ASX / Media Release
20 October 2021

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™ (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 2021.

Operational Update

Manufacturing

In September, Invex was pleased to complete an Exclusive Collaboration & Manufacturing Agreement for Presendin™ in idiopathic intracranial hypertension (IIH) with Peptron, Inc. (KOSDAQ: 087010), a biopharmaceutical company developing sustained-release peptide-based medicines with high technological barriers to treat chronic diseases, based in Daejeon, Korea.

Under the terms of the Agreement, Peptron will provide Invex with access to its intellectual property (IP), including an extensive preclinical and clinical data package relating to its proprietary sustained-release formulation of Exenatide, which will be labelled Presendin™ for all of Invex's clinical trials in IIH as well as for commercial use, if regulatory approved.

The agreement between the companies is exclusive, applies globally and provides a defined price per dose for the supply of Presendin™ for clinical studies and for the first ten years following the first commercial sale. In addition, Invex has granted Peptron an exclusive license for IIH in Korea.

The key highlights of the transaction for Invex include:

- **Strong financial benefits**
  - Approximately $3 million in cost-savings and ~12 months development time;
  - Invex gains access to all Peptron's pre-clinical and clinical data (human pharmacokinetic (PK) studies) on a 1x per week sustained release formulation of Exenatide (labelled Presendin™); and
  - Invex no longer needs to undertake these studies in its own right.

- **Strong economics**
  - Fixed cost per dose for clinical studies and commercial supply;
  - No royalties on sales, no commercial milestones payable; and

- As cost of goods known, provides flexibility for Invex in pricing discussions with future sales and marketing partners and government/private payers.

- **Significantly lowers risk profile**
  - Invex no longer reliant on an untested (new) formulation and the risks that a new formulation does not meet the requirements in human PK or tolerability studies;
  - Peptron has expertise in manufacture at scale for sustained release Exenatide; and
  - Peptron are financially robust and are certified GMP with 48,000 doses per month capacity (i.e., 12,000 patient treatments per month), with expansion planned.

- **Better for Patients**
  - 1x per week formulation, shown in human safety studies to be ideally suited for IIH patients; and
  - Greater certainty of compliance in clinical studies and commercial environment versus the 1x per day formulation originally envisaged by Invex.

During the quarter, the Company made significant progress in developing a clear regulatory and clinical trial plan for Presendin™ in IIH, based predominately on the FDA response on the proposed Phase III design received in June 2021, and expert feedback received.

Invex convened a number of scientific advisory meetings with key opinion leaders, which sought to examine the plausibility of designing a single United States / European Union (US/EU) clinical trial for registration of Presendin™ that would meet the requirements of both the US Food and Drug administration (FDA) and European Medicines Agency (EMA) for market approval. The review included an independent, comprehensive clinical review of IIH patient data as it related to Perimetric Mean Deviation (PMD) and a review of published clinical evidence in the scientific literature.

A significant improvement in PMD was considered by the FDA as an appropriate primary endpoint for a Phase III trial in IIH, whereas the scientific advice received by the EMA indicated a Phase III trial should show a statistically and clinically meaningful improvement in Intracranial Pressure (ICP) and a clinical outcome measure, such as monthly headache days, in IIH patients as part of any regulatory approval. The data analysis and interpretation undertaken during the quarter sought to understand whether a significant improvement in PMD was plausible based on the evidence analysed as a primary endpoint in IIH and therefore as part of a Phase III clinical trial.

The results of the review and strategic decision by the Invex Board, including the preferred clinical and regulatory plans are expected in early Q4 CY2021.

Intellectual Property

In August, as announced to the market, the European Patent Office notified Invex on the intention to grant the Company a European patent, designated patent number EP3188747 and titled "Elevated Intracranial Pressure Treatment." The patent was subsequently published on 8 September 2021.

As with the Company's issued US patent, this additional European patent covers the use of GLP-1 receptor agonists, including Exenatide, in reducing elevated ICP associated with IIH, with the patent providing protection until at least August 2035.

The granting of this patent for Europe, alongside the Company's issued patents in other major markets including the US and Japan provides broad IP protection as Invex progresses its clinical development plans for Presendin™. In addition, Exenatide has been granted orphan drug designations in the US and Europe, providing seven and ten years market exclusivity, respectively in these markets.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $32.0 million, with overall cash outflows for the quarter of $0.74 million.

Cash outflows from operating expenditure included:

- Research & development expenditure for the quarter of $0.32 million related to continued costs associated with the preparation of the Company's planned Phase III clinical trial, regulatory and expert advice on FDA feedback received in June 2021, 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.

Cash outflows are expected to increase in subsequent periods as the Company places initial orders for Presendin™ from Peptron for clinical trial purposes and the commencement of the Phase III trial anticipated in 1H CY2022.

Investor Relations

Following the signing of the Peptron manufacturing agreement, the Company undertook a series of investor briefings and media interviews. Copies of the interviews and investor webcast are available on the Company's website at: https://invextherapeutics.com/presentations/.

Invex has also provided an update to its Fact Sheet as at September 2021, which is available on the Company's website at: https://invextherapeutics.com/fact-sheets/.

In addition, the Company has been invited to present at the Bell Potter Healthcare Conference on 9-11 November 2021.

- ENDS -

This release dated 20 October 2021 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.

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 2021

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	(322)	(322)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(118)	(118)
	(f) administration and corporate costs	(232)	(232)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	19	19
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)	(82)	(82)
1.9	**Net cash (used in) operating activities**	**(735)**	**(735)**

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	32,716	32,716
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(735)	(735)
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**	**31,981**	**31,981**

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	931	1,716
5.2	Call deposits	31,050	31,000
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)**	**31,981**	**32,716**

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	160
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

$37,500 was paid to Prof. Alexander Sinclair for Executive Director services.

$12,500 was paid to David McAuliffe for Non-executive Director fees.

$37,500 was paid to Warambi Ltd, a company controlled by Dr Jason Loveridge for R&D consultancy services and Directors fees.

$31,250 was paid to Nemean Group Pty Ltd, a company which Dr Thomas Duthy is a director and shareholder for the provision of Executive Director services.

$32,500 was paid to Concept Biotech Pty Ltd, a company which David McAuliffe and Narelle Warren are directors and shareholders for the provision of accounting and company secretarial services.

$8,990 after tax was paid to Dr Megan Baldwin for Non-executive Director fees.

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)	(735)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	31,918
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	31,918
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	43

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 October 2021

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.