



ASX Announcement

17 January 2020

December 2019 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 December 2019.

Operational Update

Clinical Research Activities

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 the quarter, work progressed as planned and a number of potential formulations were identified which were evaluated in-vivo in the fourth quarter of calendar year 2019.

The Phase II randomised double blinded study of Exenatide in Idiopathic Intracranial Hypertension (IIH) progressed ahead of schedule due to higher than anticipated patient recruitment rates. IIH is a severe condition which can lead to disabling headaches and permanent vision loss in predominately females.

The Phase II clinical trial has been designed to demonstrate that 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).

Intellectual Property Portfolio

During the quarter the Company announced the Japanese Patent had been granted. The Company is actively pursuing patent applications at both the European and the US patent offices.



Corporate

Invex Therapeutics Ltd – UK

On the 12 December 2019 the Company incorporated a UK subsidiary, Invex Therapeutics Ltd (subsidiary). The subsidiary plans to employ a number of scientists to work alongside Professor Alexandra Sinclair to manage and support the Company's clinical trial programmes. The subsidiary has entered into a lease agreement to secure a principal place of business at the Birmingham Research Park in Edgbaston.

Annual General Meeting

The Company's Annual General Meeting (AGM) was held in Sydney on Thursday 21 November 2019. Prior to the AGM Dr Loveridge and Professor Sinclair met shareholders and potential investors.

The Company appointed Dr Tom Duthy from Nemean Group to lead investor relations in 2020 as Invex prepares for the results of its current Phase II study and preparations for a larger registration-directed study.

The Company closed the quarter with a cash position of \$10.843 million.

Subsequent Events

On 13 January Invex announced the sixteenth and final patient enrolled had completed the 12-week dosing regimen under the Company's randomised Phase II, double-blind, placebo-controlled proof of concept clinical trial examining the treatment of Idiopathic Intracranial Hypertension (IIH) with Exenatide. The completion of the Phase II clinical trial for Exenatide represents an important milestone for Invex, its shareholders and patients living with the burden of IIH. Invex eagerly awaits the independent analysis of the study findings and the reporting of the clinical results to the market.

The Company is pleased to report the formal appointment of Professor Alexandra Sinclair, Chief Scientific Officer and Executive Director of Invex, to the Board of Trustees of the prestigious International Headache Society (IHS). IHS produces and issues clinical guidelines, notably the International Classification of Headache Disorders (ICHD) and guidelines related to running controlled clinical trials across a range of headache disorders. Such guidelines will be an important component in shaping Invex's future clinical and commercial plans.



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 development activities and as recently announced to the market expects top-line results for the Phase II trial in late Q1 2020 to early Q2 2020.

This release dated 17 January 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:

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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. 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 mg 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 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

29 632 145 334

Quarter ended ("current quarter")

31 December 2019

Consolidated statement of cash flows	Current quarter \$A'000	31 Dec \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(176)	(235)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	-	-
(f) administration and corporate costs	(141)	(283)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	44	92
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other – D&O insurance	-	(53)
1.9 Net cash from / (used in) operating activities	(273)	(479)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	31 Dec \$A'000
(d) intellectual property	-	-
(e) other non-current assets	-	-
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	-	-

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	-	-
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	-	(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)	-	-
3.10 Net cash from / (used in) financing activities	-	(848)

Consolidated statement of cash flows		Current quarter \$A'000	31 Dec \$A'000
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	11,116	12,170
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(273)	(479)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
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	-	-
4.6	Cash and cash equivalents at end of quarter	10,843	10,843

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	843	1,116
5.2	Call deposits	10,000	10,000
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)	10,843	11,116

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	74
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	

\$17,500 was paid to Prof. Alexander Sinclair for Executive director services.
 \$8,750 was paid to David McAuliffe for Non-executive Director fees.
 \$8,750 was paid to Warambi Sarl, a company controlled by Dr Jason Loveridge for Non-executive director fees.
 \$8,750 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. 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 transactions included in items 7.1 and 7.2	

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-
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.		

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9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	(694)
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	(189)
9.7 Other	-
9.8 Total estimated cash outflows	(883)

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	-	-

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.



Sign here:Date: 17 January 2020.....
(Director/Company secretary)

Print name: Narelle Warren

Notes

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.