



ASX RELEASE

31 January 2020

December 2019 Quarterly Report

HIGHLIGHTS

- Paradigm met with the Therapeutic Goods Administration (TGA) on 11th November. The company was given valuable feedback for the provisional approval assessment in gaining provisional approval of Zilosul[®] for the treatment of Knee Osteoarthritis (OA) with subchondral Bone Marrow Edema Lesions (BMLs).
- As a result of this feedback Paradigm is pleased to proceed with the provisional determination assessment process (stage 2) and is now focusing on addressing the TGA feedback for the next submission to the TGA under the provisional approvals process.
- Dr Donna Skerrett has now joined as Paradigm's Chief Medical Officer. Dr Skerrett will play a vital role in Paradigm's submissions and filings with the FDA and other regulatory bodies.
- Paradigm welcomed Mitch Marrow (US) and Simon White to its Investor Relations team to assist with the increasing amount of interest in our company both domestically and internationally.
- Commercial discussions remain ongoing with pharmaceutical partners.
- As at 31 December 2019, the Company's cash balance was \$73.63m.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is pleased to provide its quarterly update for the three months ended 31st December 2019 to accompany its Appendix 4C cash flow report for the period.

Outlook

- Paradigm will meet with the FDA on the 19th of February 2020 to discuss the Phase 3 trial design for our lead osteoarthritis program in OA knee pain with subchondral BMLs. The Pre-Ind meeting will be held at the FDA office in Washington and be attended by several members of the Paradigm team and company consultants. This meeting will give Paradigm specific feedback on the proposed Phase 3 development program to support regulatory approval.
- The USA FDA and EMA (Europe) have approved a joint application for submission to discuss the Phase 2/3 mucopolysaccharidosis (MPS) clinical trial. MPS is an orphan indication and the Paradigm program intends to address the ongoing unmet need of residual musculoskeletal symptoms in patients who have received primary treatment for MPS. The submission of the application will occur in March in line with the date agreed with both regulators, where Paradigm will put forward a detailed submission for review of proposed trial design for a pivotal/registration trial within MPS. Paradigm expect the initial feedback from both regulators toward the end of Q2 CY 2020.
- Paradigm's Expanded Access Program (EAP) has been fully recruited and patient screening has commenced. We expect first patient dosing to occur mid-February with remaining patient start dates to be staggered over the following 4 weeks.
- Paradigm staff and the principal investigator are currently writing the Phase 2b clinical trial primary manuscript. Paradigm expects the Peer reviewed publication of Phase 2b OA/BMEL to be released Q3 CY 2020.
- CEO Paul Rennie and the Investor Relations team attended the 38th JP Morgan Healthcare conference in San Francisco in January. The 3-day conference was highly successful with Paradigm meeting with a large number of US and Global fund managers, analysts and potential commercial partners.

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 ARTHRITIS¹. (Barbour – MMWR [66] 2017). There are over 100 million OA sufferers in the USA, Europe and Japan².

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).

FOR FURTHER INFORMATION PLEASE CONTACT:

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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

94 169 346 963

Quarter ended ("current quarter")

31 December 2019

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	(2,360)	(5,661)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(33)	(33)
(e) staff costs	(159)	(319)
(f) administration and corporate costs	(316)	(944)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	312	695
1.5 Interest and other costs of finance paid	(14)	(14)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	373	373
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,197)	(5,903)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(93)
(d) investments	-	-
(e) intellectual property	(4)	(6)
(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	(5)	(99)

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	1,049	1,403
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(570)	(570)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings (lease liabilities)	(37)	(37)
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	442	796

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	75,390	78,836
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,197)	(5,903)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(99)

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)	442	796
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	73,630	73,630

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	73,630	75,390
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)	73,630	75,390

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

60

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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.

7.1 Loan facilities

7.2 Credit standby arrangements

7.3 Other (please specify)

7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
-	-
-	-

7.5 **Unused financing facilities available at quarter end**

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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)

2,197

8.2 Cash and cash equivalents at quarter end (Item 4.6)

73,630

8.3 Unused finance facilities available at quarter end (Item 7.5)

-

8.4 Total available funding (Item 8.2 + Item 8.3)

73,630

8.5 **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**

33

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

- 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:

- 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:

- 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: 31 January 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.