



## ASX Announcement

2 April 2020

# March 2020 Quarterly Report

---

**Invex Therapeutics Ltd (Invex, ASX: IXC, or the Company)** is pleased to provide an operational and corporate update to accompany its Appendix 4C for the quarter ended March 2020.

## Operational Update

---

### Clinical Research Activities

In January, Invex announced the last patient completed the 12 week dosing regimen under the Company's randomised Phase II, double blind, placebo-controlled clinical trial examining the treatment of Idiopathic Intracranial Hypertension (IIH) with Exenatide. The treatment component of the trial is now complete and data is being analysed, with results expected to be released in the second quarter of 2020.

The Phase II clinical trial has been designed to assess whether Exenatide can significantly reduce intracranial pressure in IIH patients, and to gather data which will be necessary to design a subsequent registration-directed, single pivotal trial to gain regulatory clearance for the Company's reformulated Exenatide in IIH in the United States (US) and Europe. Exenatide has orphan drug designation in the US (FDA) and Europe (EMA).

The Company continued to make excellent progress in the reformulation work for Exenatide and has trademarked its first repurposed dosage form of Exenatide as Presendin™. During the quarter, the Company continued to evaluate a number of potential formulations for Presendin™ which could provide up to 24 hours of therapeutic benefit in patients. The Company is finalising a lead formulation and has lodged a patent application to cover the approach and variants thereof. The Company is also working with a leading pharmaceutical consultancy to help assist with selection of a manufacturer to provide sufficient quantities of Presendin™ to conduct additional clinical research, including the Phase III study.

### Scientific Advisory Board

The Company has been actively working on the design and planning of its Phase III study for Presendin™ in IIH. The Company engaged eight leading global clinicians who specialise in headache and neuro-ophthalmology, to provide their invaluable experience and contributions to the Phase III clinical design and submissions for scientific advice to the FDA and EMA.



## Operational Update

---

### **Major Research Grant Awarded to Professor Alex Sinclair**

On 5 March 2020, the University of Birmingham announced Professor Sinclair, Invex's Chief Scientific Officer and Executive Director, had been awarded a £1.68m (A\$3.4m) grant from the Sir Jules Thorn Charitable Trust covering a 5-year programme focussing on IIH. Professor Sinclair runs one of the largest clinical services for people with IIH and was instrumental in defining the first international guidelines to drive patient care.

Professor Sinclair plans to use the research grant to better understand the potential of Exenatide in the treatment of IIH and its effects on the key hallmarks of the disease. The award of this grant reflects the growing interest in IIH medical research and the need to develop new non-surgical treatment approaches to improve both clinical symptoms of the disease (headaches, vision) and patients' quality of life.

### **Intellectual Property Portfolio**

The Company is pleased to report that during the quarter, it completed and filed a first patent application covering key intellectual property for its first reformulation of Exenatide, including a trademark for this reformulation called Presendin™ as mentioned above.

## Corporate

---

During the quarter, Invex released an updated corporate presentation for investors. The Company believes the annual incidence of Presendin™ treatable patients in the US and Europe is approximately 21,500 patients. The prevalence pool of patients is considerably larger, with approximately 93,000 patients living with the significant burden of IIH disease. The total addressable market (TAM) by value Invex believes is approximately \$1.6 billion.

The Company closed the quarter with a cash position of \$10.427 million, providing sufficient funding to complete the Phase II study analysis and to complete all major lead-in requirements for the planned Phase III study commencing in the first half of 2021.



## Milestones & Outlook

---

As recently articulated in the corporate presentation for investors, Invex has a number of key milestones for the remainder of 2020, including:

- Results of the Phase II clinical study (2Q 2020)
- Complete animal tolerability study for reformulated Exentide (2Q 2020)
- Finalisation of the Presendin™ Phase III design (3Q 2020)
- Results of the human PK study (4Q 2020)
- Filing of an Investigational New Drug (IND) application with the US FDA (1Q 2021)

***This release dated 2 April has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.***

**ENDS**

---

### **For more information, please contact:**

**Company**

David McAuliffe  
Non Executive Director  
[dmcauliffe@invextherapeutics.com](mailto:dmcauliffe@invextherapeutics.com)  
+61 408 994 313

**Investors**

Dr Thomas Duthy  
Nemean Group  
[tduthy@nemean.com.au](mailto:tduthy@nemean.com.au)  
+61 402 493 727

**Media**

Margie Livingston  
Ignite Communications  
[margie@ignitecommunications.com.au](mailto:margie@ignitecommunications.com.au)  
+61 438 661 131



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

## About Idiopathic Intracranial Hypertension

---

IIH features severely raised intracranial pressure which causes disabling daily headaches and can compress the optic nerve, causing permanent vision loss in 25% of those affected. The usual age of onset is 20-30 years, and it is most common in women who are obese. IIH is a rapidly growing orphan indication: its incidence has increased by more than 350% in the last 10 years.

## About Exenatide

---

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which received approval in the US and Europe for the treatment of type 2 diabetes in 2005 and 2006 respectively. Professor Alexandra Sinclair's research showed that GLP-1 receptors are expressed in the choroid plexus in the brain and that Exenatide can bind to these receptors and reduce secretion of cerebrospinal fluid. Current Exenatide dosage forms are not optimised for IIH.

## About Exenatide Phase II Clinical Trial

---

The Exenatide clinical trial in IIH is a single centre, randomised Phase II, double-blind, placebo-controlled clinical trial in 16 patients with active IIH comparing sub-cutaneous (s.c.) 10 µg Exenatide twice daily with placebo. The primary endpoint of the study is the change in intracranial pressure over 12 weeks of dosing as measured by real-time patient monitoring devices.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Invex Therapeutics Ltd

**ABN**

29 632 145 334

**Quarter ended ("current quarter")**

31 March 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(300)	(535)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(21)	(21)
(f) administration and corporate costs	(134)	(470)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	39	131
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(416)</b>	<b>(895)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(848)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>(848)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	10,843	12,170
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(416)	(895)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(848)
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>10,427</b>	<b>10,427</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,427	843
5.2	Call deposits	9,000	10,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>10,427</b>	<b>10,843</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

74

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

\$17,500 was paid to Prof. Alexander Sinclair for Executive director services.

\$8,750 was paid to David McAuliffe for Non-executive Director fees.

\$17,500 was paid to Warambi Ltd, a company controlled by Dr Jason Loveridge for R&D consultancy services.

\$30,000 was paid to Concept Biotech Pty Ltd, a company which David McAuliffe and Narelle Warren are directors and shareholders for the provision of accounting and company secretarial services.

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-

7.5 **Unused financing facilities available at quarter end** -

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(416)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	10,427
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	10,011
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	24

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

- Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

- Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

- Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:



## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 2 April 2020

Authorised by: Narelle Warren  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.