PARADIGM BIOPHARMACEUTICALS LIMITED

ASX RELEASE

30th October 2020

QUARTERLY ACTIVITIES REPORT

KEY HIGHLIGHTS (INCLUDING SIGNIFICANT EVENTS POST END OF QUARTER)

- **Clear Path to Registration in Europe:** Feedback from an EMA scientific advice meeting has provided Paradigm with a clear path forward to registration for Zilosul® in Europe. The regulatory engagement conducted with the EMA covered key elements of the Phase 3 clinical trial protocol and associated pre-clinical and manufacturing processes for Zilosul® that will support the submission of a Marketing Authorisation Application (MAA) in Europe after completion of the Phase 3 clinicals.
- **Extension of Exclusive Agreement with Bene pharmaChem:** Paradigm now has an exclusive supply term of 25 years from the date of marketing approval, expansion of territories to include all major Pharmaceutical markets and additional indications. As Paradigm moves towards commercialization, the exclusive supply of PPS for 25 years following marketing approval provides an elevated level of commercial protection with the only FDA approved manufacturer of PPS.
- **Successful FDA Expanded Access Program:** 65% mean reduction in WOMAC pain from baseline across total patient population (n=10) using WOMAC Pain Subscale in the FDA Expanded Access Program in the USA.
- **Consistent Real-World Evidence:** Paradigm received additional data on 42 patients bringing the cumulative average WOMAC reduction in pain from baseline for the 76-patient cohort to 47.3%. In the 76 patients treated, 73.7% reported at least a 25% reduction in WOMAC pain with 52.6% of patients reporting a greater than 50% reduction in WOMAC Pain. In addition, 76% (58 out of 76) of SAS patients had reported Patient global impression of Change (PGIC) of moderately to definite and considerable improvement in their OA condition with iPPS (Zilosul®) treatment.
- **New staff appointments:** Further strengthening of the Paradigm team with significant additions to the senior management team in Beverley Huttmann (Commercial Head), Justin Cahill (Chief Financial Officer) and Catherine Stapledon (R&D Translational Scientist). Both Beverley and Justin bring big pharma expertise to Paradigm assisting with commercailisation of Zilosul® post registration approval.
- **New Board Appointment:** Dr Donna Skerrett joined the Paradigm board as Executive Director. Dr Skerrett is Paradigm's current Chief Medical Officer based in New York and brings to the board significant medical and strategic experience from her more than 30 years in the medical practice and Pharmaceutical Industry.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) ("Paradigm" or "the Company") is pleased to provide its quarterly update for the three months ended 30th September 2020 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as at 30th September 2020 was $98.8m (at 31 March 2020: $104m) with a net operating cash outflow during the quarter of $6.32m.

- Research & development expenditure for the quarter was $5.5m compared to the previous quarter of $4.2m. Details of the research and development activities are summarised in the continuing activities under Outlook below.

OUTLOOK

- Paradigm has submitted the briefing pack to the US FDA on the 23rd October for a Type C meeting. The company expects a written response from the FDA to questions in relation to the clinical trial design and associated supporting clinical data later this quarter. Once agreed and finalised with the US FDA, Paradigm will inform the market of the Phase 3 clinical trial design.

- Paradigm's goal has been to gather and consolidate feedback from the FDA, EMA and TGA to have a pivotal protocol acceptable to all major jurisdictions and streamline the approval process globally. Paradigm's IND submission requires the feedback from the FDA's written response from the Type C meeting. Due to the current COVID-19 pandemic causing slight delays in the US, the feedback from the FDA is indicated to be received toward the end of Q4 CY2020. The Company believes it is very important that a clear path to registration is established, with the US FDA's input, prior to opening the IND and commencement of the Phase 3 clinical trials. Under this scenario this avoids the situation of completing the Phase 3 clinical trial only to find it is not a registration enabling design and is insufficient for filing.

- The Company continues to prepare information that was requested by the TGA for the next stage of submission for the Provisional Approval determination. The company will further update the market on the progress of this process once it has received feedback from the FDA from the Type C meeting.

- MPS-I open label Phase 2 clinical trial has been initiated with patient enrollment having commenced after receiving 1st patient consent. The open-label trial will evaluate the safety and tolerability of injectable pentosan polysulfate sodium in subjects with Mucopolysaccharidosis type I (MPS-I). Paradigm will provide further detail to the market once 1st patient is dosed.

- The MPS-VI program continues to progress with Paradigm expecting to provide an update on the protocol development for the proposed clinical program during the current quarter.

- Paradigm previously reported the commencement of a research program investigating safety and efficacy of iPPS in a viral induced respiratory disease model. Work is progressing to plan with top-line results of this pilot study to be announced in Q2CY2021.

- The Phase 2b osteoarthritis clinical trial and the Phase 2A Viral Arthritis clinical trial manuscripts are currently undergoing peer review. Paradigm will communicate a timeline for release once this process has been complete.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late stage drug development company with the mission to develop and commercialise pentosan polysulphate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

Disclaimer and 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, Managing Director & CEO.

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	30 September 2020

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	-	-
1.2	Payments for		
	(a) research and development	(5,549)	(5,549)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(14)	(14)
	(e) staff costs	(287)	(287)
	(f) administration and corporate costs	(644)	(644)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	139	139
1.5	Interest and other costs of finance paid	(10)	(10)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	38	38
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(6,327)**	**(6,327)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(9)	(9)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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**	**(9)**	**(9)**

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	510	510
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)	(29)	(29)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Limited recourse loan repaid under ESP)	-	-
3.10	**Net cash from / (used in) financing activities**	**481**	**481**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	104,668	104,668
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,327)	(6,327)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(9)	(9)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	481	481
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**98,813**	**98,813**

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	98,813	104,668
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)**	**98,813**	**104,668**

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	30
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)	(6,327)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	98,813
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	98,813
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	15.62

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: 30 October 2020.....

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.