ASX / Media Release
23 July 2021

June 2021 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 June 2021.

Operational Update

Type C Meeting Response from US Food and Drug Administration

On 15 June 2021, the Company received written responses from the US Food and Drug Administration (FDA) Division of Neurology relating to its proposed Phase III clinical trial design for Presendin™ (Exenatide) in Idiopathic Intracranial Hypertension (IIH).

Invex sought the FDA's guidance on the overall study design, and in particular, intracranial pressure and headache as key endpoints, which harmonised with the European Medicines Agency (EMA) requirement for demonstrating a statistically significant and clinically meaningful effect on intracranial pressure (ICP) and a clinical outcome measure (i.e., monthly headache days). The FDA recommended Invex consider a clinically meaningful effect on visual function, such as Perimetric Mean Deviation (PMD) as the primary endpoint for a Phase III trial. The FDA was open to Invex providing proposals for establishing a clinically meaningful effect of Presendin™ on visual function.

The FDA considered ICP as an appropriate secondary endpoint for a trial. Overall the FDA had very few comments on how the Company planned to examine monthly headache days and other key headache measures under a Phase III design, but did recommend an abbreviated headache severity scale as an alternative assessment.

As a result, Invex has commenced discussions with key regulatory and scientific advisors to further understand FDA thinking and clinical strategies that may allow the Company to design a Phase III trial applicable to both regulatory agencies (i.e., FDA and EMA). The finalisation of the clinical strategy for Europe and the US will be communicated to ASX once the Company has completed this important review process.

Manufacturing

The Company continued to advance discussions with Contract Manufacturing Organisations (CMOs) capable of producing Presendin™ for clinical trial supply and upon clinical/regulatory

success supply the drug commercially at scale to IIH patients. These discussions are well advanced, and the Company remains confident of a commercial outcome that benefits both parties, given IIH patients are expected to require Presendin™ long term to maintain normal levels of ICP and hence reduce the clinical symptoms of headache and vision impairment.

Intellectual Property

The Company's suite of intellectual property assets expanded during the quarter, with Invex's trademark for Presendin™ formally registered by the US Patent and Trademark Office in April (Reg. No. 6,317,927), with additional registrations granted by the European Union Intellectual Property Office (Reg. No. 1558488) for Europe and IP Australia (Reg. No. 2133540) in Australia.

In June, the Company was made aware of a UK lawsuit filed by Exelogen, Inc. against the University of Birmingham in relation to certain intellectual property rights to Exenatide. Invex Therapeutics is not a party to this lawsuit, with all intellectual property rights to Exenatide patent applications assigned to Invex by the University of Birmingham on 12 March 2019.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $32.7 million, with overall cash outflows for the quarter of $0.45 million.

Cash outflows from operating expenditure for the quarter were $0.45 million included:

- Research & development expenditure for the quarter of $0.17 million related to costs associated with the preparation and filing of a study protocol and statistical analysis plan to the US FDA and regulatory/scientific advice associated with the Type C meeting response, 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 costs ($0.10 million).

- Administration and corporate costs of $0.20 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 $0.17 million for the quarter.

- ENDS -

This release dated 23 July 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 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 June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(167)	(756)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(102)	(393)
	(f) administration and corporate costs	(196)	(688)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	20	159
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**	**(445)**	**(1,678)**

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 (12 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	33,161	26,300
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(445)	(1,678)
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 (12 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**	**32,716**	**32,716**

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	1,716	1,161
5.2	Call deposits	31,000	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)**	**32,716**	**33,161**

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	166
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.

$14,579 was paid to Dr Megan Baldwin for Non-executive Director fees from her appointment.

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)	(445)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	32,716
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	32,716
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	73

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: 23 July 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 30 June 2020 – 24 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	328	(113)	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	106	5,201	Under budget due to delays in approvals
Administration costs	1,457	1,474	17	Consistent with Budget.
Unallocated Working capital	795	1,231	(436)	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**	**5,934**	**6,565**	