



ASX RELEASE

22 February 2018

Half-year results report

Highlights:

- **CY2018 expected to be a pivotal year due to the release of commercially valuable Phase 2 trial data with Company's two arthritis Phase 2 trials still ahead of schedule.**
- **Important Real World Evidence data generated from patients treated with Pentosan Polysulfate Sodium (PPS) under the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS).**
- **In 24 patients treated under the SAS, joint pain was reduced in 83% and knee function improved in 80% of all cases treated.**
- **ACL clinical trial successful with both primary and secondary endpoints met.**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to provide a summary of its recent achievements to supplement its half-year results announcement for the period ended 31 December 2017.

Paradigm made significant progress with its two arthritis Phase 2 clinical trials during the half-year period, receiving ethics approval and commencing recruitment. Recruitment for the osteoarthritis (OA) and Bone Marrow Lesions (BMLs) trial and the Ross River virus (RRV) trial also remains well ahead of schedule. The release of the commercially valuable results for both trials are expected before the end of CY2018.

Clinical Development Progress

Phase 2 trial for Osteoarthritis and Bone Marrow Lesions

For the Phase 2b trial for OA and BMLs, 43 out of 100 participants (43%) have been recruited to date from the trial's five sites and Paradigm expects this strong momentum to continue. Results from the trial are expected in Q4 CY2018.

The trial is a Phase 2b, randomised double-blind placebo-controlled multicentre study to evaluate the effects of PPS on pain in participants with knee OA and concurrent subchondral BMLs (n=100).

Paradigm's injectable PPS has the potential to be a breakthrough treatment for OA – a condition with a significant unmet medical need. Most current treatments prescribed for the condition do not have adequate pain-relieving effects, provide no protection for the degenerating joint structures and are also associated with significant adverse side effects.

It is estimated that the size of the market is US\$5 billion per annum¹ and this figure could potentially be multiples higher if new, effective, patented treatments such as PPS are commercialised.

OA also remains the most common form of joint disease globally. In the US alone, it affects more than 27 million adults², while in Australia, arthritis affects around three million people. In both countries, the condition is a leading cause of pain and disability among the elderly and a cause of life-years lost due to disability.

Phase 2 trial for Ross River virus

Paradigm's Phase 2a trial for RRV is also progressing strongly with more than 70% of participants recruited.

The trial is a randomised, double-blinded placebo-controlled clinical trial treating a total of 24 participants across four trial sites in Victoria and Queensland. Patients with RRV-induced arthralgia (painful joints) are being evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections. Results for the trial are expected in Q2 CY2018.

Like OA, Ross River virus also remains a condition with a significant unmet need. High amounts of rainfall and warm weather have resulted in an unusually high number of infections here in Australia over the past 12 months. A total of 23 cases in Victoria alone have been identified in the year to date to 10 February 2018, whilst the 2017 total of 1,964 cases was a more than six-fold increase on 2016's total of 263 cases³.

OA SAS data

In October, Paradigm announced the results of 24 patient case studies with OA and Bone Marrow Edema Lesions (BMELs) that were treated with PPS under the Therapeutic Goods Administration's (TGA) Special Access Scheme.

In these patients, joint pain was reduced in 83% and knee function was improved in 80% of all cases treated.

These results followed the release of the published case study of PPS in an additional patient with OA and BMELs in September 2017. The published case study can be viewed here:

<https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-017-1754-3>

¹ National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.

² <http://ard.bmj.com/content/annrheumdis/early/2017/07/12/annrheumdis-2017-211396.full.pdf>

³ Source: Health Vic, Surveillance of notifiable conditions in Victoria, 10 February 2018:
http://www.health.vic.gov.au/ideas/downloads/daily_reports/rptVS_SNIDSVictorianSummary_GR.pdf

These case studies are important to Paradigm as they provide Real World Evidence (RWE) data – i.e. the data from sources other than traditional clinical trials.

The United States Food and Drug Administration (US FDA) allows RWE data to be used in combination with Randomised Controlled Clinical Trials (RCCT) to support product registration for repurposed drugs such as PPS under the FDA 505(b)(2) regulatory pathway.

ACL trial results

In November, Paradigm also announced that its Phase 2a clinical trial in BMLs (bone bruising) met its primary endpoint of safety and tolerability. Additionally, the secondary endpoint was met and showed a statistically significant reduction in bone marrow lesion volume.

These results indicate that PPS has potential to significantly improve recovery from acute ACL injury, with significant improvement in both BML volumes and effusion volumes, function improvement and improved long-term outcomes for patients.

Corporate and Financials

In November, Paradigm Biopharma raised \$5.55 million via a significantly oversubscribed Placement which was expanded to meet very strong demand from existing and new institutional, sophisticated and professional investors.

The raising means Paradigm is well funded into CY2019 and importantly, post the expected completion of its two arthritis trials at the end of CY2018.

For the half year period, the Company reported total expenditure of \$3.6 million with the majority of costs related to research and development and preparations for its Phase 2 OA and BML trial and the Phase 2 RRV trial.

Paradigm closed the half year period with \$6 million cash in the bank and is well funded to meet the research and development (R&D) costs associated with the trial and other R&D activities.

The Company expects to receive approximately \$1.5 million in R&D tax incentives during the Q3CY2018.

Outlook

The completion of both the Phase 2 Ross River virus and OA trials in CY2018 will be pivotal for Paradigm as they will be major value inflection points for the Company.

CORPORATE ENQUIRIES:

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Director & CEO
Paradigm Biopharmaceuticals Ltd
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Paradigm Biopharmaceuticals Limited
Appendix 4D
Half Year report

1. Company details

Name of entity: Paradigm Biopharmaceuticals Limited
ABN: 94 169 346 963
Reporting period: 31 December 2017
Previous reporting period: 30 June 2017

2. Results for announcement to the market

	\$	\$ and % increase/(decrease) over previous corresponding period
Revenue from continuing activities	22,335	(35,280) (61.23%)
(Loss) from continuing activities after tax attributable to members	(3,573,244)	754,834 26.78%
Net (loss) for the period attributable to members	(3,573,244)	754,834 26.78%
Dividends (distributions)	Amount per security	Franked amount per security
Final Dividend	N/A	N/A
Interim Dividend	N/A	N/A
Record date for determining entitlements to the dividends (if any)	N/A	
Brief explanation of any of the figures reported above necessary to enable the figures to be understood: N/A		

3. Net tangible assets

	Current Period	Previous corresponding period
Basic earnings per ordinary security (cents per share)	(2.96) cents	(3.05) cents
Diluted earnings per ordinary security (cents per share)	(2.96) cents	(3.05) cents
Net tangible asset backing per ordinary security (cents per share)	4.04 cents	3.42 cents

4. Control gained over entities

Not applicable.

5. Loss of control over entities

Not applicable.

6. Audit qualification or review

This report is based on accounts to which one of the following applies: (Tick one)			
The accounts have been audited	☒	The accounts are in the process of being audited	☐
If the accounts are subject to audit dispute or qualification, a description of the dispute or qualification: N/A			

7. Attachments

The report of half year ended 31 December 2017 is attached.

8. Signed



Signed _____

Graeme Kaufman
Chairman
22 February 2018



Signed _____

Paul Rennie
Chief Executive Officer and Managing Director
22 February 2018

Paradigm Biopharmaceuticals Limited

ABN 94 169 346 963

Half Year Report - 31 December 2017

Paradigm Biopharmaceuticals Limited
Directors' report
31 December 2017

The directors present their report, together with the financial statements, on the Consolidated Entity consisting of Paradigm Biopharmaceuticals Limited and the entities it controlled at the end of, or during, the half-year ended 31 December 2017.

Directors

The following persons were directors of the Consolidated Entity during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Graeme Kaufman
Paul Rennie
Christopher Fullerton
John Gaffney

Principal activities

The principal activities of the Consolidated Entity are researching and developing therapeutic products for human use.

Results

The Consolidated Entity made a loss for the period ended 31 December 2017 of \$3,573,244 (2016: Loss of \$2,818,409).

Significant changes in the state of affairs

In November 2017, the Consolidated Entity raised capital of \$5,550,000 by way of private placement.

Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on the following page.

This report is made in accordance with a resolution of directors, pursuant to section 306(3) (a) of the Corporations Act 2001.

On behalf of the directors



Signed _____

Graeme Kaufman
Chairman
22 February 2018



Signed _____

Paul Rennie
Chief Executive Officer and Managing Director
22 February 2018

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AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the financial report of Paradigm Biopharmaceuticals Limited for the half year ended 31 December 2017, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (ii) any applicable code of professional conduct in relation to the review.

**RSM AUSTRALIA PARTNERS****JASON CROALL**

Partner

22 February 2018
Melbourne, Victoria

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RSM Australia Partners ABN 36 965 185 036

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Paradigm Biopharmaceuticals Limited

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31 December 2017

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General information

The financial statements cover Paradigm Biopharmaceuticals Limited as a Consolidated Entity consisting of Paradigm Biopharmaceuticals Limited and its entities (together referred to as the "Consolidated Entity") at the end of the half-year. The financial statements are presented in Australian dollars, which is Paradigm Biopharmaceuticals Limited's functional and presentation currency.

Paradigm Biopharmaceuticals Limited is a listed public company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business are:

Principal Place of Business and Registered Office

C/-Hollingsworth & Co Pty Ltd
Level 2, 517 Flinders Lane
Melbourne VIC 3000

Telephone: (61-3) 9629 5566

A description of the nature of the Consolidated Entity's operations and its principal activities are included in the Directors' report, which is not part of the financial statements.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 22 February 2018.

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF PROFIT OR LOSS
AND OTHER COMPREHENSIVE INCOME
For the half year ended 31 December 2017

	Notes	31 December 2017 \$	31 December 2016 \$
Other Income		22,335	57,615
Research & Development		(2,708,102)	(1,716,166)
Employee Expenses		(364,724)	(322,511)
General and Administration expenses		(522,753)	(837,347)
Loss before income tax		(3,573,244)	(2,818,409)
Income tax expense / (benefit)		-	-
Loss for the year		(3,573,244)	(2,818,409)
Other comprehensive income		-	-
Total comprehensive income attributable to members of the consolidated entity		(3,573,244)	(2,818,409)
Earnings per share (cents)		(2.96) cents	(3.05) cents

There is no material difference between basic and diluted earnings per share

The above consolidated interim statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF FINANCIAL POSITION
As at 31 December 2017

		31 December 2017	30 June 2017
	Notes	\$	\$
ASSETS			
Current assets			
Cash and cash equivalents		6,002,076	2,590,812
Trade and other receivables		33,108	1,814,612
Prepaid expenses		192,135	20,993
Total current assets		6,227,319	4,426,417
Non- current assets			
Intangible assets	2	10,038,959	9,904,830
Plant and equipment		12,959	13,962
Total non- current assets		10,051,918	9,918,792
Total assets		16,279,237	14,345,209
LIABILITIES			
Current liabilities			
Trade and other payables		1,157,607	806,264
Employee benefits		204,326	149,025
Total current liabilities		1,361,933	955,289
Net assets		14,917,304	13,389,920
EQUITY			
Issued capital	3	25,807,895	21,057,052
Share options reserve	4	1,599,695	1,249,910
Accumulated losses		(12,490,286)	(8,917,042)
Total equity		14,917,304	13,389,920

The above consolidated interim statement of financial position should be read in conjunction with the accompanying notes

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY
For the half year ended 31 December 2017

	Issued Capital \$	Share Option Reserve \$	Accumulated Losses \$	Total \$
Balance at 1 July 2016	15,071,813	799,902	(4,641,596)	11,230,119
Loss for the period	-	-	(2,818,409)	(2,818,409)
Shares issued	6,504,000	270,525	-	6,774,525
Costs in relation to shares issued	(518,210)	-	-	(518,210)
Fair value of shares issued to eligible employees under the plan	-	37,553	-	37,553
Balance at 31 December 2016	21,057,603	1,107,980	(7,460,005)	14,705,578
Balance at 1 July 2017	21,057,052	1,249,910	(8,917,042)	13,389,920
Loss for the period	-	-	(3,573,244)	(3,573,244)
Shares issued	5,550,000	-	-	5,550,000
Costs in relation to shares issued	(799,157)	-	-	(799,157)
Fair value of shares issued to eligible employees under the plan	-	41,496	-	41,496
Fair value of shares issued to third party under the share-based payment arrangement	-	308,289	-	308,289
Balance at 31 December 2017	25,807,895	1,599,695	(12,490,286)	14,917,304

The above consolidated interim statement of changes in equity should be read in conjunction with the accompanying notes

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF CASH FLOWS
For the half year ended 31 December 2017

	31 December 2017	31 December 2016
Notes	\$	\$
Cash flows from operating activities		
Research and development tax incentive received	1,773,582	-
Payments to suppliers and employees	(3,015,085)	(3,185,412)
Interest received	8,989	14,284
Net cash outflow from operating activities	(1,232,514)	(3,171,128)
Cash flows from investing activities		
Payments for intangible assets	(104,013)	(779,593)
Payments for equipment	(3,052)	(15,898)
Net cash outflow from investing activities	(107,065)	(795,491)
Cash flows from financing activities		
Proceeds from the issue of share capital	5,550,000	6,504,000
Payment of share issue costs	(799,157)	(510,815)
Net cash inflow from financing activities	4,750,843	5,993,185
Net increase in cash and cash equivalents	3,411,264	2,026,566
Cash and cash equivalents at the beginning of the financial period	2,590,812	2,998,352
Cash and cash equivalents at the end of the financial period	6,002,076	5,024,918

The above consolidated interim statement of cash flows should be read in conjunction with the accompanying notes

Note 1. Significant accounting policies

These general purpose financial statements for the interim half-year reporting period ended 31 December 2017 have been prepared in accordance with Australian Accounting Standard AASB 134 'Interim Financial Reporting' and the Corporations Act 2001, as appropriate for for-profit oriented entities. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 'Interim Financial Reporting'.

These general purpose financial statements do not include all the notes of the type normally included in annual financial statements. Accordingly, these financial statements are to be read in conjunction with the annual report for the year ended 30 June 2017 and any public announcements made by the company during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

The principal accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, unless otherwise stated.

New, revised or amending Accounting Standards and Interpretations adopted

The consolidated entity has adopted all of the new, revised or amending Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

	31-Dec-17	30-Jun-17
	\$	\$
2. INTANGIBLE ASSETS		
Patents	10,038,959	9,904,830
Less: Accumulated amortisation	-	-
Total Intangible Assets	<u>10,038,959</u>	<u>9,904,830</u>
Reconciliation	\$	\$
Carrying amount at the beginning of the period	9,904,830	7,987,552
Additions during the period	134,129	1,917,278
Disposals	-	-
Amortisation expense	-	-
Balance at the end of the financial year	<u>10,038,959</u>	<u>9,904,830</u>

3. ISSUED CAPITAL

	31-Dec-17		30-Jun-17	
	Number	\$	Number	\$
Ordinary Shares				
Balance as at the beginning of the period	101,925,220	21,057,052	87,580,220	15,071,813
Ordinary shares issued	18,499,999	5,550,000	13,550,000	6,504,000
Ordinary shares issue costs (Net of GST)	-	(799,157)	-	(518,761)
Shares issued under ESP	210,000	-	795,000	-
Balance as at the end of the period	120,635,219	25,807,895	101,925,220	21,057,052

	31-Dec-17	30-Jun-17
	\$	\$
4. SHARE OPTIONS RESERVE		
Balance as at the beginning of the period	1,249,910	799,902
Fair values of shares issued to eligible employees under the ESP	41,496	179,483
Fair values of options issued to third party under the share-based payment arrangement	308,289	270,525
	1,599,695	1,249,910

5. COMMITMENTS

The Consolidated Entity has no expenditure contracted for at the reporting date but not recognised as liabilities.

6. CONTINGENT LIABILITIES

The Consolidated Entity had no contingent liabilities as at reporting date.

7. EVENTS SUBSEQUENT TO REPORTING DATE

No matters or circumstances have arisen since balance date which have impacted or are likely to impact the Consolidated Entity's operations, results and state of affairs in future financial years.

Paradigm Biopharmaceuticals Limited
Directors' declaration
31 December 2017

In the directors' opinion:

- the attached financial statements and notes comply with the Corporations Act 2001, Australian Accounting Standard AASB 134 'Interim Financial Reporting', the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the consolidated entity's financial position as at 31 December 2017 and of its performance for the financial half-year ended on that date; and
- there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 303(5) (a) of the Corporations Act 2001.

On behalf of the directors



Signed _____

Graeme Kaufman
Chairman
22 February 2018



Signed _____

Paul Rennie
Chief Executive Officer and Managing Director
22 February 2018

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INDEPENDENT AUDITOR'S REVIEW REPORT**TO THE MEMBERS OF****PARADIGM BIOPHARMACEUTICALS LIMITED**

We have reviewed the accompanying half-year financial report of Paradigm Biopharmaceuticals Limited ("the Company") which comprises the consolidated interim statement of financial position as at 31 December 2017, the consolidated interim statement of profit or loss and other comprehensive income, consolidated interim statement of changes in equity and the consolidated interim statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Directors' Responsibility for the Half-Year Financial Report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2017 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Paradigm Biopharmaceuticals Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of Paradigm Biopharmaceuticals Limited, would be in the same terms if given to the directors as at the time of this auditor's review report.

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Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Paradigm Biopharmaceuticals Limited is not in accordance with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2017 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and *Corporations Regulations 2001*



RSM AUSTRALIA PARTNERS



JASON CROALL
Partner

22 February 2018
Melbourne, Victoria