ASX RELEASE **29th July 2021**

JUNE QUARTERLY ACTIVITIES REPORT

KEY HIGHLIGHTS

- **Investigational New Drug (IND) Application:** Paradigm reported on 26th April, it had received verbal direction from the US Food and Drug Administration (**FDA**) that it had additional questions that it was not able to pose to Paradigm within the 30-day IND review period. Six questions were subsequently received from the FDA on 25th May, with the agency also suggesting response and mitigation strategies to address their questions. The Paradigm regulatory and clinical team in consultation with external experts, including a US board certified pre-clinical toxicologist and an Ex-FDA senior physician staff member, prepared a response document, which incorporated suggested responses and various mitigation strategies in sufficient detail for the FDA. The FDA received Paradigm's response on 30th June 2021 and the Company expects communication from the FDA no earlier than 30th July 2021.
- **Synovial Fluid Biomarker Study:** First subject dosing in the exploratory synovial fluid biomarker study, PARA_OA_008, was reported during Q2 CY 2021, with the study designed to generate clinical data and biomarker data to further inform Paradigm of the potential for Zilosul® as the first in class Disease Modifying Drug for Osteoarthritis (**DMOAD**).
- **First Revenue via Special Access Scheme (SAS):** Under the Therapeutic Goods Administration **(TGA)** Special Access Scheme **(SAS)**, Zilosul® was made available during Q2 to physicians with SAS approval to treat patients experiencing chronic arthralgia from Ross River virus **(RRV)** infection, previous SAS participants seeking re-treatment and other subjects that would not qualify for recruitment to the Para_OA_008 or Para_OA_002 clinical trials. This milestone marked the first revenue generated by Paradigm for the provision of Zilosul® to prescribing physicians under the TGA SAS.
- **Ethics Approval:** Paradigm confirms ethics approval has been received from the institutional ethics committee in the US and is finalising approval with the Australian ethics committee for its Pivotal Study in knee osteoarthritis.
- **Mucopolysaccharidosis type VI (MPS VI):** Regulatory approval was received from Brazil's National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária (**ANVISA**)) and ethics approval from the National Research Ethics Commission (Comissão Nacional de Ética em Pesquisa (**CONEP**)) for a Phase 2 clinical trial evaluating safety and tolerability of iPPS versus placebo in subjects with MPS VI. This will be the largest clinical trial conducted using PPS in any MPS type subjects. Paradigm's MPS program has received Orphan Drug Designation status in the US and EU for MPS I and MPS VI.
- **New Patents:** During the quarter, Paradigm filed two additional patents for the use of PPS in Acute Respiratory Distress Syndrome (**ARDS**).

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 June 2021 was $71.1m (on 31st March 2021: $81.1m) with a net cash outflow during the quarter of $10m.

- Research & development expenditure for the quarter was $8.04m compared to the previous quarter of $6.18m. The research and development expenditure are attributed to the PARA_OA_002 and 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 June 2021 were $66k. These were Director fee payments to Non-Executive Directors.

OUTLOOK

- Paradigm expects to receive communication from the US FDA no earlier than 30th July. Paradigm's Phase 3 preparation activities have been ongoing during the review period with the FDA to be 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.
- Paradigm received a further R&D tax rebate of $1.3m in July 2021. The rebate was related to an amended FY20 return. The amendment was undertaken to include the impact of recently approved Overseas Expenditure Ruling from AusIndustry.
- Para_OA_008 recruitment remains ongoing with some minor delays to recruitment due to the now multiple lockdown measures in Victoria that have occurred during the trial period. The company can report the trial has reached over 50% of required patients screened. Paradigm expects to provide an update on the Para_OA_008 trial during the current quarter.
- Paradigm's Chikungunya Virus (**CHIKV**) manuscript has completed the final feedback round with the peer-reviewers and is anticipated the pre-clinical data will be published online during the Q4 CY2021. Paradigm will provide a market release to investors with the publication link once available. These important pre-clinical data will be used in partnering discussions.
- The pre-clinical proof-of-concept study for the Company's pipeline indication in ARDS is nearing completion, with data being processed at the Menzies Institute in Queensland. Paradigm expects to provide some top-line data and commentary on the completed studies during Q3 CY 2021.
- The pre-clinical proof-of-concept study for the Company's pipeline indication in chronic heart failure is nearing completion, 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.

- The MPS-VI clinical program has begun in Brazil, with one site initiated and Paradigm expecting to gain ethics approval for a second site during the quarter. Paradigm is working closely with global key opinion leader Dr Roberto Giugliani to monitor the current Covid-19 situation and risk on participants as we commence enrolment into the study during Q3 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 the Paradigm Board of Directors.

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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	30 June 2021

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	(8,044)	(29,502)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(25)	(87)
	(e) staff costs	(995)	(2,967)
	(f) administration and corporate costs	(1,400)	(5,655)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	260
1.5	Interest and other costs of finance paid	(10)	(38)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	3,431
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(10,466)**	**(34,558)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**(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	479	1,021
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)	(121)
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**	**448**	**1,003**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	81,099	104,668
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,466)	(34,558)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(32)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	448	1,003
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**71,081**	**71,081**

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	71,081	81,099
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)**	**71,081**	**81,099**

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	66
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)	(10,466)
8.2	Cash and cash equivalents at quarter end (item 4.6)	71,081
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	71,081
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.79

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: ..29 July 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.