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ASX RELEASE **28th October 2021**

SEPTEMBER QUARTERLY ACTIVITIES REPORT

KEY HIGHLIGHTS

- **Investigational New Drug (IND) Application:** Paradigm received a written response from the FDA on 30th July, in which the Agency accepted Paradigm's responses to five of the six questions received. The FDA response required further clarification on one remaining question. The question is directed at the non-clinical interpretation and clinical mitigation relating to one of Paradigm's recently completed GLP non-clinical toxicology studies. The Company responded to the outstanding question prior to the end of August, starting an additional 30-day response period with the Agency. The Company reported on 27th September a further written response from the US FDA. The one outstanding question related to the functional relevance of a preclinical finding in the adrenal gland of rats only (not seen in the adrenal gland of dogs). Paradigm stated that evidence of adrenal gland malfunction has not previously been seen by Paradigm or bene pharmaChem in their ongoing pharmacovigilance. Paradigm has amended the clinical trial protocol to assess adrenal function in accordance with the FDA's requests, and has responded to the FDA in the communicated time. The Company expects to receive a written response from the Agency during the first week of November.
- **CHIK-V Peer Reviewed Publication:** Preclinical data was peer-reviewed and published in the scientific journal, PLoS ONE. Pentosan polysulfate sodium (PPS) treatment showed significant functional joint improvement as measured by grip strength and the anti-inflammatory effect by reduction in hind limb foot swelling in infected animals compared to infected control animals in the mouse model of CHIKV-induced arthralgia. These data support further clinical evaluation of PPS as a potential disease modifying therapy for CHIKV-induced arthralgia following the promising clinical outcomes of improved pain and function in subjects in Paradigm's phase 2a Ross River virus pilot clinical trial.
- **Ethics Approval:** Paradigm received Australian ethics approval for its pivotal Phase 3 clinical trial, PARA_OA_002, to evaluate the treatment effects of PPS against placebo on participants with knee osteoarthritis pain. Eight sites have been identified to participate in the Australian arm of the study.
- **Mucopolysaccharidosis type VI (MPS VI):** The Company reported randomisation and dosing of the first MPS-VI participant in its Phase 2 clinical trial, Para_MPSVI_001, evaluating PPS compared to placebo in up to 12 MPS VI patients in a 2:1 randomisation at two investigation sites in Brazil.

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company") is pleased to provide its quarterly update for the three months ended 30th June 2021 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as of 30th September 2021 was $64.8m (on 30th June 2021: $71.1) with a net cash outflow during the quarter of $6.3m.

- Research & development expenditure for the quarter was $6.18m compared to the previous quarter of $8.04m. The research and development expenditure is attributed to continuation of toxicology studies to support registration, PARA_OA_002 site initiation milestone, ongoing PARA_OA_008 trial, the MPS-I and MPS-VI clinical programs, as well as continuing activities described in the outlook below.
- In accordance with Listing Rule 4.7C.3 and as noted in item 6 of the Appendix 4C Cashflow Statement, payments to related parties and their associates during the quarter ended 30 September 2021 were $72k. Fees of $66k were Director fee payments to Non-Executive Directors. The additional $6k payment relates to legal services performed by BioMeltzer, of which Amos Meltzer is a director.
- In accordance with subsection 323DB (1) of the *Corporations Act 2001,* Paradigm confirms it received no job keeper payments in the financial years ended 30 June 2020 and 30 June 2021.

OUTLOOK

- Paradigm expects to receive communication from the US FDA during the first week of November. Paradigm's Phase 3 preparation activities remain ongoing with first site initiation completed in Australia and the central ethics committee in the US approving the protocol amendment that has been submitted to the US FDA. The Company is ready to commence the Phase 3 clinical trial on receipt of clearance to proceed by the FDA. Paradigm will notify the market once the FDA response has been received.
- Para_OA_008 recruitment remains ongoing, to date 30 subjects have been randomised to either PPS twice weekly or placebo and have completed the treatment phase. Paradigm has added a once weekly dosing regimen, a second trial site and an additional follow-up period to 12 months to the trial design with the remaining 30 subjects to be enrolled using a randomisation scheme which will provide a balanced number of patients to each treatment group.
- Paradigm recently completed market access research with KOLs, patients and payors in the US and Europe to better understand the reimbursement potential for the indication of pain and function in the US and Europe. The research indicated that demonstration of a durable effect on pain and function and long-term data in support of disease modification would maximise reimbursement potential.
- Positive top-line pre-clinical data for the proof-of-concept study in ARDS were presented to the market on 13th October. The proof-of-concept data supports the potential investigation of PPS for the treatment of acute lung inflammation such as ARDS with ensuing pulmonary fibrosis as a result of viral infection. Paradigm will be evaluating data to determine if additional preclinical data are required for clinical translation.
- The pre-clinical proof-of-concept study for the Company's pipeline indication in chronic heart failure has been completed, with data being processed at a leading CRO in France. Paradigm expects to provide some top-line data and commentary on the completed studies during Q4 CY 2021.
- Paradigm will present preliminary data from its Australian Phase 2 study in MPS I at the upcoming International ICIEM meeting in November 2021. During the conference a poster

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will be presented along with a discussion with Head of the Metabolic Unit at the Adelaide Women and Children's Hospital, Dr Drago Bratkovic, and Paradigm Global Head of Safety and MPS, Dr Michael Imperiale. A link to the poster and discussion will be available to shareholders at the conclusion the conference.

- The Company has been invited to present at the annual Bell Potter Healthcare Conference on the 9th November and the 40th Annual JP Morgan Healthcare Conference taking place on Jan 9 – 13, 2022. Links to the Company presentations will be available to shareholders prior to the conference commencement.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise pentosan polysulfate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, ageing, degenerative disease, infection, or genetic predisposition. Paradigm is also exploring proof-of-concept studies for the use of PPS in respiratory and heart failure indications.

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments, and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

Authorised for release by the Paradigm Board of Directors.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

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Name of entity	
Paradigm Biopharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
94 169 346 963	30 September 2021

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	29	29
1.2	Payments for		
	(a) research and development	(6,181)	(6,181)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(20)	(20)
	(e) staff costs	(893)	(893)
	(f) administration and corporate costs	(566)	(566)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	12	12
1.5	Interest and other costs of finance paid	(8)	(8)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,314	1,314
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(6,313)**	**(6,313)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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 (lease liabilities)	(33)	(33)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Limited recourse loan repaid under ESP)	33	33
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	71,081	71,081
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,313)	(6,313)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
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**	**64,768**	**64,768**

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	64,768	64,768
5.2	Call deposits		
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)**	**64,768**	**64,768**

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	72
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.

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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)	(6,313)
8.2	Cash and cash equivalents at quarter end (item 4.6)	64,768
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	64,768
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	10.25

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 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:

8.6.2 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:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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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: ..28 October 2021.....

Authorised by: ...By the board.....
(Name of body or officer authorising release – see note 4)

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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