ASX / Media Release
24 January 2022

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 31 December 2021.

Operational Update

Manufacturing

In December, Invex successfully completed an independent Qualified Person (QP) Audit of Peptron's manufacturing facility in Osong, Korea, which can produce over 48,000 vials of Presendin™ per month as well as one other key supplier. A satisfactory QP Audit and the subsequent certification of manufactured batches of drug product by a QP is a requirement under European Union (EU) and UK law prior to importation of manufactured drug product into the EU and or the UK for clinical or commercial purposes. The regulations specify that no batch of drug product can be released for supply prior to certification by a QP that the batch is in accordance with the relevant requirements.

The completion of the QP Audit of Peptron and one of Peptron's key suppliers of manufacturing material will facilitate the importation of Presendin™ and placebo doses into clinical sites in Europe and the UK participating in Invex's IIH EVOLVE Phase III clinical trial for the treatment of Idiopathic Intracranial Hypertension (IIH). The manufactured doses will be progressively deployed across Invex's planned clinical sites as sites are opened and patient recruitment commences.

Following the successful QP audit, Invex placed an initial purchase order with Peptron for supply of a clinical batch of Presendin™ and placebo drug product for the IIH EVOLVE Phase III clinical trial. Initial clinical batches have been produced and the Company's storage and distribution provider expects to take delivery shortly and complete necessary labelling requirements necessary for dispatch to clinical sites, once these sites are open.

IIH EVOVE Phase III Clinical Trial Preparation Progressing Strongly

During the quarter, Invex materially advanced its preparative work for commencement of the IIH EVOLVE clinical trial across a number of key areas.

Firstly, the Company was pleased to finalise its overall regulatory and clinical trial strategy. The completion of this strategy was an important milestone for the Company after significant scientific and regulatory consultation. The planned, single Phase III clinical trial has been designed to meet the requirements for market approval of Presendin™ for the treatment of IIH in the EU, UK and Australia. The trial plans to enrol 240 newly diagnosed IIH patients who will be randomised to receive either once weekly sub-cutaneous injections of Presendin™ or placebo across 37 centres in Europe, UK, Australia and the United States (US).

The primary endpoint of IIH EVOLVE will assess the mean difference in Intracranial Pressure (ICP) from baseline at 24 weeks between patients receiving Presendin™ and those on placebo. Secondary endpoints will assess the relative difference in vision (Perimetric Mean Deviation (PMD) and papilloedema) and Monthly Headache Days (MHD) between the two groups over 24 weeks.

Outcomes from the IIH EVOLVE clinical trial are expected to facilitate future discussions with the US Food and Drug Administration (FDA) regarding registration of Presendin™ in the US in the future.

The Company successfully filed the first Clinical Trial Application (CTA) to commence the IIH-EVOLVE trial in Australia in the month of December as planned through an application to a specific Human Research Ethics Committee (HREC). In Australia, HRECs are required under the Therapeutic Goods Act to review and monitor all clinical trials of unregistered drugs. If successful, HREC clearance will allow Invex to commence recruitment of IIH patients under the parameters of the approved trial protocol. A number of clinical sites in Australia are planned.

Invex anticipates completing additional CTAs for the UK, Europe and the US during the 1H CY2022.

In late December 2021, Invex announced the appointment of Professor Michael Wall, MD as the Trial Steering Group Chairperson for the IIH EVOLVE Phase III clinical trial. Dr Wall is a Professor of Ophthalmology and Neurology at the University of Iowa College of Medicine and Director of the Iowa Visual Field Reading Center. He is considered a global key opinion leader in IIH, having made a significant contribution to the clinical and scientific literature pertaining to the diagnosis, treatment and management of this disease and has led a significant number of important IIH clinical trials.

Professor Wall has a distinguished career in the field of IIH, has published widely in international peer-reviewed journals, and has significant experience and expertise in the execution of clinical trials in neurology and ophthalmology for pharmaceutical companies undertaking studies in the United States and around the globe.

R&D Tax Rebate of £100k Received

In December, the Company's UK subsidiary received approximately £100k (A$184k) in a Research and Development (R&D) tax rebate from the UK government for the 2021 financial year. Invex anticipates an increase in UK rebates and the commencement of Australian R&D tax rebates in future periods as the Company accelerates R&D expenditure necessary to support our important registration directed IIH EVOLVE Phase III clinical trial.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $31.4 million, with overall cash outflows for the quarter of $0.6 million.

Cash outflows from operating expenditure included:

- Product manufacturing & operating costs for the quarter of $0.14 million related to initial purchases of Presendin™ and placebo drug product from Invex's manufacturing partner Peptron, in preparation for the IIH EVOLVE Phase III clinical trial.

- Research & development expenditure for the quarter of $0.33 million related clinical and regulatory consultants, along with intellectual property costs related to Invex's patent and trademark portfolio. In addition, the Company incurred costs associated with direct R&D staff of $0.12 million.

- Administration and corporate costs of $0.23 million related to compliance costs associated with an ASX listed company, including ASX and 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 $0.16 million for the quarter.

In addition, government grants and tax incentives of $0.18 million were received from the UK government for eligible FY21 R&D expenditure.

Cash outflows are expected to increase in subsequent periods as the Company prepares for the start of the IIH-EVOLVE study. Notwithstanding the increase in cash utilisation in subsequent periods, the Company is fully funded to complete the Phase III trial for Presendin™ registration purposes in the EU, UK and Australia from current cash reserves.

Investor Relations

In November, Invex hosted an interactive webcast for investors and analysts on the Company's regulatory and clinical trial strategy with Chairman Dr Jason Loveridge, Executive Director and CSO Professor Alex Sinclair and Executive Director Dr Thomas Duthy. The Company thanks investors for their participation and questions. The webcast is available on the Invex website at: https://invextherapeutics.com/presentations/

In November, Invex presented at the Bell Potter Healthcare conference to predominately institutional and private clients of the firm. A copy of the webcast and presentation is available on the Invex website https://invextherapeutics.com/presentations/.

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

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/10019195-fk0art.html

Alternatively, you may dial in with the following details, approximately ten minutes before the scheduled start time and provide the Conference ID to an operator.

Conference ID: **10019195**

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 24 January 2022 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, 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 December 2021

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	(333)	(655)
	(b) product manufacturing and operating costs	(141)	(141)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(119)	(237)
	(f) administration and corporate costs	(225)	(457)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	19	38
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	184	184
1.8	Other (D&O insurance)	-	(82)
1.9	**Net cash (used in) operating activities**	**(615)**	**(1,350)**

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.	-	-
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	31,981	32,716
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(615)	(1,350)
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)	-	
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**31,366**	**31,366**

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	1,306	931
5.2	Call deposits	30,050	31,050
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)**	**31,366**	**31,981**

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	266
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)	(615)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	31,366
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	31,366
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	51

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: 24 January 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.