

# **ASX Announcement**

24 July 2019

# June 2019 Quarterly Report

**Invex Therapeutics Ltd (Invex**, ASX: **IXC**, or the **Company**) is pleased to provide a corporate and operational update to accompany its Appendix 4C for the quarter ended June 2019.

## Corporate

Invex was established in March 2019 as a later-stage 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 completed a successful Initial Public Offering (IPO) to raise \$12 million at an issue price of \$0.40 per share and commenced trading on the Australian Securities Exchange (ASX) on 5 July 2019.

The IPO closed oversubscribed and received strong support from investors, with cornerstone investor Minderoo Group Pty Ltd securing a 9.09% holding in the Company.

Having completed a successful IPO the Company was assigned the intellectual property rights from the University of Birmingham, UK, including the Orphan Drug Designations for both Europe and the USA, which underpins the Company's focus on developing and commercialising more than 10 years of scientific discovery and technology development by Professor Alexandra Sinclair and her team at the University of Birmingham.

Upon completion of the IPO Professor Sinclair was appointed an Executive Director and Chief Scientific Officer of Invex.

Invex plans to use the funds from the IPO to support the expansion of its intellectual property portfolio, complete the repurposing of Exenatide for the treatment of neurological conditions derived from or involving raised intracranial pressure, finalise an on-going clinical study in IIH and initiate a second proof of concept clinical study in another indication.

The Company closed the quarter with a cash position of \$12.17m.



# **Operational Update**

#### **Preclinical and Clinical Research Activities**

Invex was established on the basis of research undertaken at the University of Birmingham, UK, by Professor Sinclair. Professor Sinclair is an Executive Director and the Chief Scientific Officer of the Company, and a clinician and global leader in the treatment and pathophysiology of IIH.

Professor Sinclair's extensive preclinical research has demonstrated that Exenatide, already approved for treatment of type 2 diabetes, can reduce intracranial pressure in animal models. This research was published in 2017 in the leading scientific journal, *Science Transitional Medicine*.

The Company is currently in the process of reformulating Exenatide to optimise the delivery of the drug for patients with diseases involving raised intracranial pressure. In addition, a proof of concept phase II randomised double blinded study of Exenatide in IIH is progressing to plan with the enrolment of 10 out of 16 patients. Topline data from the study is expected in the first half of 2020.

IIH is a severe condition which can lead to disabling headaches and permanent vision loss. There are currently no effective pharmaceutical treatments for IIH, and its prevalence in women has more than tripled between 2005-2017.

#### **Intellectual Property Portfolio**

The Company has acquired from the University of Birmingham relevant patent applications covering the use of GLP-1 receptor agonists in conditions featuring raised intracranial pressure. In addition, Orphan Drug Designations for the use of Exenatide in the treatment of IIH from the European Medicines Authority and the US Food & Drug Administration have been assigned to the Company.

## **Recently Published Research**

The Company welcomed the recent publication of Professor Sinclair's study on IIH in the prestigious publication *JAMA Neurology* on 8 July 2019. The study titled 'Association between idiopathic intracranial hypertension and risk of cardiovascular diseases in women in the United Kingdom' provided evidence that IIH patients are at twice the risk of heart conditions and stroke.



### Outlook

Invex has laid strong foundations and plans to rapidly progress the development and commercialisation of treatments for IIH and other specific neurological conditions derived from raised intracranial pressure. The Company has already made significant progress in its research activities and is anticipating data from its first phase II proof of concept clinical study in the first half of 2020.

Dr Jason Loveridge, Chairman of Invex commented: "Invex has the necessary commercial strategy, partnerships, leadership and a world class scientific team in place to make a difference and provide real solutions for patients of diseases involving raised intracranial pressure.

I am delighted to welcome Minderoo Group as our cornerstone investor and would like to thank all our shareholders for the strong and continued support we received since listing.

I am very pleased at the high calibre team we have in place and in particular welcome Professor Sinclair to the Invex Board and congratulate her on the IIH study published in *JAMA Neurology*. Professor Sinclair's recent round table talks with NASA, seeking solutions to reduce brain pressure, further highlights the strength and quality of our research base. I look forward to updating the market with more of our upcoming activities as we enter our first quarter as an ASX listed company."

#### **ENDS**

### For more information, please contact:

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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. <a href="https://www.invextherapeutics.com">www.invextherapeutics.com</a>

#### **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 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.

## **Idiopathic Intracranial Hypertension (IIH)**

- IIH features severely raised intracranial pressure which causes disabling daily headaches and compresses 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.

# **Appendix 4C**

# Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

### Name of entity

Invex Therapeutics Ltd	
ABN	Quarter ended ("current quarter")
29 632 145 334	30 June 2019

Cons	olidated statement of cash flows	Current quarter \$A'000	From incorporation 8 March to 30 June \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(60)	(60)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	-	-
	(f) administration and corporate costs	(52)	(52)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other – asx listing fee and due diligence costs	(118)	(118)
1.9	Net cash from / (used in) operating activities	(230)	(230)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	(8)	(8)
	(e) other non-current assets	-	-

<sup>+</sup> See chapter 19 for defined terms

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<sup>1</sup> September 2016

Consoli	idated statement of cash flows	Current quarter \$A'000	From incorporation 8 March to 30 June \$A'000
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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)	-	-
2.6	Net cash from / (used in) investing activities	(8)	(8)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	12,500	12,500
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	(92)	(92

3.10	Net cash from / (used in) financing activities	12,408	12,408
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	-	<u>-</u>
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(230)	(230)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(8)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	12,408	12,408

<sup>+</sup> See chapter 19 for defined terms

3.5

3.6

3.7

3.8

3.9

Proceeds from borrowings

Repayment of borrowings

borrowings

Dividends paid

Transaction costs related to loans and

Other (provide details if material)

Consc	plidated statement of cash flows	Current quarter \$A'000	From incorporation 8 March to 30 June \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	12,170	12,170

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	12,170	12,170
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	12,170	12,170

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	30
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

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

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
7.3	Include below any explanation necessary to understand the transaction and 7.2	s included in items 7.1

<sup>+</sup> See chapter 19 for defined terms

Financing facilities available Add notes as necessary for an understanding of the position	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
oan facilities	-	-
Credit standby arrangements	-	-
Other (please specify)	-	-
2	Add notes as necessary for an understanding of the position  oan facilities  Credit standby arrangements	at quarter end \$A'000  oan facilities  Credit standby arrangements  at quarter end \$A'000

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

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	(215)
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	-
9.6	Administration and corporate costs	(196)
9.7	Other – capital raising costs	(848)
9.8	Total estimated cash outflows	(1,259)

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

<sup>+</sup> See chapter 19 for defined terms

#### **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.

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Date: 24 July 2019.....

(Director/Company secretary)

Print name: Narelle Warren

#### **Notes**

Sign here:

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2. If this quarterly 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 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.

<sup>+</sup> See chapter 19 for defined terms