

ASX RELEASE

27 July 2018



## June 2018 Quarterly Report

### Highlights:

- Final recruitment for Paradigm's phase 2b placebo controlled randomised clinical trial in participants with knee osteoarthritis and concurrent bone marrow lesions is imminent. **Expected read-out Q4 CY2018**
- Phase 2a placebo controlled randomised clinical trial in participants with viral arthralgia (Ross River virus) is currently over 80% recruited. **Expected read-out late Q4 CY2018**
- In addition to the two current Phase 2 clinical trials, **doctors have now treated or are currently treating over 370 osteoarthritis patients** via the TGA Special Access Scheme ("TGA SAS").
- Paradigm reported a maintained **50% reduction in pain (on average)**, from an additional 30 patients with osteoarthritis treated with injectable pentosan Polysulfate Sodium (iPPS) via the TGA SAS. **Paradigm has now reported on 75 patients treated under the TGA SAS.**
- Continued growth of past and present elite sportspeople being treated by their doctors with PPS for osteoarthritis and/or acute injuries with concurrent bone marrow edema lesions. **Patients have now been treated across various elite sporting codes.**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company") is pleased to provide its quarterly report for the three months ending 30 June 2018 to accompany its Appendix 4C cash flow report for the period.

### Clinical Development Progress

#### Phase 2b - Osteoarthritis / Bone Marrow Lesions

Paradigm is progressing ahead of schedule with the phase 2b, randomised double-blind placebo-controlled multicentre clinical trial to evaluate the effects of injectable pentosan polysulfate sodium (iPPS) on pain in participants with knee osteoarthritis and concurrent subchondral bone marrow lesions (n=110).

#### Recruitment Status

- Trial is ahead of schedule, **with final recruitment imminent**
- Interest in the clinical trial has been exceedingly high from people with osteoarthritis

Paradigm is very pleased with the management of the clinical trial and the strong momentum it has been able to maintain. **The phase 2b clinical trial remains ahead of schedule with the pivotal results expected in Q4 CY2018.**

### **Phase 2a - Viral Arthralgia – Ross River Virus**

Paradigm continues to recruit patients for the phase 2a, randomised, double-blinded placebo-controlled pilot clinical trial treating a total of 24 participants across five trial sites in Victoria and Queensland. Patients with Ross River virus (RRV) induced arthralgia (painful joints) are being evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections.

#### **Recruitment Status**

- The clinical trial is currently over 80% recruited
- Recruitment is now progressing as expected after a slow recruitment period impacted by the changeable prevalence of the disease.

Paradigm remains confident that the trial will recruit fully, and will complete within budget. **The results from this viral arthralgia phase 2a clinical trial are expected in late Q4 CY2018**

### **Real World Evidence – TGA Special Access Scheme**

In addition to the two current phase 2 clinical trials, doctors have treated or are currently treating over 370 osteoarthritis patients via the TGA Special Access Scheme (“TGA SAS”). Paradigm reported the results from the third group (n:30) of patients treated and assessed via the TGA SAS, increasing the total number of reported patients to 75.

Paradigm is pleased that the results from the TGA SAS have been consistent. Patients, self-reported pain scores were reduced by 50% (on average) from baseline pain scores in 75 patients with knee osteoarthritis and concurrent bone marrow lesions. The 50% reduction in pain scores observed with PPS in knee OA demonstrates superiority over the “15% pain reduction scores reported for opioid treatments for chronic pain in OA of the knee and hip”<sup>1</sup>

All patients were symptomatic with OA pain for at least six months and had failed current standard of care which involved treatment with analgesics, NSAIDs (non-steroidal anti-inflammatory drugs) or corticosteroids.

- 60% of the patients had moderate to severe BMELs with a size ranging from five millimetres to more than 20 millimetres in diameter.
- 40% had lesions less than five millimetres in diameter.

Results from additional TGA SAS groups are expected to be released before the readout of the pivotal Phase 2b results.

### **Elite Sportspeople**

The number of past and present elite sportspeople that are being treated by their doctors via the TGA SAS with Pentosan Polysulfate Sodium (PPS) for osteoarthritis and/or acute injuries, with concurrent bone marrow lesions continues to grow.

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<sup>1</sup> Seghal N, Colson J and Smith H; Expert Rev Neurother. 2013;13(11):1201-1220

To date, club physicians from a variety of elite Australian sporting codes, including nine Australian Football League (AFL) clubs have successfully treated players that have presented bone marrow lesions concurrently with a variety of orthopaedic conditions. Paradigm and the respective club physicians remain very encouraged by the results and the positive impact the treatment is having on the players.

### **Financial and Corporate Update**

Paradigm is funded beyond the completion of both the Phase 2b OA and the Phase 2a RRv trials, due to be completed at the end of CY 2018.

As at 30 June 2018, the Company's cash balance was A\$2.45 million. The Appendix 4C report attached contains the Company's cash flow statement for the quarter.

During the current reporting period Paradigm received A\$955,357 from the exercise of Options (exercise price A\$0.375 and A\$0.50). Paradigm has **received a further \$464,285** between 01 July 2018 – 26 July 2018 and expects an **additional A\$571,428 before 7<sup>th</sup> August 2018, totaling A\$1,035,713.**

Additionally, Paradigm has received confirmation from AusIndustry of its R&D registration for 2017/18 financial year and expects to receive a **cash rebate of approximately A\$1.9M** in August or September 2018.

The Option exercise and R&D rebate significantly bolsters the Company's cash position at a point in time where clinical trial expenditure is expected to reduce significantly as both trials near completion.

**As at end of August, the Company anticipates its cash position will be over \$4 million which places the company in a capitalized position to carry on its business into CY2019 and post the release of both upcoming Phase 2 Clinical trials which will be major value inflexion points for the Company.**

## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

Paradigm Biopharmaceuticals Limited

**ABN**

94 169 346 963

**Quarter ended ("current quarter")**

30 June 2018

| <b>Consolidated statement of cash flows</b>               | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(12 months)<br/>\$A'000</b> |
|---|------------------------------------|---|
| <b>1. Cash flows from operating activities</b>            |                                    |   |
| 1.1 Receipts from customers                               | -                                  | -   |
| 1.2 Payments for  |                                    |   |
| (a) research and development                              | (2,081)                            | (6,024)   |
| (b) product manufacturing and operating costs             | -                                  | -   |
| (c) advertising and marketing                             | -                                  | -   |
| (d) leased assets   | -                                  | -   |
| (e) staff costs   | (153)                              | (550)   |
| (f) administration and corporate costs                    | (210)                              | (858)   |
| 1.3 Dividends received (see note 3)                       | -                                  | -   |
| 1.4 Interest received                                     | 34                                 | 52  |
| 1.5 Interest and other costs of finance paid              | -                                  | -   |
| 1.6 Income taxes paid                                     | -                                  | -   |
| 1.7 Government grants and tax incentives                  | -                                  | 1,774   |
| 1.8 Other (provide details if material)                   | -                                  | -   |
| <b>1.9 Net cash from / (used in) operating activities</b> | <b>(2,410)</b>                     | <b>(5,606)</b>                                  |

|  |   |     |
|--|---|-----|
| <b>2. Cash flows from investing activities</b> |   |     |
| 2.1 Payments to acquire:                       |   |     |
| (a) property, plant and equipment              | - | (3) |
| (b) businesses (see item 10)                   | - | -   |
| (c) investments                                | - | -   |

| <b>Consolidated statement of cash flows</b>                      | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(12 months)<br/>\$A'000</b> |
|--|------------------------------------|---|
| (d) intellectual property  | (97)                               | (242)   |
| (e) other non-current assets                                     | -                                  | -   |
| <b>2.2</b> Proceeds from disposal of:                            |                                    |   |
| (a) property, plant and equipment                                | -                                  | -   |
| (b) businesses (see item 10)                                     | -                                  | -   |
| (c) investments  | -                                  | -   |
| (d) intellectual property  | -                                  | -   |
| (e) other non-current assets                                     | -                                  | -   |
| <b>2.3</b> Cash flows from loans to other entities               | -                                  | -   |
| <b>2.4</b> Dividends received (see note 3)                       | -                                  | -   |
| <b>2.5</b> Other (provide details if material)                   | -                                  | -   |
| <b>2.6</b> <b>Net cash from / (used in) investing activities</b> | <b>(97)</b>                        | <b>(245)</b>                                    |

|   |            |              |
|---|------------|--------------|
| <b>3.</b> <b>Cash flows from financing activities</b>                           |            |              |
| 3.1 Proceeds from issues of shares  | -          | 5,550        |
| 3.2 Proceeds from issue of convertible notes                                    | -          | -            |
| 3.3 Proceeds from exercise of share options                                     | 955        | 955          |
| 3.4 Transaction costs related to issues of shares, convertible notes or options | -          | (799)        |
| 3.5 Proceeds from borrowings  | -          | -            |
| 3.6 Repayment of borrowings   | -          | -            |
| 3.7 Transaction costs related to loans and borrowings                           | -          | -            |
| 3.8 Dividends paid  | -          | -            |
| 3.9 Other (provide details if material)   | -          | -            |
| <b>3.10</b> <b>Net cash from / (used in) financing activities</b>               | <b>955</b> | <b>5,706</b> |

|  |         |         |
|--|---------|---------|
| <b>4.</b> <b>Net increase / (decrease) in cash and cash equivalents for the period</b> |         |         |
| 4.1 Cash and cash equivalents at beginning of quarter/year to date                     | 3,998   | 2,591   |
| 4.2 Net cash from / (used in) operating activities (item 1.9 above)                    | (2,410) | (5,606) |
| 4.3 Net cash from / (used in) investing activities (item 2.6 above)                    | (97)    | (245)   |
| 4.4 Net cash from / (used in) financing activities (item 3.10 above)                   | 955     | 5,706   |

| <b>Consolidated statement of cash flows</b> |  | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(12 months)<br/>\$A'000</b> |
|---|--|------------------------------------|---|
| 4.5   | Effect of movement in exchange rates on cash held  | -                                  | -   |
| <b>4.6</b>                                  | <b>Cash and cash equivalents at end of quarter</b> | <b>2,446</b>                       | <b>2,446</b>                                    |

| <b>5.</b>  | <b>Reconciliation of cash and cash equivalents</b><br>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | <b>Current quarter<br/>\$A'000</b> | <b>Previous quarter<br/>\$A'000</b> |
|------------|---|------------------------------------|-------------------------------------|
| 5.1        | Bank balances   | 2,446                              | 3,998                               |
| 5.2        | Call deposits   | -                                  | -                                   |
| 5.3        | Bank overdrafts   | -                                  | -                                   |
| 5.4        | Other (provide details)   | -                                  | -                                   |
| <b>5.5</b> | <b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>  | <b>2,446</b>                       | <b>3,998</b>                        |

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

| <b>Current quarter<br/>\$A'000</b> |
|------------------------------------|
| 60                                 |
| -                                  |

Payments to Chairman and Non-Executive Directors

**7. Payments to related entities of the entity and their associates**

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

| <b>Current quarter<br/>\$A'000</b> |
|------------------------------------|
| -                                  |
| -                                  |

| 8. <b>Financing facilities available</b><br><i>Add notes as necessary for an understanding of the position</i>   | Total facility amount<br>at quarter end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |
|--|--|---|
| 8.1 Loan facilities  | NIL  | NIL                                       |
| 8.2 Credit standby arrangements  | NIL  | NIL                                       |
| 8.3 Other (please specify)   | NIL  | NIL                                       |
| 8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well. |  |   |

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|--|

| 9. <b>Estimated cash outflows for next quarter</b> | \$A'000      |
|--|--------------|
| 9.1 Research and development                       | 1,906        |
| 9.2 Product manufacturing and operating costs      | -            |
| 9.3 Advertising and marketing                      | -            |
| 9.4 Leased assets                                  | -            |
| 9.5 Staff costs                                    | 156          |
| 9.6 Administration and corporate costs             | 270          |
| 9.7 Other (provide details if material)            | -            |
| <b>9.8 Total estimated cash outflows</b>           | <b>2,332</b> |

| 10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b> | Acquisitions | Disposals |
|--|--------------|-----------|
| 10.1 Name of entity  | N/A          | N/A       |
| 10.2 Place of incorporation or registration  | N/A          | N/A       |
| 10.3 Consideration for acquisition or disposal   | N/A          | N/A       |
| 10.4 Total net assets  | N/A          | N/A       |
| 10.5 Nature of business  | N/A          | N/A       |

### 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.



27 July 2018

Sign here: .....  
Company secretary

Date: .....

Kevin Hollingsworth

Print name: .....

### Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.