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ASX Announcement
23 October 2020

September 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 30 September 2020.

Operational Update

Regulatory Feedback

On 23 July 2020, the Company announced it has received initial scientific advice from both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), regarding its proposed development plans for Presendin in IIH. Under the auspices of its Orphan Drug Designation Invex sought scientific advice from both the EMA and FDA so as to reduce the likelihood of major objections regarding the development pathway being raised later in development or when seeking approval. The key highlights of the feedback were:

- EMA indicated a single pivotal study of Presendin v placebo would be sufficient to support a filing for regulatory approval for IIH in Europe
- The FDA stated they would need more information to evaluate the Company's proposed design but did guide that two well controlled studies would likely be required to support registration in the US
- Invex's proposed preclinical and human pharmacokinetic approach was broadly acceptable to both EMA and the FDA
- Both regulatory bodies indicated a reduction in monthly headache days of moderate to severe headaches is a clinically meaningful endpoint

The Company has since sought expert review of the initial feedback received from both the EMA and the FDA on the proposed development plan for Presendin in IIH, including advice from Invex's regulatory consultants, study statisticians and an independent scientific advisory board comprised of experts in both neurology and ophthalmology clinical trials and Chaired by Invex's Executive Director and Chief Scientific Officer Professor Alex Sinclair.

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The Company expects to announce the results of this review and next steps in late October to early November 2020.

Intellectual Property

Invex continues to build out its core intellectual property (IP) portfolio. In July, the Company announced a notice of allowance from the United States Patent and Trademark Office for a key Invex patent application covering the use of GLP1 receptor agonists, including Exenatide, in reducing elevated intracranial pressure (ICP) in a given subject. Elevated ICP is associated with a range of diseases including IIH and is a secondary complication in other brain diseases including traumatic brain injury, tumours and meningitis. The patent will provide protection until at least August 2035. The Company secured a Japanese patent in late 2019. Additional patents are pending for other key territories including the European Union and Australia.

In addition, the Company successfully registered a trademark for Presendin in the UK during the quarter. The Company has filed for additional trademark registrations for Presendin in additional jurisdictions which are pending.

Corporate

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $33.9 million.

Cash outflows from operating expenditure for the quarter were $0.49 million included:

- Research & development expenditure for the quarter of $0.25 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 related to compliance costs associated with an ASX listed company; including ASX, Director's fees, D&O insurance, audit and legal costs.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were $120k for the quarter.

Cash inflows from financing of $8.1 million related to the allotment of tranche 2 of the share placement ($8.7 million), less offer costs ($0.55 million).

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Annual General Meeting

The Company will hold its Annual General Meeting (AGM) virtually on Wednesday 18 November 2020. A Notice of Meeting for the AGM was dispatched and lodged with ASX on 12 October 2020.

Shareholders wishing to attend the virtual meeting can pre-register attendance here: https://us02web.zoom.us/webinar/register/WN_2z0RDi_nRxqf2IirQPF4Fg

Shareholders will be able to attend and ask questions as the virtual Meeting. Shareholders are strongly 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.

This release dated 23 October has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.

ENDS

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About Invex Therapeutics Ltd

Invex is a clinical-stage, 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.

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About Idiopathic Intracranial Hypertension

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	30 September 2020

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	(253)	(253)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(70)	(70)
	(f) administration and corporate costs	(193)	(193)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	68	68
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 from / (used in) operating activities**	**(448)**	**(448)**

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	-	-

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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)	8,648	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)	(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**	**8,094**	**8,094**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	26,300	26,300
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(448)	(448)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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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)	8,094	8,094
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**33,946**	**33,946**

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	1,946	3,300
5.2	Call deposits	32,000	23,000
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)**	**33,946**	**26,300**

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	120
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.

$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.

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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)	(448)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	33,946
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	76

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:

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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: 23 October 2020

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.

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

	Prospectus use of funds 24 months $' 000	Actual YTD funds used to 30 Sept 2020 – 15 months $' 000	Variance $'000	Comment
Reformulation of Exenatide	490	266	224	Ongoing work to complete.
Bridging Toxicology	170	86	84	Ongoing work to complete.
Patent Costs	215	257	(41)	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	-	5,240	Currently being planned
Administration costs	1,457	979	478	Consistent with Budget.
Unallocated Working capital	795	677	118	Consistent with Budget.
Costs of the Offer	1,002	2,373	(1,303)	$554k relates to June Placement, $848k relates to May Placement, $971k related to costs of IPO which were budgeted for.
Total	**12,499**	**4,658**	**7,841**	

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