ASX Announcement

24th July 2020

June 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 for the quarter ended June 2020.

Highlights

- Reported statistically significant and clinically meaningful results from the Phase II clinical study of Exenatide in Idiopathic Intracranial Hypertension (IIH) patients
- Successfully completed a two tranche share placement raising $26.2 million to fully fund the planned Phase III development program of Invex's proprietary Presendin™ formulation of Exenatide
- Completed a pharmacokinetic (PK) study of its proprietary formulation Presendin™ in a rat model
- New senior executive appointment to Head of Clinical Operations
- Presentation of Phase II data at the 14th European Headache Federation (EHF) Congress.
- Well funded with current cash reserves of approximately $34 million after completion of the share placement

Operational Update

Phase II Results for Exenatide in IIH

During the quarter the Company focused predominantly on the completion and reporting of the Phase II clinical study, which compared Exenatide versus placebo in the treatment of Idiopathic Intracranial Hypertension (IIH). The Company achieved its first significant milestone in successfully completing the Phase II trial. On 20 May, Invex announced the results of the Phase II, double-blind, placebo controlled clinical trial of twice per day Exenatide versus placebo in the treatment of Idiopathic Intracranial Hypertension (IIH).

The key results from the study are shown below:

- Statistically significant reduction in Intracranial Pressure (ICP, the Primary Endpoint) shown in IIH patients receiving Exenatide at 2.5 hours, 24 hours and 12 weeks (range 18.1-20.8% versus study hurdle of >10%)

- First ever human study to demonstrate ICP lowering effects of Exenatide in IIH patients

- Statistically significant & clinically meaningful 7.7 day (37%) reduction in Monthly Headache Days for IIH patients receiving Exenatide (key hurdle for migraine drug approval is 1.5-2.0 days per month)

- Statistically significant & clinically meaningful improvement in visual acuity at 12 weeks, equating to one line improvement on a LogMAR eye chart

The study provided clear statistical and clinical evidence of efficacy in the primary and in some key secondary endpoints and demonstrates both an immediate reduction in ICP and a strong and sustained clinical benefit in the IIH cohort at 12 weeks.

The Phase II study outcomes were presented by the study investigators during the scientific sessions at the 14th European Headache Federation Congress on 29th June 2020 in a talk titled; *"A randomised, placebo controlled, double blind trial of the effect of the GLP-1 receptor agonist Exenatide on intracranial pressure in Idiopathic Intracranial Hypertension (IIH: Pressure Trial)."*

Lead-in Animal Studies Ahead of Presendin Phase III Clinical Trial

During the quarter, the Company completed a pharmacokinetic (PK) study of its proprietary formulation Presendin™ in the rat. These data provide necessary and valuable information regarding the Company's different formulations of Exenatide and will be used for further development and in its new patent application filed in Q1, 2020.

Manufacturing of Presendin™

During the quarter the Company commenced a process to identify a supplier of GMP grade Exenatide and a Final Drug Product manufacturer for sufficient quantities of Presendin™ to undertake further clinical studies and provide sufficient inventory to support initial commercialisation activities. The Company is currently in active discussions with a number of potential suppliers and anticipates completing its selection process in Q3, 2020.

Appointment of Head of Clinical Operations

Invex has appointed Carol Parish as Head of Clinical Operations to drive the Company's clinical programs, including its Phase III clinical program for Presendin™ as well as the necessary lead-in requirements including regulatory and quality initiatives.

Carol has over 30 years' experience within large and medium size pharmaceutical companies, having been accountable for all phases of drug development and in multiple therapy areas, including neurology. She was formally Executive Director, Clinical Operations at Intercept Pharma (NASDAQ:ICPT), where she was responsible for strategically planning clinical trials, resourcing, and providing oversight/execution to achieve study and program objectives and high quality deliverables within established timelines and budgets. Carol implemented processes to develop a clinical operations organisation to successfully plan and conduct multiple clinical trials in early to late stage to achieve corporate objectives.

Prior to Intercept, Carol was Senior Director Project Management at Covance, a global contract research organisation and drug development services company, and also held numerous senior executive roles at GlaxoSmithKline (LON:GSK) including Senior Director, Head Global Clinical Development Skin Health and Senior Director, Clinical Development: Head of EU and Asia Pacific, Japan and Emerging Markets. Carol will be a valuable addition to the Invex team as the Company moves into its Phase III study for Presendin™.

Post End of Quarter Events

On 21st July 2020, Invex announced the United States Patent and Trademark Office has issued a notice of allowance for Invex's patent application 15/504,399, titled "Elevated Intracranial Pressure Treatment". This patent covers the use of GLP-1 receptor agonists, including Exenatide, in reducing elevated intracranial pressure (ICP) in a given subject. The allowance of this key US patent will provide protection until at least August 2035.

On 23rd July 2020, the Company announced it has received preliminary 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 in 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 be required to support registration in the US

- Invex's proposed preclinical and human pharmacokinetic approach was acceptable to both EMA and the FDA
- Invex to optimise the registration strategy for both the EU and US over the coming weeks

Corporate

Share Placement to Support Further Clinical Development of Presendin™

On 22nd May 2020, Invex announced a successful $26.2 million share placement, which was undertaken following the Phase II clinical trial results. The share placement was to institutional, professional and sophisticated Australian and overseas investors. The Company received cornerstone commitments totalling $10.5 million from existing investors, including $5.0 million from Tattarang (formerly Minderoo Group).

The first tranche of the share placement issued 12.5 million shares at $1.30 on the 28th May 2020 to raise $16.25 million. The second tranche of the share placement was approved by shareholders at a General Meeting held on 29th June 2020, resulting in the issue of approximately 7.65 million shares at $1.30 on 2nd July 2020 to raise approximately $9.95 million before costs.

The Company is now well funded to undertake the Phase III study for Presendin™ in IIH, which is anticipated to commence in the 1H of CY2021. Additionally, funds raised under the share placement will be deployed in the manufacture and supply of Presendin™ for the trial and the commencement of a Phase II study for Presendin™ in a second indication in 1H CY2021, most likely the orphan disease IIH-Without Papilloedema (IIH-WOP).

Investor Presentations

Prior to the release of the Phase II results, the Company presented to a number of analysts and investors on the study design, the meaning and interpretation of the primary and secondary endpoints, along with a framework for progression into a Phase III trial subject to a successful Phase II result. Additionally, Invex presented at the NWR Virtual Health Conference on 1st May 2020 to a number of retail and institutional investors, as announced to ASX.

General Meeting of Shareholders

The Company held a virtual General Meeting of Shareholders on 29th June 2020. The Company confirmed to the ASX all the resolutions put to the meeting were passed unanimously.

Financial Summary and Analysis

The Company closed the quarter in a strong financial position with cash and cash equivalents of $26.3 million at year-end. Subsequent to year-end a further $8.65 million before costs from the second tranche of the share placement was received. Shares were allotted on 2nd July 2020.

Cash outflows from operating expenditure for the quarter were approximately $708,000, up 70% on the prior quarter, this was due to:

- an increase in research & development expenditure for the quarter of approximately $414,000 up 38% on the prior quarter. R&D activities during the quarter were principally directed to completing the Phase II trial, intellectual property protection and reformulation of Exenatide; and

- Administration and corporate costs increased to approximately $316,000 for the quarter due to the additional costs associated with the Placement including ASX, corporate advisory, general meeting and legal costs.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were approximately $224,000 for the quarter.

Cash inflows from financing related to the allotment of tranche 1 of the share placement less costs and a portion of the tranche 2 share placement funds received which were allotted subsequent to 30 June 2020.

Milestones & Outlook

As recently articulated in the corporate presentation for investors, Invex has a number of key milestones planned for the remainder of 2020, including:

- Finalisation of the Presendin™ Phase III design (Q3 2020)
- Finalise supply of GMP Exenatide and Presendin™ manufacturing (Q3 2020)
- Complete animal tolerability study for reformulated Exenatide, known as Presendin™ (Q4 2020)
- Initiate human pharmacokinetic (PK) study for Presendin™ (Q4 2020)

This release dated 24th July 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.

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 June 2020

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	(414)	(962)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(13)	(21)
	(f) administration and corporate costs	(316)	(786)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	35	166
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**	**(708)**	**(1,603)**

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)	16,250	16,250
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	(971)	(1,819)
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	Tranche 2 Placement funds to be allotted.	1,302	1,302
3.10	**Net cash from / (used in) financing activities**	**16,581**	**15,733**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,427	12,170
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(708)	(1,603)
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)	16,581	15,733
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**26,300**	**26,300**

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	3,300	1,427
5.2	Call deposits	23,000	9,000
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)**	**26,300**	**10,427**

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	224
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

$17,500 was paid to Prof. Alexander Sinclair for Executive director services. A bonus of $70,000 was paid for services in relation to the Phase II clinical trial results and successful capital raising.

$8,750 was paid to David McAuliffe for Non-executive Director fees.

$17,500 was paid to Warambi Ltd, a company controlled by Dr Jason Loveridge for R&D consultancy services and Directors fees. A bonus of $70,000 was paid for services in relation to the Phase II clinical trial results and successful capital raising.

$40,000 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 and additional work associated with Placement and General Meeting of Shareholders.

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)	(**708**)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	26,300
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	26,300
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	37

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 July 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.