ASX / Media Release
20 April 2023

March Quarterly Activities Report & Appendix 4C

The Company will host an investor conference call today at **10.00am AEST** 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 31 March 2023 (Q3 FY23).

Operational Update

IIH EVOLVE Phase III Clinical Trial

Invex continued to progress site activations and secure additional regulatory approvals to expand the global footprint for the IIH EVOLVE Phase III clinical trial in Idiopathic Intracranial Hypertension (IIH) patients. This has been a major focus of the Company, and its contract research organisation, Premier Research.

The number of activated sites as at 31 March 2023 was nine (Q2 FY23: 5). A significant number of new site activations are expected in Q4 FY23, towards the targeted global number of sites, with 38 clinical sites having been selected by Invex to participate in the trial, following a comprehensive qualification process (additionally two are completing the qualification process). Site activations are an essential component towards accelerating patient recruitment in the trial. Invex has now implemented a higher level of site engagement to optimise the process from site qualification to site activation (i.e. contracting).

On 19 January 2023, Invex announced the first US site at the Eye Wellness Center in Bellaire, Texas with Dr Rosa Tang. Dr Tang is a neuro-ophthalmologist of significant international standing. As the Co-Medical Director of The Eye Wellness Center, Neuro-ophthalmology of Texas, and Neuro Eye Clinical Trials Inc., she has been a principal investigator on previous Idiopathic Intracranial Hypertension (IIH) Trials in the US. Invex anticipates a total of 10 clinical sites in the US will be activated as part of the IIH EVOLVE trial. As at 31 March 2023, Invex had initiated four US sites.

On 20 March 2023 Invex was pleased to announce the approval from the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) in Germany for patients with IIH. In addition, Invex has secured Central Ethics Committee (CEC) approval for commencement of the IIH EVOLVE trial. Both

BfArM and CEC approval are required to commence a clinical trial in Germany. Up to five sites are planned to be activated in Germany.

As announced to ASX yesterday, the Company received Central Ethics Committee (CEC) and State of Israel Ministry of Health for patients with IIH in Israel. Invex intends to activate up to nine clinical sites in Israel as part of the IIH EVOLVE Phase III clinical trial.

In addition, Invex expects to receive competent authority clearance and ethics approval to commence the IIH EVOLVE clinical trial in France during the current quarter (Q4 FY23).

Invex IIH Phase II 'Pressure' Trial Published in the Prestigious Scientific Journal Brain

The Invex Phase II 'Pressure' clinical trial, which provided initial safety and efficacy of Exenatide in IIH patients was published in the leading scientific journal *Brain* on 14 March 2023.

The scientific results of the Pressure trial were released to ASX on 20 May 2020. The Pressure trial was a double-blind, placebo controlled clinical trial of twice per day Exenatide versus placebo in the treatment of IIH. The primary endpoint of the study was the change in intracranial pressure at 2.5hrs, 24hrs and 12 weeks post drug administration as measured by real-time patient monitoring devices. Secondary outcomes included monthly headache days, headache severity and monthly analgesia days and visual acuity.

Conference Presentations

During the quarter, the Company attended or presented at several medical conferences during the quarter, including the Israeli neuro-ophthalmology meeting, the 49th annual meeting of the North American Neuro-Ophthalmology Society (NANOS) and the UK neuro-ophthalmology society (UKNOSoc) also in March. The Company was able to build awareness with key clinician-researchers on the IIH-EVOLVE clinical trial at these conferences.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a continued strong financial position with cash and cash equivalents of $23.8 million (Q2 FY23: $25.4 million), with overall cash outflows for the quarter of $1.6 million (Q2 FY23: $1.9 million).

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of $1.2 million (versus $1.9 million in Q2 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 $0.21 million (versus $0.21 million in Q2 FY23).

- Administration and corporate costs of $0.19 million (versus $0.32 million in Q2 FY23) include compliance costs associated with an ASX listed company, Director's fees, audit and legal costs.

- Interest received on cash deposits held of $0.22 million (versus $0.22 million in Q2 FY23).

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 Q2 FY23).

Government grants and tax incentives were nil compared to $0.45 million in Q2 FY23, reflecting the timing effect of annual R&D tax rebates for research undertaken in the UK. Invex anticipates an increase in UK rebates and the commencement of Australian R&D tax rebates this financial year.

The Company continues to anticipate cash outflows to increase in subsequent periods as the Company further expands site activations, receives new country-based regulatory approvals (including the recent approval in Israel as announced today on ASX) and further recruitment for the Phase III IIH-EVOLVE trial during CY23. 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 clinical trial and expects the following milestones in the 1H of CY2023:

- Hospital Clearance / Ministry of Health – Israel (achieved 20 April 2023)
- National Competent Authority Approval & Ethics clearance – France

Investor Relations

Invex has provided an update to its Fact Sheet as at April 2023, which will be shortly 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 10.00am 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.

https://s1.c-conf.com/diamondpass/10030232-jk12kj.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: **10030232**

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

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This release dated 20 April 2023 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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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	31 March 2023

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	(1,192)	(4,237)
	(b) product manufacturing and operating costs	(236)	(707)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(211)	(684)
	(f) administration and corporate costs	(186)	(822)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	220	568
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	447
1.8	Other – (D&O insurance)	-	(84)
1.9	**Net cash (used in) operating activities**	**(1,605)**	**(5,519)**

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	25,425	29,339
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,605)	(5,519)
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**	**23,820**	**23,820**

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	770	1,375
5.2	Call deposits	23,050	24,050
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)**	**23,820**	**25,425**

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	242
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 $33,750 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)	(1,605)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	23,820
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	23,820
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	15

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: 20 April 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.