ASX / Media Release
23 July 2024

June Quarterly Activities Report & Appendix 4C

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a biopharmaceutical company focused on the development and commercialisation of Exenatide for neurological conditions relating to raised intracranial pressure (ICP), today provides an operational and corporate update to accompany its Appendix 4C cash flow statement for the quarter ended 30 June 2024 (Q4 FY24).

Operational Update

IIH EVOLVE Phase III Clinical Trial Closure

During the quarter, the Company completed the final close-out payments to the Contract Research Organisation (CRO) under the termination agreement negotiated by Invex. The Company does not anticipate any further material costs associated with the IIH EVOLVE clinical trial moving forward.

In addition, with the CRO, the Company completed the analysis of the safety and efficacy data of those 14 Idiopathic Intracranial Hypertension (IIH) patients who commenced treatment with Presendin™ (sustained release Exenatide) or placebo prior to the early termination of the trial. Under the Food and Drug Administration Amendments Act (FDAAA) s801 Invex is required to report all results of the trial.

Due to the early termination of the study, planned analyses were not fully conducted but were restricted to the most relevant safety endpoints. Outcome measure (efficacy) data was limited to raw data from individual subjects, with the Company and its advisors undertaking negligible analysis. Measures included intracranial pressure (ICP), change in perimetric mean deviation (PMD), papilloedema, monthly headache days and moderate to severe headaches.

Where an outcome measure specified change from baseline to Week 24, baseline and Week 24 values were disclosed with no interpretation. Efficacy data were not subject to the same verification as safety data and no efficacy conclusions can be drawn, given the very small numbers and the fact most patients (10 of 14) did not complete the full 24 weeks of treatment per the study protocol due to Invex stopping recruitment into the trial in August 2023.

The Company completed the necessary updates, which was accepted by clinicaltrials.org and published on its website on 25 April 2024.

The data is available at https://clinicaltrials.gov/study/NCT05347147.

IIH Orphan Drug Designations Renewed

During the quarter, the Company successfully completed and submitted the annual review of its granted Orphan Drug Designations (ODDs) for IIH, held with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). The maintenance of the Company's ODD portfolio in IIH provides market exclusivity of seven years (United States) and ten years (Europe) upon market approval(s).

SME Status Renewed in Europe

Invex prepared and renewed its micro, small and medium-sized enterprise (SME) status with the EMA during the quarter. Securing SME status provides a number of incentives for the Company including regulatory, administrative and procedural assistance, fee reductions and deferrals for certain regulatory interactions with the EMA during development and following approval, along with translation of documentation into all European Union languages.

Traumatic Brain Injury

The Company continues to explore opportunities to develop Exenatide in the treatment of moderate to severe Traumatic Brain Injury (TBI). A review of the scientific literature is supportive of the benefits of Exenatide (and sustained-release formats) based on certain animal models of TBI. Invex retains a strong intellectual property position in TBI with a granted US patent and an ODD in Europe for TBI.

During the quarter the Company held discussions with certain potential collaborators regarding the application of Exenatide in TBI.

Corporate Development

The Company continues to assess certain corporate partnerships that may complement Invex's existing intellectual property assets within the neurological field or more generally that could generate additional shareholder value over time. A number of potential assets were reviewed during the quarter. However, none are sufficiently developed to warrant further comment by the Company at this time and no binding commitments have been made.

Corporate Update

UK R&D Tax Incentive

On 21 June 2024, Invex announced the receipt of £633k ($1.2 million) to the Company's wholly owned UK subsidiary from the UK government for eligible R&D expenditures made by Invex during the 2023 financial year. Processing of this claim by the UK HM Revenue and Customs (HMRC) was significantly delayed, as announced to the market in March 2024.

The 2023 financial year represented a significant R&D spend for the organisation, predominately associated with the IIH EVOLVE Phase III clinical trial. These funds partially offset our gross R&D spend for the 2023 financial year.

The Company anticipates making an additional claim under the UK government R&D tax relief for small and medium-sized enterprises (SMEs) following additional costs incurred for the IIH EVOLVE Phase III clinical trial in FY24, including the effective close-out of the trial.

Retirement of Non-Executive Director Dr Megan Baldwin

On 18 June the Company announced that Dr. Megan Baldwin has advised of her decision to retire as a Non-executive director of the Company effective 30 June 2024.

On behalf of the Board, the Company would like sincerely thank Dr Baldwin for her service to Invex where she has served as a director since February 2021. Dr Baldwin was a strong and significant contributor to the Board, joining the Company at a critical point as Invex advanced Exenatide from Phase II to Phase III clinical trials in IIH. Her ophthalmology expertise was invaluable. Invex wishes her all the best in her future endeavours.

Financial Summary and Analysis

The Company continued to reduce overheads and prudently manage its cash reserves during the quarter. The Company closed the quarter with cash and cash equivalents of $6.02 million (Q3 FY24: $5.5 million), with overall operating cash inflows for the quarter of $0.57 million (Q3 FY24: outflow of $0.70 million). The cash inflow related predominantly to the $1.2 million received for the 2023 R&D tax rebate (as noted above).

Cash outflows from operating expenditure included:

- Payments for Research & Development expenditure for the quarter of $0.44 million (versus $0.25 million in Q3 FY24) reflecting outstanding invoices associated with the Company's contract research organisation managing the close out of IIH EVOLVE, along with close out of clinical and regulatory consultants, and intellectual property costs related to Invex's patent and trademark portfolio. The Company did not incur any costs associated with direct R&D staff ($0.14 million in Q3 FY24), as the Company no longer has any R&D employees retained within its UK subsidiary.

- Administration and corporate costs of $0.19 million (versus $0.37 million in Q3 FY24) include the compliance costs associated with an ASX listed company, Director's fees, audit and legal costs.

- Other costs relate to the D&O insurance of $70k paid in advance for the 2024/25 year.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were $84k for the quarter.

- ENDS -

This release dated 23 July 2024 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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

Appendix 4C

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

Name of entity	
Invex Therapeutics Ltd	

ABN	Quarter ended ("current quarter")
29 632 145 334	30 June 2024

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(437)	(2,404)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	-	(565)
	(f) administration and corporate costs	(187)	(1,014)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	56	491
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,212	1,212
1.8	Other – (D&O insurance) paid in advance	(72)	(164)
1.9	**Net cash (used in) operating activities**	**572**	**(2,444)**

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 (12 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 – capital return	-	(14,001)
3.10	**Net cash from / (used in) financing activities**	**-**	**(14,001)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,453	22,470
4.2	Net cash from / (used in) operating activities (item 1.9 above)	572	(2,444)
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 (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(14,001)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,025**	**6,025**

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	1,275	403
5.2	Call deposits	4,750	5,050
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)**	**6,025**	**5,453**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	84
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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 $28,000 for company secretarial accounting 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) (12 months)	(2,444)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,025
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,025
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	9

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

1. 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:

2. 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:

3. 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: 23 July 2024

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.