ASX / Media Release
12 October 2023

September Quarterly Activities Report & Appendix 4C

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 (ICP), today provides an operational and corporate update to accompany its Appendix 4C cash flow statement for the quarter ended 30 September 2023 (Q1 FY24).

Operational Update

IIH EVOLVE Phase III Clinical Trial Closure

On 21 August 2023, the Company announced the immediate closure of the IIH EVOLVE Phase III clinical trial for new Idiopathic Intracranial Hypertension (IIH) patients with immediate effect. The Board decision followed an extensive review of proposed changes to the IIH EVOLVE study protocol announced on 28 June 2023 given slower than expected recruitment, and an independent assessment of the market opportunity of Presendin™ in IIH in light of the emergence of certain GLP-1 receptor agonists (GLP-1RAs), notably semaglutide branded as Ozempic®, Wegovy® and Rybelsus® for the treatment of obesity and weight loss in Europe.

The primary principle of IIH management is weight loss, which is considered the disease modifying intervention of choice. Exenatide does not exhibit the same weight loss characteristics as other GLP-1RAs and therefore could be at material risk of obsolescence or substitution in treating IIH patients if regulatory approval and reimbursement was eventually sought by Invex following a clinical trial. This was a key focus of the independent assessment for the Board.

The Board engaged Clarivate, a global leader in providing trusted insights and analytics, with specialist expertise in biopharma intelligence to evaluate the opportunity landscape and market access for Presendin™ for the treatment of IIH in Europe considering approvals for the GLP-1RAs mentioned.

The independent market assessment highlighted major future impacts to the IIH market opportunity for Presendin™. Unfortunately, the current pricing structures for GLP-1RAs make Presendin™ uneconomic in IIH and achieving reimbursement at a price required by Invex to justify the investment and future economic returns, noting the small number of patients, did not warrant the expenditure of the majority of Invex cash holdings over the next several years, and the significant resources to complete a revised IIH EVOLVE clinical trial.

Following the Board decision, the Company, through its Contract Research Organisation, immediately ceased new patient enrollment into IIH EVOLVE, with all regulators and clinical trial vendors, including study investigators across the world, notified of the decision. Since 21 August, Invex has been focussed on winding down the trial.

As at 10 October 2023, there were 4 active patients on the trial, with all patients expected to complete their last visit before the end of October, commensurate with an early close out of the trial. The Company continues to work with a number of key vendors to identify and quantify the direct and indirect pass-through costs attributable to the IIH EVOLVE trial and the likely impact on the Company's cash position. In parallel, the Company has implemented a number of cost-cutting initiatives in various support and advisory functions expected to benefit cash expenditures in Q2 FY2024.

US Patent Issued for Traumatic Brain Injury

On 23 August 2023, the Company announced the United States Patent and Trademark Office (USPTO) granted the Company a US patent entitled "*Elevated Intracranial Pressure Treatment*" (patent number 11,738,067) to be issued on 29 August, covering the use of Exenatide in disorders associated with raised ICP with additional new claims in brain injury and brain trauma.

The issue of this second US patent for Exenatide is important in providing additional intellectual property protection in traumatic brain injury (TBI) until at least August 2035.

In addition, the Company secured an orphan drug designation in Europe for TBI in June 2023, which provides 10 years' market exclusivity, among other incentives for the Company.

Research Collaboration in Glaucoma

Invex has commenced early pre-clinical activity on the use of Exenatide in the treatment of non-neurological disorders, specifically glaucoma. Glaucoma describes a group of progressive optic neuropathies that have the potential to cause irreversible blindness and for the most common form, primary open angle glaucoma (POAG), the only modifiable risk factor is raised intraocular pressure (IOP). According to BrightFocus, there are 80 million people worldwide with glaucoma, and this number is expected to increase to over 111 million by 2040. Glaucoma costs the U.S. economy US$2.86 billion every year in direct costs and productivity losses. 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.[i]

To date, no neuroprotective therapy is approved for use in glaucoma. Exenatide has already demonstrated efficacy to lower cerebral spinal fluid (CSF) secretion and may also show efficacy in the eye to reduce IOP whilst providing neuroprotection to preserve retinal function.

The Company has entered into an 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.

First *in vitro* proof of concept studies to be conducted will test the release of Exenatide from their matrix and Exenatide stability. Thereafter, the Company plans to initiate an *in vivo* study of this formulation in a rat model of glaucoma at the University of Birmingham.

The Company has filed patent applications in Europe, the United States and Canada to protect this intellectual property.

Corporate Update

Director Resignations and Appointment of Non-Executive Chairman

On 3 July 2023, Invex announced the resignations of Dr Jason Loveridge, Non-Executive Chairman and Professor Alexandra Sinclair, Executive Director and Chief Scientific Officer, effective 10 July 2023.

The resignations of Dr Loveridge and Professor Sinclair was in response to discussions with major shareholders who indicated to the Company that, following the ASX release on 28 June 2023, they no longer supported their positions as Directors of the Company. Consequently, both Directors felt it was in the best interests of all shareholders to tender their resignations at that time.

Mr David McAuliffe, Invex Non-Executive Director, was appointed the Interim Non-Executive Chairman of the Company, effective 10 July 2023.

Professor Sinclair and Dr Loveridge ceased their engagement with the Company, consistent with their contractual commitments on 10 October 2023. These additional executive responsibilities have been taken over by Dr Thomas Duthy, Executive Director with the support of the Chief Operating Officer, Carol Parish.

Financial Summary and Analysis

The Company closed the quarter in a continued strong financial position with cash and cash equivalents of $21.2 million (Q4 FY23: $22.5 million), with overall cash outflows for the quarter of $1.3 million (Q4 FY23: $1.4 million).

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of $0.94 million (versus $1.2 million in Q4 FY23) reflected 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 $0.23 million (versus $0.22 million in Q4 FY23). During the period, the Company terminated two clinical trial consultants engaged to assist the Company with the IIH EVOLVE clinical trial.

- Administration and corporate costs of $0.23 million (versus $0.19 million in Q4 FY23) include compliance costs associated with an ASX listed company, Director's fees, audit, legal costs and costs associated with the preparation and reporting of an independent market assessment of

the IIH market prepared by Clarivate. As indicated, former Directors Dr Jason Loveridge (Chairman) and Professor Alex Sinclair (Executive Director and Chief Scientific Officer) left the Company, effective 10 October 2023.

- Interest received on cash deposits held of $0.23 million (versus $0.23 million in Q4 FY23), which offset the Company's administration and corporate costs for the quarter.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were $0.13 million for the quarter (versus $0.25 million in Q4 FY23). The decline was attributable to the resignations of Directors Alex Sinclair and Jason Loveridge.

Outlook

The IIH EVOLVE trial is on-track to close-out in the majority by 31 December 2023.

A proof of concept clinical trial for Exenatide to lower ICP in moderate to severe TBI remains under consideration with further work being undertaken to determine the appropriate Exenatide formulation and dosing/administration in these patients within the Intensive Care Unit setting.

In addition, the Company expects to generate some early pre-clinical research data from its collaboration in glaucoma with novel delivery methods.

Invex continues to explore strategic options to increase the value of the Company's core intellectual property associated with raised intracranial pressure in neurological disorders.

- ENDS -

This release dated 12 October 2023 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, such as acute stroke and traumatic brain injury. Invex has trademarked its repurposed Exenatide as Presendin™. www.invextherapeutics.com.

[i] https://www.grandviewresearch.com/industry-analysis/glaucoma-market-report#:~:text=Report%20Overview,4.61%25%20from%202023%20to%202030.

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 September 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(944)	(944)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(225)	(225)
	(f) administration and corporate costs	(231)	(231)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	229	229
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)	(92)
1.9	**Net cash (used in) operating activities**	**(1,263)**	**(1,263)**

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 (3 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	22,470	22,470
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,263)	(1,263)
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 (3 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**	**21,207**	**21,207**

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	157	420
5.2	Call deposits	21,050	22,050
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)**	**21,207**	**22,470**

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	125
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. Jason Loveridge and Alexandra Sinclair resigned as Directors effective 10 July 2023. Payments of $36,250 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)	(1,263)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	21,207
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	21,207
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	17

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: 12 October 2023

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.