



ASX / Media Release
19 April 2022

March Quarterly Activities Report & Appendix 4C

The Company will host an investor conference call today at 12.00pm AEST with Dr Thomas Duthy, Executive Director, details below
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Invex Therapeutics Ltd (Invex, ASX:IXC, or the Company) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release Exenatide) for neurological conditions relating to raised intracranial pressure, is pleased to provide an operational and corporate update to accompany its Appendix 4C cash flow statement for the quarter ended 31 March 2022 (Q3 FY22).

Operational Update

IIH EVOVE Phase III Clinical Trial

During the quarter, Invex continued to advance the necessary preparative work for commencement of the global IIH EVOLVE Phase III clinical trial. The Company completed a number of key service contracts with third party vendors, including with a leading contract research organization as well as drug importation, packaging, labelling and distribution companies.

In addition, Invex is working closely with its manufacturing partner Peptron (KOSDAQ: 087010) and advisors to complete the necessary technical manufacturing and control documentation alongside a comprehensive review of non-clinical and clinical data for Exenatide in preparation for Invex's Clinical Trial Applications (CTAs) planned for the UK, Europe and the US during the June quarter.

The Company has also been actively engaging with potential clinical sites for participation in the IIH EVOLVE clinical trial. Progress has been excellent to date, with more than 40 centres identified. Invex aims to open approximately 37 clinical sites across the US, Europe, the UK, Australia, New Zealand and Israel.

Scientific Meeting Presentations and Peer Review

In February, two oral presentations relating to the Phase II Pressure trial in Idiopathic Intracranial Hypertension (IIH) were given by Professor Alex Sinclair and Dr James Mitchell at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS) on 12-17 February 2022 in Austin, Texas. The oral abstract "A Randomized Controlled, Trial of the GLP-1 Receptor Agonist Exenatide in Idiopathic Intracranial Hypertension" was subsequently awarded the best abstract by a resident at the NANOS meeting.

Conference presentations and ‘podium presence’ are key components of the peer review process, with Invex representatives at the NANOS meeting pleased with the interest and engagement from the neuro-ophthalmology community on the results of the Phase II Pressure trial and Invex’s plans for the Phase III IIH EVOLVE clinical trial. Further presentations will be undertaken at the European Neuro-Ophthalmology Society (EUNOS) meeting in June in Birmingham, UK.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a continued strong financial position with cash and cash equivalents of \$30.4 million (Q2 FY22: \$31.4 million), with overall cash outflows for the quarter of \$1.0 million (Q2 FY22: \$0.62 million).

Cash outflows from operating expenditure included:

- Product manufacturing & operating costs for the quarter of nil (Q2 FY22: \$0.14 million) represented the timing effect of initial purchases of Presendin™ and placebo drug product from Invex’s manufacturing partner Peptron in Q2 FY22. Additional purchases of drug product for Invex’s Phase III trial are expected in subsequent periods as the Phase III trial ramps and patient recruitment increases.
- Research & Development expenditure for the quarter of \$0.67 million (versus \$0.33 million in Q2 FY22) reflected an increase in costs associated with the Company’s contract research organisation managing the Phase III trial, along with clinical and regulatory consultants, and intellectual property costs related to Invex’s patent and trademark portfolio. In addition, the Company incurred costs associated with direct R&D staff of \$0.16 million (versus \$0.12 million in Q2 FY22).
- Administration and corporate costs of \$0.21 million (versus \$0.23 million in Q2 FY22) decreased 9%. These costs include compliance costs associated with an ASX listed company, Director’s fees, audit and legal costs.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were \$0.3 million for the quarter (versus \$0.27 million in Q2 FY22). This increase reflects the transition of Professor Alex Sinclair to an employee of Invex for three days per week and an increase to consulting fees of the Chairman Jason Loveridge, both announced to ASX on 31 January 2022.

Government grants and tax incentives were Nil compared to \$0.18 million received from the UK government for eligible FY21 R&D expenditure in Q2 FY22. As the Company is undertaking active R&D in Australia with the Phase III trial, Australian government R&D Tax Incentives are expected to be recognised in future financial years.

Cash outflows are expected to increase in subsequent periods as the Company commences recruitment for the Phase III IIH-EVOLVE trial. Notwithstanding the increase in cash utilisation in

subsequent periods, the Company is fully funded to complete this trial for Presendin™ registration purposes in the EU, UK and Australia from current cash reserves.

Investor Relations

In March, Invex presented at the Tech/Biotech Broker Briefing. Broker Briefing is one of Australia's premier digital broker and investor platform for leading ASX listed companies with over 6,000 members and 5,000 subscribers. The webcast is available on the Invex website at: <https://invextherapeutics.com/presentations/>.

In March, MST Access initiated equity research on the Company, with a valuation of \$3.38 per share. This issuer sponsored research was undertaken by healthcare and biotech equities analyst Chris Kallos. The MST Access offering includes full research coverage, equity research briefs, showcase events, firmwide access and distribution network into institutional & other investors. A copy of the research is available at: <https://invextherapeutics.com/analyst-reports/>

Invex has also provided an update to its Fact Sheet as at April 2022, which is available on the Company's website at: <https://invextherapeutics.com/fact-sheets/>.

Investor Conference Call

The Company will host an investor conference call today at 12.00pm AEST with Dr Thomas Duthy, Executive Director.

Details of the call are set out below.

In order to pre-register for the conference call and avoid a queue when calling, please follow the link below. You will be given a unique pin number to enter when you call which will bypass the operator and give you immediate access to the event. Investors are advised to register for the conference in advance by using the Diamond Pass link to avoid delays in joining the call directly through the operator:

<https://s1.c-conf.com/diamondpass/10021298-agsy6w.html>

Alternatively, you may dial in with the following details, approximately five minutes before the scheduled start time and provide the Conference ID to an operator.

Conference ID: **10021298**

Participant Dial-in Numbers:

Australia Toll Free: 1800 908299

Australia Local: +61 2 9007 8048

New Zealand: 0800 452 795

Canada/USA: 1855 624 0077

Hong Kong: 800 968 273

Japan: 006 633 868 000

China: 108 001 401 776
Singapore: 800 101 2702
United Kingdom: 0800 0511 453

- ENDS -

This release dated 19 April 2022 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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. Invex has trademarked its repurposed Exenatide as Presendin™. www.invextherapeutics.com.

About Idiopathic Intracranial Hypertension (IIH)

IIH features severely raised intracranial pressure which causes disabling daily headaches and can compress the optic nerve. 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 Presendin™

Presendin™ is a once per week, sub-cutaneous, sustained-release (SR) Exenatide microsphere formulation originally developed by Peptron, Inc. (KOSDAQ: 087010). In September 2021 Invex entered into an exclusive collaboration, manufacturing and supply agreement with Peptron for Presendin™ in IIH for all major markets, with the exception of South Korea.

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which is currently approved for the treatment of type 2 diabetes. In 2017, Invex received orphan drug designation for Exenatide in IHH from the US Food and Drug Administration and European Medicines Agency.

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 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(655)	(1,311)
(b) product manufacturing and operating costs	-	(141)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs – R&D	(164)	(401)
(f) administration and corporate costs	(207)	(664)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	18	57
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	184
1.8 Other (D&O insurance)	-	(82)
1.9 Net cash (used in) operating activities	(1,008)	(2,358)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
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	-	-
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.	-	-
3.10	Net cash from / (used in) financing activities		

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	31,366	32,716
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,008)	(2,358)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	30,358	31,366

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	1,308	1,306
5.2 Call deposits	29,050	30,050
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)	30,358	31,366

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**

295

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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

Relates to salaries, consulting and fees paid to Directors. Payments of \$32,500 for company secretarial and financial services to Concept Biotech of which Mr McAuliffe is a director and shareholder are included.

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.

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

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.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,008)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	30,358
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	30,358
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	30

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: 19 April 2022

Authorised by: Narelle Warren
(On behalf of the Board of Directors)

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.