PARADIGM BIOPHARMACEUTICALS LTD

ASX RELEASE 31 October 2018

SEPTEMBER 2018 QUARTERLY REPORT

HIGHLIGHTS

- Phase 2b placebo controlled randomised clinical trial in participants with knee osteoarthritis and concurrent bone marrow lesions is fully recruited with the last patient's results being collected during the month of October. **Headline Results expected read-out late Q4 CY2018**
- Recruitment finalised for Phase 2a placebo controlled randomised clinical trial in participants with viral arthralgia (Ross River virus). **Headline Results expected read-out late Q4 CY2018/early CY2019**
- Paradigm maintained a >51.5% reduction in pain (on average), from an additional 50 patients with osteoarthritis treated with injectable Pentosan Polysulfate Sodium (iPPS) via the TGA Special Access Scheme ("TGA SAS"). **Paradigm has now reported on 125 patients treated under the TGA SAS.**
- Approximately 500 patients have been treated or are currently being treated by their doctors via the TGA SAS for a variety of orthopaedic indications.
- Paradigm will report on additional groups of patients treated with iPPS via the TGA SAS as the data becomes available.
- In October, Paradigm announced it has entered into a Heads of Agreement with the US based NFL Pro Players' Elite Network (PPEN) to assist with recruiting and commencing treatment of US based sportspeople, via their doctors, under a proposed FDA Expanded Access program (TGA SAS equivalent).
- The PPEN is a member organisation of over 11,000 retired NFL players and other elite sportspeople and share the same desire in treating patients in the US given the scope of the opioid epidemic and the lack of safe, effective non-opioid pain treatments.
- By initiating treatment of US based elite sportspeople, Paradigm expects to dramatically raise its profile globally and gather valuable Real World Evidence human data.
- Balance sheet and share register significantly strengthened by a successful A$9m, two tranche Placement to institutional (7), professional and sophisticated investors across Australia and Asia.
- R&D rebate of approximately A$2.3m due in November 2018.
- Upon the receipt of the Placement (tranche 2, due 30 Nov) and the R&D rebate, **Paradigm's cash position will be improved by ~A$11.3m.**

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

CLINICAL PROGRAMS

Phase 2b – Osteoarthritis / Bone Marrow Lesions

Paradigm's 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 is fully recruited (n=110).

All 110 patients included in the phase 2b clinical trial have concluded the six-week treatment regimen. The clinical trial sites are in the final stages of collecting KOOS pain and function scores from the latter patients recruited into the trial. Upon receipt of these data, the trial will be concluded, and the data will be unblinded, processed and analysed by the independent third party contract research organisation. The analysis of these data, of which there is a significant amount from the 110 patients, is a thorough process and generally takes a period of time post the very last patient's results being recorded.

As such the results from this OA/BMEL phase 2b clinical trial are expected in late Q4 CY2018.

Phase 2a - Viral Arthralgia – Ross River Virus

During the quarter, Paradigm finalised the recruitment of its Phase 2a randomised, double-blinded placebo-controlled clinical study in participants with persistent Ross River virus (RRV) induced arthralgia (painful joints) treated with iPPS.

As a result of the seasonal and epidemiological factors on recruitment and the low RRV infection incidence predicted for 2018, Paradigm's clinical development team rationalized that capping of participant recruitment to 20 instead of 24 would effectively meet the clinical milestones without escalating trial maintenance costs or delaying trial read-out.

Paradigm is satisfied that 20 participants will meet the outcome objectives for the pilot Phase 2a study and will provide valuable clinical data demonstrating safety (primary endpoint) and effects on disease symptoms (secondary endpoint) in participants with recent Ross River virus infection treated with iPPS.

Similar to the Phase 2b OA/BMEL clinical trial, all patients have completed treatment, although final data collection is still required.

The results from this viral arthralgia phase 2a clinical study are expected in late Q4 CY2018/Early CY2019.

REAL WORLD EVIDENCE – TGA SPECIAL ACCESS SCHEME

In addition to the two current phase 2 clinical trials, doctors have treated or are currently treating approximately 500 patients via the TGA Special Access Scheme ("TGA SAS") for a variety of orthopaedic indications. During the quarter, Paradigm reported the results from the forth and fifth groups (n:25 & n:25) of patients treated and assessed via the TGA SAS, increasing the total number of reported patients to 125.

Paradigm is pleased that the results from the TGA SAS have been consistent. Patients, self-reported pain scores were reduced by 51.5% (on average) from baseline pain scores in 125 patients with knee osteoarthritis and concurrent bone marrow lesions. The 51.5% 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."[1]

[1] 1 Seghal N, Colson J and Smith H; Expert Rev Neurother. 2013;13(11):1201-1220

The 125 patients [65 males and 60 females, median age of 57.9 years (range 27 to 84 years) had been clinically diagnosed with OA and subchondral BMELs (as determined by multiple MRI). At the onset of PPS treatment:

- 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.
- 70% of the patients had moderate to severe BMLs with a size ranging from five millimetres to more than 20 millimetres in diameter.
- 30% 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.

TREATMENT OF PAST AND PRESENT ELITE ATHLETES

Australian Athletes

Past and present elite sportspeople continue to be treated by their doctors via the TGA SAS with iPPS for osteoarthritis and/or acute injuries, with concurrent bone marrow lesions.

A growing number of club physicians from a variety of elite Australian sporting codes (AFL, NRL, A-League) have successfully treated players. Positive anecdotes from these respected physicians has led to an exponential number of inquiries and subsequent applications for access to iPPS, via the TGA SAS.

United States Athletes

In October, Paradigm announced it had entered into a Heads of Agreement (HoA) with the New York, USA, based retired professional sporting network organization, the Pro Players' Elite Network (PPEN). The PPEN is a membership organization of over 11,000 thousand retired NFL players & elite athletes.

The HoA between Paradigm and the Pro Players Elite Network aims to identify and assist with recruiting and commencing treatment of US based sportspeople with existing knee and joint pathologies with iPPS, via their doctors, under a proposed FDA Expanded Access program (TGA SAS equivalent).

Both Paradigm and the PPEN share the same desire in treating patients in the US given the scope of the opioid epidemic and the lack of safe, effective non-opioid pain treatments. Paradigm views this partnership as a logical step forward, providing an excellent opportunity to not only treat people in need, but to gain significant exposure and promotion of the Company and iPPS in the US. The US market is a key focus for Paradigm, given the significant number of OA sufferers and in particular the large number of sportspeople and NFL players suffering from OA who are being prescribed opioids to treat chronic pain.

The US market is a key focus for Paradigm, given the significant number of OA sufferers (31 million[2]) and in particular the large number of sportspeople and NFL players suffering from OA who are being overprescribed/incorrectly treated with opioids[3].

Paradigm is confident that the TGA SAS results (average of 51.5% or greater pain reduction for knee OA pain), produced from 125 patients treated by their doctors in Australia, will be able to be

[2] https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf
[3] https://source.wustl.edu/2011/01/retired-nfl-players-misuse-painkillers-more-than-general-population/

replicated in the US. This would then provide valuable RWE data that supplements and diversifies the data already produced in Australia.

FINANCIAL AND CORPORATE UPDATE

Paradigm is well capitalised as a result of a A$9m Placement (announced October 25, 2018) to professional, institutional and sophisticated investors across Australia and Asia, including existing shareholders.

Paradigm was well received by the institutional investment community, successfully passing the rigorous due-diligence process of seven institutions. The inclusion of these institutions, further strengthens the share register, adding shareholders that are aligned with the Company and understand opportunity it presents.

Post the finalisation of tranche 2 of the Placement and the receipt of the R&D rebate, Paradigm will have in excess of A$11m cash, providing sufficient capital to execute its business development strategies over the coming 18 months. In the event that Paradigm pursues and executes a Big Pharma licensing transaction post phase 2b success, this runway may be significantly extended by associated upfront and subsequent milestone payments.

Funds raised in the placement will be used to:

- accelerate the timeline to commencement of a phase 3 trial in 2019;
- NFL Pro Player's Elite Network compassionate use program;
- employ US Based staff; and
- working capital, offer costs and future IP acquisitions.

ABOUT PARADIGM PHARMACEUTICALS LTD

Paradigm Pharmaceuticals Limited (ASX: PAR) is an ASX-listed biotechnology company focused on repurposing Pentosan Polysulfate Sodium (PPS), an FDA approved drug that has a long track record of safely treating inflammation and dissolving blood clots over 60 years.

The Company is currently undertaking a phase 2b randomised, double blind, placebo controlled multicentre trial investigating subjects with osteoarthritis and concurrent bone marrow edema lesions. The recruitment of the 110 subjects into the clinical trial commenced in November 2017 and concluded in August 2018. Paradigm will read out the results of this clinical trial in December 2018. There is a global trend for safe and effective non-opioid and non-steroid pain relief for chronic disease such as osteoarthritis which presents a huge market opportunity for Paradigm's PPS treatment.

Subject to successful phase 2b results, the Company is aiming to achieve fast track designation with the US FDA and conduct a phase 3 trial in the US in 2019, completing in 2020. Successful phase 2b trials and fast track designation would be expected to generate significant big pharma interest.

In July 2017 the Company commenced a phase 2A clinical trial to treat people recently infected with the Ross River virus. The results of this trial are also expected to be released in mid/late December 2018.

The Company continues to execute on its drug repurposing strategy. The key benefits of this strategy are lower costs, accelerated development timelines and higher success rates than the standard clinical development timeline.

To learn more please visit: www.paradigmbiopharma.com

For more information, please contact

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+Rule 4.7B

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	**Quarter ended ("current quarter")**
94 169 346 963	30 September 2018

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	(1,864)	(1,864)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(141)	(141)
	(f) administration and corporate costs	(203)	(203)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	7
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,201)**	**(2,201)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(d) intellectual property	(21)	(21)
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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**	**(21)**	**(21)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	1,036	1,036
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
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)	-	-
3.10	**Net cash from / (used in) financing activities**	**1,036**	**1,036**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	2,446	2,446
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,201)	(2,201)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(21)	(21)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,036	1,036

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**1,260**	**1,260**

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	1,260	1,260
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)**	**1,260**	**1,260**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	60
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

Payments to Chairman and Non-Executive Directors

7.	**Payments to related entities of the entity and their associates**	**Current quarter $A'000**
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

8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $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.

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	1,850
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	147
9.6	Administration and corporate costs	208
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**2,205**

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**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.



31 October 2018

Sign here: ..... Date: .....
Company secretary

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.