PARADIGM BIOPHARMA

ASX RELEASE **30th April 2021**

QUARTERLY ACTIVITIES REPORT

KEY HIGHLIGHTS

- **JP Morgan Healthcare Conference:** Paradigm was invited to present at the 39th J.P. Morgan Healthcare conference in January. Paradigm has previously attended the conference, but this marked the first presentation the company has given to the conference through the J.P. Morgan platform. The company received strong feedback from the conference presentation and participated in a number of one-on-one meetings with US investment funds during the conference.
- **Special Access Scheme (SAS):** Pain reduction in 89 SAS patients (13 new patient data) being treated by physicians under the Therapeutic Goods Administration (TGA) SAS with Zilosul®. The chronic pain response as measured by the WOMAC® pain subscale demonstrated a 49.6% average pain reduction across the 89-patient cohort. A change in WOMAC® pain scores was recorded at baseline and at day 84 or 12 weeks from first injection for this SAS subset. Paradigm's PARA_OA_002 clinical trial primary endpoint will be a change in WOMAC® pain from baseline to day 56 or 8 weeks from first injection, which is when the peak Zilosul® response was recorded in the Phase 2B clinical trial.
- **Ross River Virus (RRV):** Peer review and publication of Paradigm's successful Phase 2A RRV clinical trial results in the journal BMC Musculoskeletal Disorders. The data demonstrated iPPS was well tolerated and improved patient clinical outcomes in pain and function. The data also supported the anti-inflammatory and chondroprotective (cartilage) actions of PPS through the reduction of inflammatory biomarkers. The data produced in the Phase 2 trial provided clinical evidence that PPS may offer patients a treatment option for a disease that has little or no therapeutic options for chronic RRV infection.
- **Ethics Approval:** Paradigm received ethics committee approval for the PARA_OA_008 Phase 2 exploratory study which will evaluate the treatment effect of Zilosul® compared to Placebo on synovial fluid biomarkers in participants with knee osteoarthritis (OA). The trial which will recruit sixty (N=60) participants will investigate changes in synovial fluid biomarkers associated with pain, inflammation and disease progression of OA.
- **IND Submission:** During the quarter Paradigm made the major submission for its Pivotal study in subjects with pain associated with knee OA with the submission of the Investigation New Drug (IND) application to the US Food and Drug Administration (FDA). The IND application followed several informative and collaborative meetings with our Key Opinion Leaders (KOLs) and key regulatory agencies in the US (US FDA) and Europe (the European Medicines Agency (EMA).
- **Collaboration Agreement:** Paradigm announced a new collaboration agreement with our exclusive manufacture and supply partner, bene pharmaChem (bene), which allows for further development of iPPS and other formulations of PPS to address unmet needs in new clinical indications. Bene remains the only FDA approved manufacturer and supplier of PPS and has agreed to jointly fund activities to understand the chemical, scientific and clinical attributes of

PPS formulations with Paradigm retaining exclusive commercial rights to information and developments resulting from this collaboration.

Paradigm Biopharmaceuticals Ltd (ASX: PAR) (Paradigm or the Company) is pleased to provide its quarterly update for the three months ended 31st March 2021 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as of 31st March 2021 was $81.1m (on 31st December 2020: $85.95m) with a net cash outflows during the quarter of $4.85m.

- Research and development expenditure for the quarter was $6.18m compared to the previous quarter of $9.73m. The research and development expenditure is attributed to the initiation of sites for the PARA_OA_002 clinical trial and commencement of the PARA_OA_008 trial, as well as the continuing activities under 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 31 March 2021 were $63k. These were Director fee payments to Non- Executive Directors.

OUTLOOK

- Paradigm reported on Monday 26th April, it has received verbal direction from the FDA that the FDA has additional questions that were not able to be posed to the company within the 30-day IND review period. Paradigm will now await questions from the regulator over the next 30-days and respond as quickly as possible to any queries the FDA has in regard to Paradigms' comprehensive IND submission package. Paradigm will communicate updates to the market once it submits its response to the FDA which will then trigger a 30-day review period.
- The company made submissions to the US and Australian ethics committees for Paradigm's PARA_OA_002 clinical trial and PARA_OA_006 clinical trial (which is an extension of PARA_OA_002) in parallel with the IND submission to the US FDA. Paradigm expects to have ethics approval granted prior to the opening of the PARA_002 IND clinical trial. Paradigm has received ethics committee approval at some sites in the USA for PARA_OA_002 and ethics review is underway at the Australian sites.
- First subject dosing in the exploratory synovial fluid biomarker study, PARA_OA_008, was announced on April 14th, with the study designed to generate clinical data to further inform Paradigm of the potential for Zilosul® as the first in class Disease Modifying Drug for Osteoarthritis (DMOAD). Enrollment in the Phase 2 clinical trial is progressing with Paradigm anticipating to randomise the last subject early in Q3 CY2021, with a readout of top line results (primary endpoint) Q4 CY2021 or Q1 CY2022.
- Paradigm has made stock available to support physicians prescribing Zilosul® under the TGA SAS. These physicians are trained and experienced in the use of Zilosul® and are able to complete the testing and monitoring required by the company. The company expects to receive notification from physicians on first patient approval from the TGA to be

treated under the pay-for-use SAS. This milestone will mark first revenues achieved by the company.

- Paradigm has submitted its Chikungunya Virus (CHIKV) manuscript for peer-review and publication. It is anticipated the pre-clinical data will be published in 2H CY 2021. This publication will present the findings of a non-clinical study investigating the anti-inflammatory effects of PPS and the arthritic disease modifying effects of PPS in animals infected with the alpha virus - Chikungunga.
- Research program activities investigating the safety and efficacy of iPPS in several pipeline indications remain ongoing. Paradigm currently has two pilot studies being conducted, a viral induced respiratory disease model with top-line results expected during the current quarter and Chronic Heart Failure (CHF) model with top-line data expected to be available 2H CY 2021 or Q1 CY 2022.
- The company previously reported during its inaugural R&D day that it was conducting due diligence on several potential new repurposing candidates. This work is ongoing.
- Paradigm has been invited to take part in the 7th Annual Truist Life Science Conference which will be held on May 4-5 (US), 2021. During the event the company has been invited to participate in a 40-minute fireside chat during the event with one of Truist's healthcare analysts. Members of the company's executive leadership team will also engage in 1x1 investor meetings throughout the conference. Details on how to view the fireside chat will be announced to the market via a separate news release once the details are confirmed.

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)

FOR FURTHER INFORMATION PLEASE CONTACT:

Simon White
Director of Investor Relations
Tel: +61 (0) 404 216 467
Paradigm Biopharmaceuticals Ltd
ABN: 94 169 346 963
Level 15, 500 Collins St, Melbourne, VIC, 3000, AUSTRALIA
Email: investorrelations@paradigmbiopharma.com

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 March 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(6,180)	(21,458)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(25)	(62)
	(e) staff costs	(722)	(1,972)
	(f) administration and corporate costs	(1,279)	(4,255)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	252
1.5	Interest and other costs of finance paid	(9)	(28)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,381	3,431
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(4,811)**	**(24,092)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(11)	(31)
	(d) investments	-	-
	(e) intellectual property	-	(1)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**(11)**	**(32)**

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	-	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)	(31)	(90)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Limited recourse loan repaid under ESP)	-	103
3.10	**Net cash from / (used in) financing activities**	**(31)**	**555**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	85,952	104,668
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,811)	(24,092)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(32)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(31)	555
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**81,099**	**81,099**

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	81,099	85,952
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)**	**81,099**	**85,952**

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	63
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.

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)	(4,811)
8.2	Cash and cash equivalents at quarter end (item 4.6)	81,099
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	81,099
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	16.86

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.

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: ..30 April 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.