ASX / Media Release
11 January 2021

December 2020 Quarterly Report

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 31 December 2020.

Operational Update

Protocol Assistance Feedback from EMA

On 23 December 2020, the Company announced to ASX it had received additional protocol assistance from the European Medicines Agency (EMA) on the Company's proposed clinical development plan for Presendin™ in Idiopathic Intracranial Hypertension (IIH).

The Committee for Medicinal Products for Human Use (CHMP) of the EMA were supportive of a single pivotal Phase III trial comparing Presendin™ to placebo in IIH patients with the acceptability of a reduction in headache days over the trial period, subject to establishing that Presendin™ also reduces Intracranial Pressure (ICP) as a trial outcome measure. The protocol assistance confirmed CHMP's acceptability of headache days as a logical and relevant trial endpoint, which was one of the key submissions made by Invex, given the importance of headache in the clinical setting.

This additional feedback completed the protocol assistance sought from the EMA, which has now provided Invex with the necessary regulatory input to complete a single Phase III clinical trial design of Presendin™ versus placebo in IIH patients, to support market approval in Europe. Consistent with Invex's regulatory strategy, the Company now plans to file a pre-IND / Type B meeting request with the US Food and Drug Administration (FDA) inclusive of a complete trial protocol and statistical analysis plan following initial FDA feedback obtained in July 2020.

Reformulation and Manufacturing

The selection of the preferred formulation candidate of Presendin™ for the planned Phase III clinical trial, which was expected in Q4 CY2020 was delayed owing to continued difficulties accessing testing facilities to run sample analyses due to COVID-19 related shutdowns in Europe and the US.

The Company will update the market once the formulation selection process has been completed and the appointment of a contract manufacturer of Presendin™ for clinical trials concluded. Contract manufacturing discussions are in process and well-advanced.

Intellectual Property

Invex continues to build out its core intellectual property (IP) portfolio. In November, the Company received formal correspondence from the from the United States Patent and Trademark Office (USPTO) on the issuance of a US patent for Invex covering the use of GLP1 receptor agonists, including Exenatide, in reducing elevated intracranial pressure (ICP) in a given subject. Invex announced to ASX it had received a notice of allowance for this same patent on 21 July 2020. The patent will provide protection until August 2035 and will provide additional barriers to entry over and above market exclusivity provided by the Company's US and European orphan drug designations for Exenatide in IIH. Additional patents are pending for other key territories including the European Union and Australia.

In November 2020, the Company successfully registered a trademark for Presendin™ in the European Union. This follows the successful registration of the same mark in the UK in Q2 CY2020. The Company has filed for trademark registrations for Presendin™ in additional jurisdictions which are currently pending.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $33.6 million.

Cash outflows from operating expenditure for the quarter were $0.36 million included:

- Research & development expenditure for the quarter of $0.17 million related to completing the necessary lead-in clinical and non-clinical research activities to support planned regulatory submissions to commence a Phase III clinical trial in IIH.

- Administration and corporate costs of $0.14 million related to compliance costs associated with an ASX listed company, including ASX, 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 $0.15 million for the quarter.

Appointment of an Executive Director

On 1 October 2020, Invex appointed Dr Thomas Duthy to the Board. Dr Duthy is currently the CEO of Nemean Group Pty Ltd, a boutique corporate advisory and investor relations (IR) firm based in Adelaide, Australia. Dr Duthy was formerly the Global Head of Investor Relations & Corporate Development at Sirtex Medical Limited (Sirtex), which was sold to CDH Investments in September

2018 for $1.9 billion He currently advises several ASX Listed companies in both IR and Corporate Development roles. At Nova Eye Medical Limited (ASX:EYE) this included the recent completion of a $100 million sale of the ophthalmic laser business to Lumibird Group SA.

As the Company continues to develop its proprietary portfolio in pressure-related disorders of the brain, additional non-executive director appointments with suitable industry, commercial and financial expertise may be considered by the Board.

Annual General Meeting

On 18 November 2020, the Company held its 2020 Annual General Meeting (AGM) of investors by way of a fully virtual meeting platform. Given the significant health concerns and restrictions issued by the respective Australian state and federal governments due to COVID-19, the Company elected to hold a virtual meeting consistent with the temporary modifications to the Corporations Act 2001 introduced by the Commonwealth Treasurer.

Invex's Chairman Dr Jason Loveridge updated investors on the progress of the Company over the previous financial year and provided additional insights into the Company's activities for the remainder of the 2020 calendar year and into the first half of 2021.

The Company received strong shareholder support for each of the resolutions put forward at the AGM, with all resolutions passed by way of a poll.

Participation at Investor Conferences

The Company continues to actively engage with investors, and during the fourth quarter presented at the NWR Small Caps Investment Conference and the Bell Potter Healthcare Conference. At both events, Invex Executive Director Dr Tom Duthy outlined the Company's strategy for clinical and commercial development of Presendin™ in IIH. In addition, Professor Alex Sinclair, Invex's Chief Scientific Officer and Executive Director provided a pre-recorded interview giving a clinician's perspective on the diagnosis, treatment and healthcare burden of IIH and the patients she managed at her clinic in the UK, which is one of the world's largest dedicated to IIH patients.

A copy of the investor presentation and webcast for both investment conferences can be located at: https://invextherapeutics.com/presentations/

- ENDS -

This release dated 11 January 2021 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.

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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, causing permanent vision loss in 25% of those affected. 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 Exenatide

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which received approval in the US and Europe for the treatment of type 2 diabetes in 2005 and 2006 respectively. Professor Alexandra Sinclair's research showed that GLP-1 receptors are expressed in the choroid plexus in the brain and that Exenatide can bind to these receptors and reduce secretion of cerebrospinal fluid. Current Exenatide dosage forms are not optimised for IIH.

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 2020

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	(166)	(419)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(102)	(172)
	(f) administration and corporate costs	(142)	(335)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	46	114
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash (used in) operating activities**	**(364)**	**(812)**

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)	-	8,648
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	-	(554)
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	33,946	26,300
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(364)	(812)
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)	-	8,094
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**33,582**	**33,582**

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	1,582	1,946
5.2	Call deposits	32,000	32,000
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)**	**33,582**	**33,946**

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	151
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.

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)	(364)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	33,582
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	33,582
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	92

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: 11 January 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.

Appendix 1 – Reconciliation of the Use of Funds Statement from the Prospectus

	Prospectus use of funds 24 months $' 000	Actual YTD funds used to 31 Dec 2020 – 18 months $' 000	Variance $'000	Comment
Reformulation of Exenatide	490	316	174	Ongoing work to complete.
Bridging Toxicology	170	86	84	Ongoing work to complete.
Patent Costs	215	271	(56)	Over budget due to higher costs than expected.
Phase II IIH POC Study	690	20	670	Study completed not yet invoiced/paid.
Phase II TBI POC Study	1,680	-	1,680	Revised strategy to focus cash on IIH studies and market registrations
Phase II Stroke POC Study	760	-	760	Revised strategy to focus cash on IIH studies and market registrations
Phase III IIH Registration Study	5,240	38	5,202	Ongoing work to complete
Administration costs	1,457	1,121	336	Consistent with Budget.
Unallocated Working capital	795	843	(48)	Over budget due to additional R&D employees
Costs of the Offer	1,002	2,373	(1,371)	$554k relates to June Placement, $848k relates to May Placement, $971k related to costs of IPO which were budgeted for.
Total	**12,499**	**5,068**	**7,431**	