ASX / Media Release
6 July 2022

June Quarterly Activities Report & Appendix 4C

The Company will host an investor conference call today at **11.00am AEST** with Dr Thomas Duthy, Executive Director, details below

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release 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 2022 (Q4 FY22).

Operational Update

IIH EVOLVE Phase III Clinical Trial

During the quarter Invex made considerable progress towards the commencement of its global IIH EVOLVE Phase III clinical trial for patients with Idiopathic Intracranial Hypertension (IIH). Based on extensive CMC, clinical and regulatory input, the Company successfully compiled a number of key documents, including the Investigational Medicinal Product Dossier (IMPD) for Presendin™, Investigator's Brochure and Study Protocol required for commencement of the IIH EVOLVE study in the European Union, United Kingdom (UK) and in the US following Food and Drug Administration (FDA) approval.

In addition, the IIH EVOLVE clinical trial design was submitted and accepted onto the leading database of privately and publicly funded clinical studies conducted around the world, clinicaltrials.gov (assigned identifier: NCT05347147).

Clinical supplies of both Presendin™ and placebo drug product manufactured by Peptron under the terms of the Collaboration and Manufacturing Agreement signed in 2021 are currently awaiting customs clearance for labelling in the US before dispatch to the initial clinical sites.

Late in the quarter, Invex secured its first regulatory approval for the trial, with the Medicines and Healthcare products Regulatory Agency (MHRA) clearing the Company's Clinical Trial Authorisation (CTA) to commence the IIH EVOLVE Phase III clinical trial in the UK. In addition, Invex received a favourable ethical opinion from a Research Ethics Committee (REC), which was also a requirement prior to commencing the trial in the UK. Invex intends to open a number of clinical sites across the UK and will now progress institutional contracts to facilitate the commencement of patient recruitment.

Shortly after the end of the quarter, in early July Invex announced the receipt of Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods administration (TGA) to commence the IIH EVOLVE Phase III clinical trial in Australia.

The HREC approval covers a number of private hospital sites in Australia that are planned to participate in the IIH EVOLVE trial, with Invex shortly to file an additional separate HREC application for a single public hospital in Australia. Invex has commenced the initiation of Australian IIH EVOLVE clinical trial sites and remains on track to commence patient recruitment once separate institutional authorisations are completed.

Appointment of Carol Parish to Chief Operating Officer (COO) from 1 July

Commencing 1 July 2022, Carol Parish assumed the key executive role of COO at Invex. Carol has been a pharmaceutical professional for over 33 years within the Pharmaceutical/Biotech industry, where she has been accountable for all Phases of drug development (I-IV, ISS, Outcomes Research) in multiple therapy areas. Prior to joining Invex as Head of Clinical Operations, Carol was the Global Clinical Operations Lead at Intercept Pharmaceuticals (NASDAQ: ICPT) and has held various senior clinical positions at Stiefel Laboratories (acquired by GlaxoSmithKline in 2009) including Senior Director, Global Clinical Development for a new drug product, including collaborating with GSK Japan and China. Additionally, Carol spent over 20 years at Merck & Co (NYSE:MRK) and Johnson & Johnson (NYSE:JNJ).

She has held senior global roles in Clinical Operations, Clinical Development and Medical Affairs, while her roles have been responsible for clinical research activities, organisational development, change management, training, competency development, team development, personnel recruitment, QC audits, budget and strategic alliance development and contract negotiations, commercial support and product launches.

Scientific Meeting Presentations and Peer Review

In May, several oral presentations were delivered at the 92nd Aerospace Medical Association Annual Scientific Meeting.

Dr James L. Mitchell of the Institute of Metabolism and Systems Research, University of Birmingham, UK on behalf of Invex's Phase II PRESSURE Trial in IIH presented key findings of this clinical trial with an oral presentation titled *"A randomized controlled, Trial of the GLP-1 Receptor Agonist Exenatide in Idiopathic Intracranial Hypertension."* Professor Alex Sinclair, Invex Executive Director and Chief Scientific Officer of Invex presented data on monitoring intracranial pressure in IIH using telemetric monitoring from the Phase II PRESSURE Trial.

In June, several oral presentations were given at the 15th European Neuro-Ophthalmology Society (EUNOS) in Birmingham, UK. EUNOS is the major society representing and promoting clinical neuro-ophthalmology in Europe.

Dr James L. Mitchell presented *"IIH Pressure: A randomised controlled, trial of the GLP-1 receptor agonist exenatide in idiopathic intracranial hypertension."* In addition, Dr Alex Sinclair, Invex

Executive Director and Chief Scientific Officer presented as part of the IIH Symposium titled *"Piecing the jigsaw together - new insights to IIH pathophysiology."*

Noting the scientific merit of the Invex Phase II PRESSURE trial researchers, Dr James Mitchell presenting on behalf of the Invex Phase II PRESSURE study investigators, was awarded Best Abstract by a resident at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS) held in February and the award for Best Scientific Paper at the 92nd Aerospace Medical Association Annual Scientific Meeting

The peer review process for Invex's Phase II PRESSURE trial by way of numerous presentations at specialist medical conferences has resulted a strong level of scientific and medical interest in the IIH EVOLVE Phase III trial and has greatly facilitated discussions relating to participation in the trial.

Corporate Update

Financial Summary and Analysis

The Company closed the quarter in a continued strong financial position with cash and cash equivalents of $29.3 million (Q3 FY22: $30.4 million), with overall cash outflows for the quarter of $1.0 million (Q3 FY22: $1.0 million).

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of $0.60 million (versus $0.67 million in Q3 FY22) reflected costs associated with the Company's contract research organisation managing the Phase III trial, along with clinical and regulatory consultants, and intellectual property costs related to Invex's patent and trademark portfolio. In addition, the Company incurred costs associated with direct R&D staff of $0.21 million (versus $0.16 million in Q3 FY22).

- Administration and corporate costs of $0.24 million (versus $0.21 million in Q3 FY22) include compliance costs associated with an ASX listed company, 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 $0.24 million for the quarter (versus $0.30 million in Q3 FY22).

Government grants and tax incentives were Nil compared to $0.18 million in Q3 FY22. As the Company is undertaking active R&D in Australia with the Phase III trial, Australian government R&D Tax Incentives are expected to be recognised in future financial years.

As previously stated, cash outflows are expected to increase in subsequent periods as the Company commences recruitment for the Phase III IIH-EVOLVE trial. Notwithstanding the increase in cash utilisation in subsequent periods, the Company is fully funded to complete this trial for Presendin™ registration purposes in the EU, UK and Australia from current cash reserves.

Investor Relations

Invex has provided an update to its Fact Sheet as at July 2022, which is available on the Company's website at: https://invextherapeutics.com/fact-sheets/.

The Company also updated its website (www.invextherapeutics.com) during the quarter. The new website went live in early May 2022.

Investor Conference Call

The Company will host an investor conference call today at 11.00am AEST with Dr Thomas Duthy, Executive Director.

Details of the call are set out below.

In order to pre-register for the conference call and avoid a queue when calling, please follow the link below. You will be given a unique pin number to enter when you call which will bypass the operator and give you immediate access to the event. Investors are advised to register for the conference in advance by using the Diamond Pass link to avoid delays in joining the call directly through the operator:

https://s1.c-conf.com/diamondpass/10023168-sams22d.html

Alternatively, you may dial in with the following details, approximately five minutes before the scheduled start time and provide the Conference ID to an operator.

Conference ID: **10023168**

Participant Dial-in Numbers:

Australia Toll Free: 1800 908299
Australia Local: +61 2 9007 8048
New Zealand: 0800 452 795
Canada/USA: 1855 624 0077
Hong Kong: 800 968 273
Japan: 006 633 868 000
China: 108 001 401 776
Singapore: 800 101 2702
United Kingdom: 0800 0511 453

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This release dated 6 July 2022 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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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 June 2022

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	(599)	(1,910)
	(b) product manufacturing and operating costs	-	(141)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs – R&D	(205)	(606)
	(f) administration and corporate costs	(238)	(902)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	80
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	184
1.8	Other (D&O insurance)	-	(82)
1.9	**Net cash (used in) operating activities**	**(1,019)**	**(3,377)**

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)	-	-
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	30,358	32,716
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,019)	(3,377)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**29,339**	**29,339**

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	1,289	1,308
5.2	Call deposits	28,050	29,050
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)**	**29,339**	**30,358**

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	244
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

Relates to salaries, consulting and fees paid to Directors. Payments of $32,500 for company secretarial and financial services to Concept Biotech of which Mr McAuliffe is a director and shareholder are included.

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)	(1,019)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	29,339
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	29,339
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	29

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: 6 July 2022

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.