ASX RELEASE **29th January 2021**

DECEMBER QUARTERLY ACTIVITIES REPORT

KEY HIGHLIGHTS

- **Phase 3 Clinical Trial:** Preparation for the forthcoming pivotal Phase 3 clinical trial has begun in both the USA and Australia.
- **Type C Meeting Feedback:** Feedback from the US FDA following a Type-C meeting was received on 15th December 2020. As a result of the feedback from the following: a Pre-IND and Type-C meeting with the US FDA; and a Scientific Advice meeting with the EMA. Paradigm expects to submit its IND application during the current quarter (Q1, CY21).
- **Inaugural R&D Day:** On December 21st, Paradigm held its inaugural R&D Day where the company detailed to the market the proposed clinical program for Zilosul® ahead of the IND submission and upcoming Phase 3 Pivotal study in the treatment of patients with Knee Osteoarthritis. Paradigm management also presented key additional studies that will be conducted concurrently with the two Phase 3 clinical trials and will provide important data to broaden the label for Zilosul® once an NDA is submitted. The R&D presentation also detailed the multiple mechanisms of action of PPS and their role on the other exciting indications in the company's pipeline.
- **MPS I Open Label Study**: Paradigm announced the initiation of a Phase 2 open-label clinical trial of injectable Pentosan Polysulfate Sodium (PPS), in patients with the ultra-rare orphan disease Mucopolysaccharidosis Type 1 (MPS-1). The study is being conducted at the Adelaide Women's and Children's Hospital (WCH) with 3 patients currently undergoing treatment. The first patient initiated in the Phase 2 trial has completed the initial once weekly dose for 12 weeks and will proceed to fortnightly dosing out to week 48. The safety and data monitoring board have met after the second patient completed dose 4 and recommended study to continue without alteration.
- **New Board Appointment:** Mr. Amos Meltzer joined the Paradigm board as Non-Executive Director. Mr. Meltzer brings to the Paradigm board his intellectual property expertise and his very commercial approach to business. As a non-executive director Amos will sit on both the Audit and Risk committee and the Nomination and Remuneration Committee. Additional appointments to the Paradigm Board are expected in the coming months.

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company") is pleased to provide its quarterly update for the three months ended 31st December 2020 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as of 31st December 2020 was $85.95m (on 30 September 2020: $98.8m) with a net operating cash outflow during the quarter of $12.95m.

- Research & development expenditure for the quarter was $9.73m compared to the previous quarter of $5.5m. The increase in research and development expenditure is attributed to some start-up costs for the PARA-002 Phase 3 Pivotal study as well as the continuing activities under the Outlook below.

OUTLOOK

- Paradigm expects to file its Investigational New Drug (IND) application with the FDA this quarter. The Company has begun the planning and start-up phase for Zilosul® and once the IND is open, study participants from the USA and Australia will be enrolled into Paradigm's pivotal Phase 3 randomised double-blind, placebo controlled, multicentre, multinational clinical trial (PARA002). PARA002 will firstly determine the minimally effective dose and then investigate the safety and efficacy of Zilosul in subjects with osteoarthritis (Kellgren Lawrence Grade 2-4). Paradigm is targeting enrolling the first patient for its clinical program in mid-2021.
- PARA-008 is expected to achieve ethics approval and enroll the first patient in Q2 CY 2021. PARA-008 will evaluate key biomarkers in the blood and synovial fluid as indicators of the cartilage protective Mechanism of Action (MOA) of Zilosul® in patients with OA. This study will be conducted in Australia and will be a randomized, placebo-controlled study of n=60 subjects. Paradigm believes the results of this study will provide additional important data into the potential disease modifying effects of PPS and will support Paradigm's submission to the TGA for Provisional Approval of Zilosul®.
- Final WOMAC Pain and Function data for Paradigm's Special Access Scheme (SAS) will be released this quarter. The final data for an additional 13 patients will bring the total data package to 89 patients who have had their clinical outcomes evaluated with the same WOMAC pain and function tools that will be the primary endpoint in Paradigm's pivotal Phase 3 clinical trial.
- MPS-I open label Phase 2 clinical trial will continue enrollment of up to 10 patients. Total patients enrolled will be dependent on patient's ability to travel interstate to Adelaide to be treated at the Adelaide WCH.
- The MPS-VI program continues to progress with Paradigm expecting during the current quarter to file a submission to the Brazilian Regulatory Authority, ANVISA. The Phase 2 double-blind placebo-controlled trial will evaluate PPS in MPS-VI patients who have residual pain and impaired functional symptoms associated with MPS-VI disease who have received ERT. This clinical trial will provide important comparator data of the effects of PPS on MPS-VI patients versus placebo.
- Paradigm has received preliminary data in the research program investigating safety and efficacy of iPPS in a viral induced respiratory disease model. The company is working closely with the Menzies Health Institute researchers on this project and will conduct further experiments to gather additional information. The company will detail to the market once this data is available.
- Phase 2A Viral Arthritis clinical trial manuscript is undergoing Peer Review and is expected to be published in early Q2, CY 2021.

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, aging, degenerative disease, infection or genetic predisposition.

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 Paul Rennie, CEO & Interim Chairman.

Zilosul® is a registered Trademark of Paradigm Biopharmaceuticals Ltd (ASX: PAR).

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Appendix 4C

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

Name of entity	
Paradigm Biopharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
94 169 346 963	31 December 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(9,729)	(15,278)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(23)	(37)
	(e) staff costs	(963)	(1,250)
	(f) administration and corporate costs	(2,332)	(2,976)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	90	229
1.5	Interest and other costs of finance paid	(9)	(19)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	12	50
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(12,954)**	**(19,281)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(11)	(20)
	(d) investments	-	-
	(e) intellectual property	(1)	(1)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(12)**	**(21)**

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	32	542
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)	(30)	(59)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Limited recourse loan repaid under ESP)	103	103
3.10	**Net cash from / (used in) financing activities**	**105**	**586**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	98,813	104,668
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,954)	(19,281)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(12)	(21)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	105	586
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**85,952**	**85,952**

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	85,952	98,813
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)**	**85,952**	**98,813**

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	25
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

Director Fees payment to Non-Executive Directors

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)	(12,954)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	85,952
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	85952
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	6.64

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: 29 January 2021.....

By the board

Authorised by: .....
(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.