PARADIGM BIOPHARMACEUTICALS LIMITED

ASX RELEASE 28th April 2020

PARADIGM - MARCH 2020 QUARTERLY REPORT

KEY HIGHLIGHTS (INCLUDING SIGNIFICANT EVENTS POST END OF QUARTER)

- Paradigm presented its MPS VI poster at the MPS World Symposium on 13th February in Orlando, Florida.
- Paradigm reported first patient dosing (18th February), commencement of treatment for all 10 patients and first patient treatment completion (24th March) in the USA under the FDA approved EAP.
- Paradigm announced a positive meeting with the US FDA (21st February), where the company discussed its clinical, pre-clinical and CMC (Manufacturing) data with the Agency.
- The FDA minutes (refer ASX announcement 6th April) confirmed the primary and secondary endpoints for Paradigm's proposed phase 3 trial will be (i) reduced WOMAC pain from baseline and (ii) improved Patient Global Impression of Change (PGIC) at week 8 (Day 53).
- The Agency also stated a requirement for Paradigm to complete two adequately sized and well-controlled Phase 3 clinical trials. Paradigm plans to conduct two efficacy studies (adequately sized and well-controlled) Phase 3 clinical trials consisting of:
    - 750 patients in 1st Phase 3 trial (Seamless and adaptive Phase 3 clinical study design) 18-month duration)
    - 400 patients in 2nd Phase 3 trial (12-month duration but can be run concurrently).
- The FDA recognized in their minutes the complexity of the Bene pharmaChem PPS molecule, being the only FDA approved PPS, and suggest a generic PPS could only be approved by the US FDA if the material was proven to be identical in molecular structure and purity to the Bene PPS.
- Paradigm reported new SAS data on 6th April for 34 patients using the product and endpoints that will be used in the Phase 3 clinical trials.
- The chronic pain response as measured by the WOMAC pain score demonstrated a mean reduction of 44.9%.
- On 8th April the company completed a successful A$35M placement which was strongly supported by Domestic and International Institutions.
- The proceeds from the Placement will be applied to costs of the second Phase 3 osteoarthritis (**OA**) clinical trial.
- Paradigm reported COVID-19 is unlikely to have a material long term impact on the business.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is pleased to provide its quarterly update for the three months ended 31st March 2020 to accompany its Appendix 4C cash flow report for the period. Cash position as at 31st March 2020 was $74.5m.

OUTLOOK

- The final patient under the EAP is scheduled to receive the final dosing of Zilosul® in May. Paradigm expects to release results on the first five patients treated under the EAP by Q2 Cy2020 and entire patient population (n=10) treated under the EAP in Q3 CY2020.

- New data on 100 patients under the TGA SAS using the primary and secondary endpoints for Paradigm's proposed phase 3 trials, (i) reduced WOMAC pain from baseline and (ii) improved Patient Global Impression of Change (PGIC) at week 8 (Day 53). The company expects the data to be released to the market in Q3 CY 2020

- Paradigm expects initial feedback from the Joint Parallel Scientific Advice submission to both the FDA and EMA during Q2 CY 2020. The submission put forward by Paradigm staff detailed the proposed trial design for a pivotal/registrational trial for MPS.

- Commencement of Paradigm's MPS 1 Phase 2 clinical trial in Adelaide, Q3 CY 2020.

- Paradigm staff and the principal investigator are currently writing the Phase 2b clinical trial primary and Phase 2A Viral Arthritis clinical trial manuscripts. Paradigm expects to submit both manuscripts to the journal editor for review in Q2 CY 2020. The publication date for both Peer Reviewed articles is likely Q4 CY 2020.

- Following the completion of the Capital Raise Paradigm has a strong cash position of >$107m which will see the company fully funded through to completion of the Phase 3 trial. Trial readout is expected to take place in late 2022.

Addressable Market: Osteoarthritis (OA) is the most common joint disorder in the United States. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic. ABOUT 54.4 MILLION ADULTS IN THE U.S. HAVE DOCTOR-DIAGNOSED ARTHRITIS[1]. (Barbour – MMWR [66] 2017). There are over 100 million OA sufferers in the USA, Europe and Japan[2].

About injectable PPS (Zilosul®): Injectable PPS is not currently registered in Australia, but it is registered in four of the seven major global pharmaceutical markets. In those European markets, injectable PPS is registered as an antithrombotic agent. In Australia, injectable PPS for human use is not currently available for sale. Injectable PPS for human use is only available by inclusion into a Paradigm Sponsored clinical trial or via a treating physician applying for its use in patients via the TGA's SAS - Category B.

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

Authorised for release by Paul Rennie, Managing Director & CEO.

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 2020

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	(2,417)	(8,078)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(29)	(62)
	(e) staff costs	(83)	(402)
	(f) administration and corporate costs	(375)	(1,319)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	245	940
1.5	Interest and other costs of finance paid	(10)	(24)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,198	3,571
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**529**	**(5,374)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(15)	(108)
	(d) investments	-	-
	(e) intellectual property	(2)	(8)
	(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**	**(17)**	**(116)**

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	429	1,832
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(570)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings (lease liabilities)	(28)	(65)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**401**	**1,197**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	73,630	78,836
4.2	Net cash from / (used in) operating activities (item 1.9 above)	529	(5,374)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(17)	(116)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	401	1,197
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**74,543**	**74,543**

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	74,543	73,630
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)**	**74,543**	**73,630**

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	60
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

Payments to Chairman and 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)	529
8.2	Cash and cash equivalents at quarter end (Item 4.6)	74,543
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	74,543
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	28

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: 28 April 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.