ASX / Media Release
11 January 2024

December 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 31 December 2023 (Q2 FY24).

Operational Update

IIH EVOLVE Phase III Clinical Trial Closure

Invex has completed the necessary activities to meet the Company's stated objective of a close-out of the IIH EVOLVE trial in the majority by 31 December. All patients on the trial have completed treatment and all previously activated clinical trial sites across the US, UK, Germany, Australia and New Zealand have now closed. On 22 December, Invex mutually terminated its manufacturing agreement with Peptron. There was no financial impact on the termination, as both Peptron and Invex waived a reciprocal regulatory fee that was payable upon each party receiving an initial Investigational New Drug (IND) application with the US Food and Drug Administration, which Invex achieved on 18 August 2022.

The Company's contract research organisation (CRO) Premier Research has now completed the bulk of close out activities under the revised work order, with other third-party vendors and advisors outside of the CRO having been contractually terminated or advised of trial discontinuation. The Company does anticipate the payment of additional costs attributable to the close out during the current March quarter from the CRO.

Invex and Premier Research have completed a Clinical Study Report (CSR), which is a requirement by regulatory authorities to report and summarise the outcomes of a clinical study. Given the trial was closed very early, no statistical analysis on safety and efficacy was performed. The trial master file (TMF) will be archived in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP).

The TMF is a collection of essential documents that facilitates the conduct and management of the clinical trial and allows the integrity of the trial data and the compliance of the trial with good clinical practice to be evaluated by regulatory authorities in each of Invex's jurisdictions. The Company completed the electronic TMF in late 2023.

Dr Thomas Duthy, Executive Director of Invex Therapeutics commented "*Following the termination of IIH EVOLVE our goal was to close out the study in an expeditious and cost-effective manner, while continuing to meet the necessary regulatory requirements associated with closing and archiving data for this study, which remains ongoing. Our small team has delivered on these objectives admirably, which permitted the Company to return $14.0 million during the quarter to our loyal shareholders quite quickly once our costs and timelines were established and stress tested by the Board*."

The Company has now completed a near 100% wind down of its UK operations, specifically in clinical trials management. All clinical staff were made redundant and completed their notice periods to the end of December 2023.

In addition, the Company's current Chief Operating Officer, Ms Carol Parish will complete her service with Invex on 1 February 2024.

Dr Thomas Duthy said *"Along with our clinical staff, we thank Carol for all her dedicated service to Invex, especially in managing the Company's operations and her significant expertise in the oversight of the clinical trial program and its subsequent close. We wish her and the clinical team all the very best with their future endeavours."*

UK R&D Tax Incentive

The Company anticipates receiving an R&D tax refund payable 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. Most of the Company's FY2023 R&D expenditures into IIH EVOLVE was via its UK subsidiary.

Unfortunately, His Majesty's Revenue and Customs (HMRC) is experiencing significant delays in the processing of R&D claims for recipients, which has been exacerbated by significantly more disclosure requirements by companies to tackle abuse and improve compliance. Invex and its advisors remain confident of a successful HMRC claim, although the timing of this payment remains uncertain at present.

European Patent for Exenatide in Hydrocephalus

On 22 November 2023, the Company announced a decision to grant from the European Patent Office for European patent number EP4000630 titled "Elevated intracranial pressure treatment". The patent provides additional claims for the use of Exenatide and other GLP-1 receptor agonists in reducing elevated intracranial pressure (ICP) associated with the treatment of hydrocephalus, normal pressure hydrocephalus or meningitis.

The grant of the patent was published on 13 December 2023 in the European Patent Bulletin under number EP4000630.This patent further extends the protection of Exenatide across multiple human diseases associated with raised ICP.

Hydrocephalus is a neurological disorder associated with an increased volume of cerebrospinal fluid (CSF) within the cerebral ventricles that typically is associated with increased ICP. The overall

global prevalence of hydrocephalus is approximately 85 per 100,000 individuals. Normal pressure hydrocephalus (NPH) is most common for persons over the age of 65, and is similar to hydrocephalus, except ICP is not dangerously high.

Current treatments for hydrocephalus rely on the surgical implantation of a shunt into the brain to drain excess CSF. Shunts are associated with significant mortality and morbidity in patients. The hydrocephalus market was worth US$3.3 billion globally in 2022.

Meningitis is the inflammation of the tissues surrounding the brain and spinal cord and is mostly associated with infection, which also has an established association with increased ICP. There are no approved treatments for treating raised ICP in meningitis despite it being a common complication of meningitis irrespective of the pathogen causing the underlying infection.

Research Collaboration in Glaucoma

The Company has an ongoing early-stage collaboration with a Birmingham, UK based healthcare company that engineers and locally delivers 'pro-healing' micro-environments to maximise the quality of healing and function of diseased and damaged tissues. The intention of the collaboration is to combine Exenatide with their gel-based delivery approach for glaucoma.

During the quarter, first *in vitro* proof of concept studies was conducted to test the release of Exenatide from a novel fluid-gel material that flows like a liquid, and self-structures into a thin, clear, protective layer over the surface of the eye which is gradually dispersed and cleared away by blinking over 2-8 hours. Initial appearance, pH and viscosity of Exenatide incorporated into the proprietary gel polymer was normal.

Additional experiments were performed to assess the release of Exenatide from the formulated fluid gel drop after 1,4 and 24 hours. The results indicated that Exenatide released from the ocular gel was functionally intact, with approximately 45% of Exenatide released at 24 hours. The Company plans to initiate an *in vivo* study of this formulation in a rat model of glaucoma at the University of Birmingham following further release assays.

The global glaucoma market size was estimated at US$8 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 4.61% from 2023 to 2030.

Corporate Update

Capital Return

On 1 November 2023, the Company announced a return of $14.0 million to shareholders representing approximately 19 cents per share, by way of an equal access capital return for the purposes of the Corporations Act. Invex applied for and received from the ASX a waiver from listing rule 7.25 to the extent necessary to permit the Company to undertake the capital return.

The return of $14.0 million considered the discharge of remaining forecast costs relating to the closure of the IIH EVOLVE Phase III clinical trial, while balancing the medium-term funding

requirements of Invex's existing programs in traumatic brain injury (TBI) and glaucoma, which are at a much earlier stage of development and require significantly less investment.

The Board resolved to return surplus capital in the interests of all shareholders, while allowing the balance sheet flexibility to continue Invex's existing programs and to explore new strategic opportunities to add value to the Company's core intellectual property.

The Company sought and received shareholder approval at a General Meeting of shareholders on 28 November 2023. The capital return payment was made on 18 December 2023, and is reflected in the Company's Appendix 4C cash flow attached.

During the quarter Invex prepared an application for a Class Ruling was lodged with the Australian Taxation Office (ATO) in relation to the form and taxation treatment of the final proposed distribution. The form of the distribution is dependent on the Class Ruling, but is likely to be entirely capital in nature, with no dividend component. Invex will announce the ATO ruling to ASX, once received.

New Non-Executive Director Appointment

In November, Invex announced the appointment of Mr David Wheeler as a Non-Executive Director of the Company.

David has more than 30 years of Senior Executive Management, Directorships, and Corporate Advisory experience. He is a foundation Director and Partner of Pathways Corporate a boutique Corporate Advisory firm that undertakes assignments on behalf of family offices, private clients, and ASX listed companies. David is a Fellow of the Australian Institute of Company Directors (FAICD). He is currently Non-Executive Chairman of Protean Energy Ltd, PVW Resources Ltd and Avira Resources Ltd and a Non-Executive Director of Ragnar Metals Ltd, Tyranna Resources Ltd, MOAB Ltd, Cycliq Group Ltd, Cradle Resources Ltd and OZZ Resources Ltd.

Cancellation and Lapse of Options

During the period, approximately 8.5 million employee/consultant options either lapsed or were cancelled because the conditions were incapable of being satisfied relating to IIH EVOLVE.

The Company currently has on issue approximately 1.2 million options at an exercise price of $0.87 expiring 1 December 2026 and 400,000 options with an exercise price of $1.10 expiring 8 April 2024 representing approximately 2% of the total issued capital.

Financial Summary and Analysis

The Company closed the quarter with cash and cash equivalents of $6.2 million (Q4 FY23: $21.2 million), with overall operating cash outflows for the quarter of $1.1 million (Q1 FY24: $1.3 million) and financing cash outflow of $14.0 million (Q1 FY24: nil) reflecting the capital return made to investors on 18 December 2023.

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of $0.78 million (versus $0.94 million in Q1 FY23) reflecting costs 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. In addition, the Company incurred costs associated with direct R&D staff of $0.20 million (versus $0.25 million in Q1 FY24). Former Directors Dr Jason Loveridge (Chairman) and Professor Alex Sinclair (Executive Director and Chief Scientific Officer) left the Company, effective 10 October 2023.

- During the period, two clinical trial employees were made redundant and completed service on 31 December.

- Administration and corporate costs of $0.23 million (versus $0.23 million in Q1 FY24) include compliance costs associated with an ASX listed company, Director's fees, audit and legal costs.

- Interest received on cash deposits held of $0.15 million (versus $0.23 million in Q1 FY24). Following the capital return, interest on cash will decline in future periods consistent with a lower cash position.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were $0.15 million for the quarter (versus $0.13 million in Q1 FY24).

Invex continues to focus on IIH EVOLVE associated costs, including completing a strategic review of the Company's intellectual property assets and the use of external consultants.

- ENDS -

This release dated 11 January 2024 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

For more information, please contact:

Company/Investors
Dr Thomas Duthy
Executive Director
tduthy@invextherapeutics.com
+61 402 493 727

Media
Margie Livingston
Ignite Communications
margie@ignitecommunications.com.au
+61 438 661 131

To subscribe to Invex email alerts, please visit www.invextherapeutics.com and follow us on Twitter **@InvexThera_ASX**

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	31 December 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(778)	(1,722)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(197)	(422)
	(f) administration and corporate costs	(227)	(458)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	148	377
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)	-	(92)
1.9	**Net cash (used in) operating activities**	**(1,054)**	**(2,317)**

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 (6 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)	(14,001)
3.10	**Net cash from / (used in) financing activities**	**(14,001)**	**(14,001)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	21,207	22,470
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,054)	(2,317)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(14,001)	(14,001)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,152**	**6,152**

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	1,102	2,157
5.2	Call deposits	5,050	19,050
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)**	**6,152**	**21,207**

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	146
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 $45,000 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)	(1,054)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	6

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: 11 January 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.