ASX / Media Release
27 October 2022

September Quarterly Activities Report & Appendix 4C

The Company will host an investor conference call today at **12.00pm AEDT** with Dr Thomas Duthy, Executive Director, details below

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 30 September 2022 (Q1 FY23).

Operational Update

IIH EVOLVE Phase III Clinical Trial

The Company continues to invest significant time and resources to the IIH EVOLVE Phase III clinical trial, which has made excellent progress towards commencing patient recruitment during the last quarter (Q1 FY23).

During the quarter the Company received United States (US) Food and Drug Administration (FDA) Investigational New Drug Application (IND) approval for Presendin™ and for the commencement of the IIH EVOLVE Phase III clinical trial in the US for patients with Idiopathic Intracranial Hypertension (IIH). Engagement from US clinicians to participate in the trial has been strong, with Invex planning on opening up to ten clinical sites in the US. The achievement of the IND is a major milestone for the Company, following a significant level of cooperation with Peptron to ensure the Company's manufactured drug product (Presendin™) was able to meet the stringent requirements of the FDA.

In addition, Invex secured a second Human Research Ethics Committee (HREC) approval that covers three additional public hospitals in Melbourne (the Alfred Hospital) and Sydney (Liverpool Hospital / Sydney Eye Hospital). These sites expect to commence recruitment of patients following completion of institutional authorisations in Q4 CY2022.

As at 30 September 2022, Invex has received approvals from the UK Medicines and Health products Regulatory Agency (MHRA)/ethics approval, Australian HREC/TGA approval (private and public) and US FDA IND approval. The Company anticipates receiving further clearances in New Zealand, Israel and Europe from Q4 CY2022 onwards.

Clinical supplies of both Presendin™ and placebo drug product manufactured by Peptron under the terms of the Collaboration and Manufacturing Agreement signed in 2021 have been received at the Company's Australian and UK depots following customs clearance for transfer to active clinical sites ahead of first patient dosing. In addition, a second shipment of initial drug and placebo supplies arrived in the US for packaging and labelling for the US clinical trial sites during the quarter.

The Company remains on-track to activate a number of sites for patient recruitment in Australia, the UK, and US, along with the first patient randomised and treated as part of the IIH EVOLVE trial expected during Q4 CY2022. In total, the Company has already selected 32 clinical sites to participate in the trial across the globe, following a comprehensive qualification process.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a continued strong financial position with cash and cash equivalents of $27.3 million (Q4 FY22: $29.3 million), with overall cash outflows for the quarter of $2.0 million (Q4 FY22: $1.0 million).

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of $1.1 million (versus $0.60 million in Q4 FY22) 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 $0.26 million (versus $0.21 million in Q4 FY22).

- Administration and corporate costs of $0.31 million (versus $0.24 million in Q4 FY22) 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 $0.24 million for the quarter (versus $0.24 million in Q4 FY22).

Government grants and tax incentives were Nil compared to Nil in Q4 FY22. The Company anticipates receipt of an R&D tax rebate for eligible R&D expenditure during FY22, in Q4 CY2022. Invex anticipates an increase in UK rebates and the commencement of Australian R&D tax rebates this financial year.

As previously stated, cash outflows are expected to increase in subsequent periods as the Company commences recruitment for the Phase III IIH-EVOLVE trial in 2H CY2022. 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.

Outlook

Invex continues to progress the IIH EVOLVE study, including the completion of additional regulatory filings and/or approvals as follows:

- Medsafe Approval - New Zealand
- Hospital Clearance / Ministry of Health - Israel
- National Competent Authorities – Europe
- Progressive opening of clinical sites in Australia and UK (*achieved on 24 October 2022*) and the United States

Invex anticipates the first IIH patient will be recruited and dosed (likely UK or Australia) in the IIH EVOLVE Phase III clinical trial prior to the end of CY2022.

Investor Relations

Invex has provided an update to its Fact Sheet as at October 2022, which will be available on the Company's website from 28 October 2022 at: https://invextherapeutics.com/fact-sheets/.

The Company was invited to present at the ASX Small to Mid Cap Investor Conference (On-Demand event) in September. The video can be accessed at: https://invextherapeutics.com/presentations/

In addition, the Company was invited to present at the TCN Emerging ASX Gems Conference, which will be live streamed on 4 November 2022. For more details, visit: https://www.thecapitalnetwork.com.au/

Annual General Meeting

Invex will hold a hybrid Annual General Meeting (AGM) at 9am on 22 November 2022 at BDO: Level 9, Mia Yellagonga Tower 2, 5 Spring Street, Perth. Investors who are not able to attend the meeting in person, are encouraged to join the virtual event using the link:

https://us02web.zoom.us/webinar/register/WN_50IsqIBzT-qC8dord8p5vw

Shareholders will be able to attend and ask questions online. Shareholders are also encouraged to submit questions in advance of the Meeting to the Company. Questions must be submitted in writing to the Company secretary, Narelle Warren nwarren@invextherapeutics.com at least 48 hours before the Meeting.

All Directors of the Company will be in physical attendance this year (including the Company's two UK based directors, Dr Jason Loveridge and Professor Alex Sinclair). In addition, the Company intends to undertake an investor roadshow with investors luncheon briefings planned in Perth, Melbourne and Sydney.

Investor Conference Call

The Company will host an investor conference call today at 12.00pm AEDT 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/10026404-hg6fg5.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: **10026404**

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 27 October 2022 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 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 IIH 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	Quarter ended ("current quarter")
29 632 145 334	30 September 2022

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	(1,148)	(1,148)
	(b) product manufacturing and operating costs	(321)	(321)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(259)	(259)
	(f) administration and corporate costs	(315)	(315)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	131	131
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)	(84)	(84)
1.9	**Net cash (used in) operating activities**	**(1,996)**	**(1,996)**

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	29,339	29,339
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,996)	(1,996)
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**	**27,343**	**27,343**

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	1,293	1,289
5.2	Call deposits	26,050	28,050
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)**	**27,343**	**29,339**

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	237
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 $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)	(1,996)
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)	27,343
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	14

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: 27 October 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.