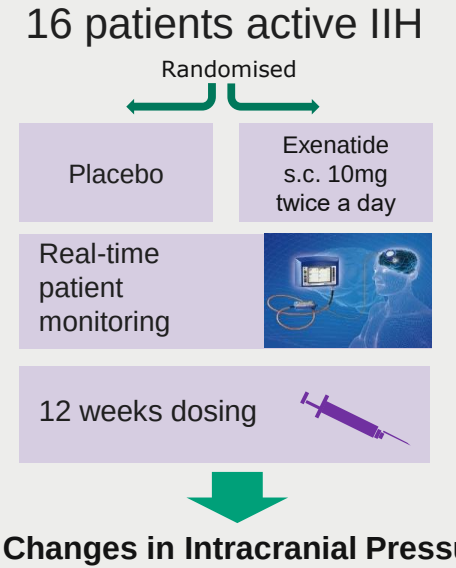
- Phase II proof of concept single centre study
- Randomised double blinded Phase II clinical study
  - 10 patients enrolled & completed to date
  - *6 patients still to be enrolled*
  - top-line dataset available 1H, 2020

Secondary

- Headache measures (frequency, severity, duration, analgesic use, Hit-6)
- Visual assessments (visual field, papilloedema measured by OCT)
- Quality of Life measures

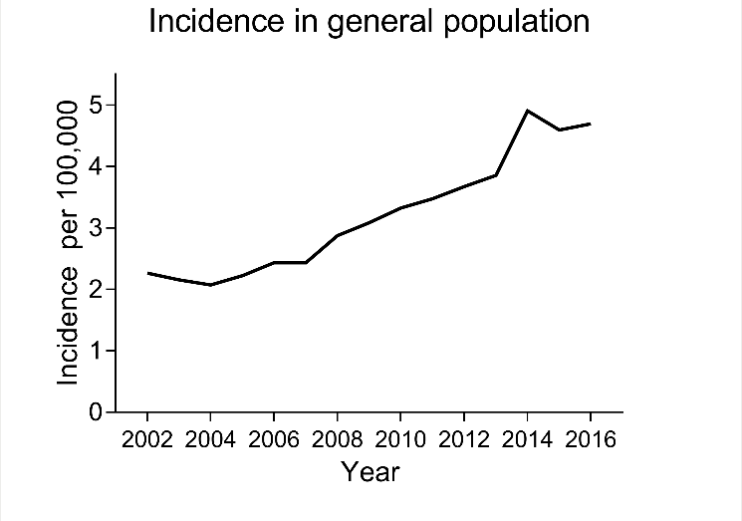
Exploratory

- Serum and cerebrospinal fluid (CSF) Exenatide levels
- Modulation of serum and CSF (adipokines, gut neuropeptides, biomarkers and fat distribution)



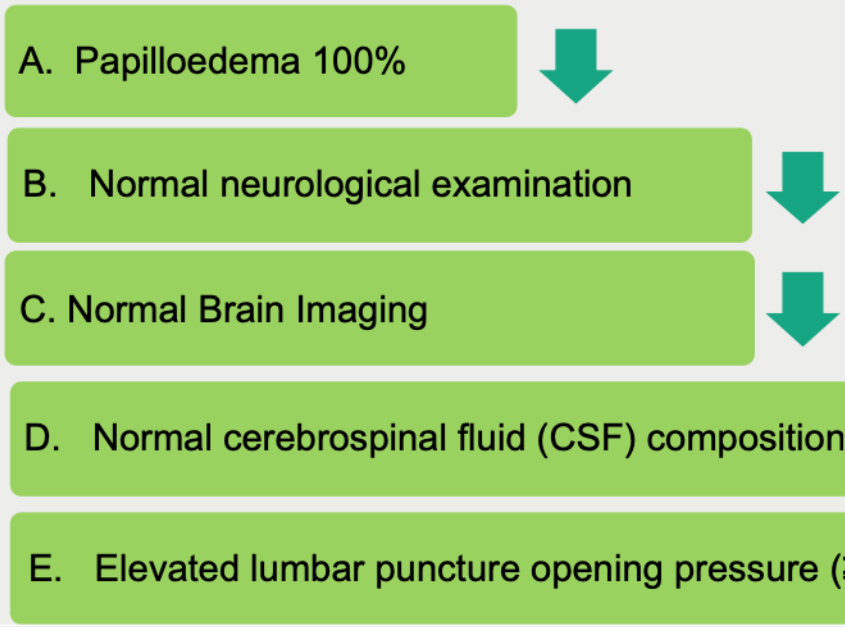
Rising IIH Incidence Linked to Obesity

- IIH is a rapidly growing orphan indication
  - incidence of IIH has more than doubled in the last 10 years
  - incidence is strongly linked to obesity in women



The expanding burden of idiopathic intracranial hypertension, Susan P. Mollan, Magda Aguiar, Felicity Evison, Emma Frew & Alexandra J. Sinclair, Nature Eye volume 33, pages 478–485 (2019)

IIH diagnosis
5-steps, Standardised, Rapid



95% of IIH patients present at either A&E or opticians and are referred to a neurologist for diagnosis & treatment

No approved drugs in IIH and a lack of an effective treatment is the real issue!!

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Mollan SP, *et al. J Neurol Neurosurg Psychiatry* 2018;**0**:1–13

IIH Treatment Guidelines

- Leading role played by Invex's founder Prof Alexandra Sinclair
- Currently no approved drugs for IIH

General neurology

OPEN ACCESS

REVIEW

Idiopathic intracranial hypertension: consensus guidelines on management

Susan P Mollan,[1,2] Brendan Davies,[3] Nick C Silver,[4] Simon Shaw,[5] Conor L Mallucci,[6,7] Benjamin R Wakerley,[8,9] Anita Krishnan,[4] Swarupsinh V Chavda,[10] Satheesh Ramalingam,[10] Julie Edwards,[11,12] Krystal Hemmings,[13] Michelle Williamson,[13] Michael A Burdon,[2] Ghaniah Hassan-Smith,[1,12] Kathleen Digre,[14] Grant T Liu,[15] Rigmor Højland Jensen,[16] Alexandra J Sinclair[1,2,12,17]

Hoffmann *et al. The Journal of Headache and Pain* (2018) 19:93
https://doi.org/10.1186/s10194-018-0919-2

The Journal of Headache and Pain

CONSENSUS ARTICLE Open Access

European Headache Federation guideline on idiopathic intracranial hypertension

Jan Hoffmann[1*], Susan P Mollan[2], Koen Paemeleire[3], Christian Lampl[4], Rigmor H Jensen[5] and Alexandra J Sinclair[6]

HOW TO DO IT

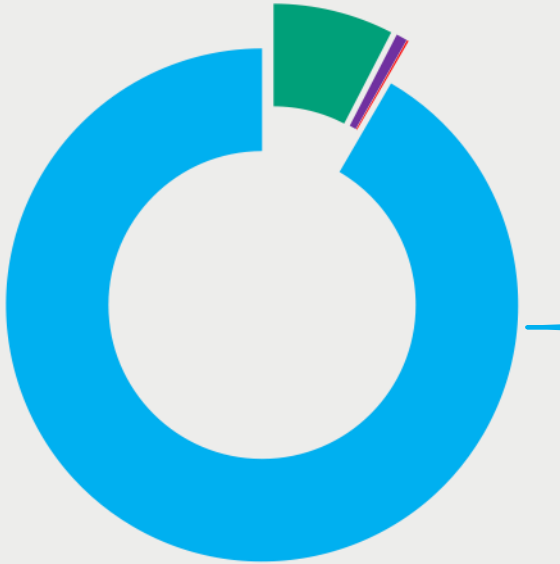
OPEN ACCESS

Evaluation and management of adult idiopathic intracranial hypertension

Susan P Mollan,[1,2] Catherine Hornby,[1,3] James Mitchell,[1,3,4] Alexandra J Sinclair[1,2,3,4]

Current Therapeutic Options are Ineffective

All current medicines for IIH are unapproved*, outdated, work poorly and cause debilitating side effects



Acetazolamide (1954)
Most commonly used drug in IIH
Cochrane review IIH in August 2015 concluded:
"Insufficient evidence to recommend or reject the efficacy of acetazolamide for treating IIH"

Cochrane Library
Cochrane Database of Systematic Reviews

Topiramate (2012)
Prospective open label trial ACZ vs. TOP (Çelebisoy et al. 2007)
Reduction in ICP in both groups, equivalence between groups

Furosemide/Amiloride
Animal studies only, showing reduction in CSF production (Vogh et al. 1982, Melby et al. 1982)

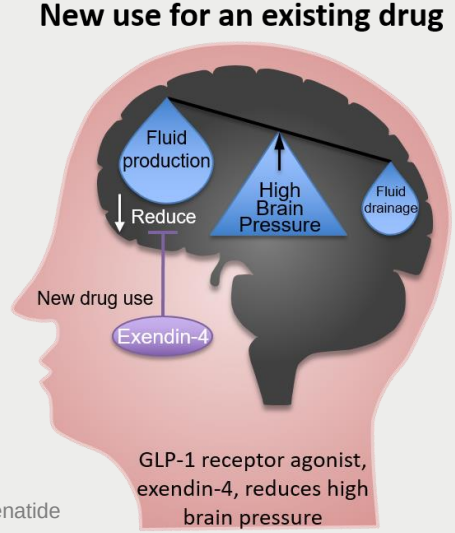
Octreotide
Small prospective open label study with no control showed significant reduction in headache, ICP, and papilloedema (Panagopolous et al. 2007)

* In IIH, ONSF: Optic Nerve Sheath Fenestration, ICP: Intracranial pressure,

The expanding burden of idiopathic intracranial hypertension, Susan P. Mollan, Magda Aguiar, Felicity Evison, Emma Frew & Alexandra J. Sinclair, Nature Eye volume 33, pages 478–485 (2019)

Exenatide – Novel Approach to Raised ICP

- Exenatide is a small peptide that binds the GLP-1 receptor
- GLP-1 receptor agonists – like Exenatide - decrease fluid secretion in the kidney and are used extensively to treat diabetes
- Prof Alexandra Sinclair has shown that GLP-1 receptors are also expressed in the choroid plexus (in the brain), and that in animals
  - Exenatide can bind to these receptors
  - reduce cerebrospinal fluid secretion
  - provide fast onset of action making it suitable for treating patients with raised intracranial pressure



Exendin-4 = Exenatide

Botfield et al., Sci. Transl. Med. 9 (2017)

Invex Proprietary Patented* ICP Blocker

- Exenatide - in its Byetta® form - was approved in 2005 for the treatment of type II diabetes in both the EU & US
  - administered as a twice-daily sub-cutaneous injection
  - commercialized by AstraZeneca
  - safe and well tolerated drug used in millions of diabetic patients**
- Current Exenatide dosing forms are not optimised for IIH
  - only available in 5 or 10mg pre-filled injection pens or long acting weekly injection
- Invex intends to utilise its unique insight into diseases characterised by raised ICP to develop proprietary, patented* dosage forms of Exenatide for IIH and other diseases characterised by raised ICP

ICP: intracranial pressure, * Patent applications licensed for Birmingham University & additional IP filed in 2019 ** https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021773_byettatoc.cfm

Invex's Repurposed Pressure Blocker

- Proprietary and patented
- Aim to be the first & only drug for IIH patients
  - approved for the disease (IIH) by EMA & FDA
  - safety and efficacy established by statistical significance in randomised, double blinded clinical trials
  - assigned unique National Drug Codes
- First mover advantage ensures competing drugs would need to be compared to and be better than Invex's IIH drug in order to gain approval
- Proprietary dosage supported by clinical safety and efficacy prevents substitution with Byetta®

Repurposing Approved Drugs - An Established, Successful Business Model

Drug	Original Disease	New Orphan Disease
Azathioprine	Rheumatoid arthritis	Renal transplant
Bleomycin	Various cancers	Pleural effusion
Colchicine	Gout	Mediterranean fever
Cycloserine	Urinary tract infection	Tuberculosis
Cyclosporine	Rheumatoid arthritis	Transplant rejection
Eflornithine	Unwanted facial hair	Sleeping sickness
Everolimus	Renal cancer	Renal transplant
Histrelin	Prostate cancer	Precocious puberty
Infliximab	Ulcerative colitis	Chron's disease
Interferon alpha	Hepatitis B & C	Cancer
Rituximab	Rheumatoid arthritis	Cancer

Source: The US FDA

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