



ASX RELEASE

24 February 2017

Half-Year Results Report

Key Highlights:

- Recruitment complete and treatment has commenced of the 40 patients in the Company's Phase 2a allergic rhinitis (hay fever) clinical trial in Lund, Sweden.
- The Phase 2a clinical trial is a double blind, placebo controlled, cross-over allergen challenge study treating subjects with allergic rhinitis with PPS.
- Paradigm's PPS product is a non-steroid based drug which provides a unique treatment for hay fever sufferers as it treats both the early stages of the disorder (rhinorrhea/runny nose) as well as the late stage inflammation (congestion).
- Company successfully raised over \$7 million during the financial year through an oversubscribed Placement and SPP.
- The funds raised provide the Company with the balance sheet strength and financial flexibility to accelerate clinical programs and take advantage of growth opportunities.
- Paradigm making solid progress with its additional human in-life data of Ross River fever and osteoarthritis patients with Bone Marrow Edemas.

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 2016.

Clinical Development Progress

Post the reporting period, Paradigm Biopharma announced that it had completed recruitment and commenced treatment for its 40-patient Phase 2a allergic rhinitis (hay fever) clinical trial in Lund, Sweden.

The Phase 2a clinical trial is a double blind, placebo controlled, cross-over allergen challenge study treating subjects with allergic rhinitis (hay fever) with Paradigm Biopharma's Pentosan Polysulfate Sodium (PPS) product.

The product is a unique treatment for hay fever sufferers as it treats both stages of hay fever. In the early stage, the drug inhibits the release of histamines reducing the symptom of rhinorrhea or runny nose. In the late stage the drug also blocks the inflammatory cytokines (IL-4, IL-5 and IL-13) which drive the inflammatory response (congestion). The drug is non-steroid and it has the potential to be first in class as a dual treatment (early and late stage) in one nasal spray making the final product convenient and safer than current medicines.

The Phase 2 trial is being conducted under the leadership of Dr Lennart Greiff at Skane University Hospital who has previously conducted similar clinical trials, using the established allergen challenge clinical model for allergic rhinitis, for Big Pharma including Astra Zeneca.

The first group of 15 clinical trial subjects finished treatment in February, while Paradigm Biopharma expects the second group of 15 clinical trial subjects will finish treatment by mid-March, and the third group of 10 clinical trial subjects will finish treatment by the end of March 2017.

The last subject is expected to be out of the study in March 2017 with a readout of results anticipated in late Q2 or early Q3 CY2017.

The commencement of the trial follows Paradigm Biopharma receiving approval from the Independent Ethics Committee, Lund, and regulatory approval from the Swedish Medical Products Authority (MPA) in November 2016.

It also follows the release of compelling animal efficacy data and safety profile in the Phase 1 clinical trial in September 2016 and the release of favourable toxicology results from the Company's 28-day intra-nasal toxicology study in rats in August 2016.

Paradigm is pleased with the progress of the Phase 2a clinical trial and reaffirms the clinical trial is on schedule and on budget.

Corporate and Financials

Paradigm Biopharma successfully raised over \$7 million during the financial year through a Placement totaling \$6.21 million and a Share Purchase Plan raising an additional \$1 million.

The funds raised provide the Company with the balance sheet strength and financial flexibility to accelerate clinical programs and take advantage of growth opportunities.

The Placement was oversubscribed and was well supported by existing investors and new sophisticated and institutional investors.

For the half year period, the Company reported total expenditure of \$2.88 million with the majority of costs related to research and development and preparations for its Phase 2a hay fever trial

Paradigm Biopharma closed the half year period with over \$5 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.

Paradigm expects to receive approximately \$1.34 million in R&D tax incentives during the March quarter.

Outlook

The achievements made during 1H2017 put Paradigm Biopharma in a strong position in terms of its clinical development efforts and the Company expects to achieve further key milestones in the second half.

As well as its Phase 2a hay fever clinical trial, Paradigm is progressing well with its alphavirus program, with the Company having a patent to use PPS to treat alphaviruses, including Ross River Virus (RRV) and Chikungunya Virus (CHIKV).

In-life human data on ten RRA patients has been obtained and preparations for a Phase 2 clinical trial for RRV (Australia) and CHIKV (South America) have commenced.

The Company expects to receive ethics approval for the trial within the next two months and the trial to commence around June. The double-blinded trial will treat 24 patients in Queensland and Victoria.

The Company is also making good progress with its Phase 2 clinical trial for bone marrow edema (BME) or bone bruising. Paradigm is conducting an open label clinical trial investigating the safety, tolerability and efficacy of ZILOSUL[®] in patients with a bone marrow edema from a recent anterior cruciate ligament (ACL) injury. Ten patients have been treated and close-out of the study is expected in June 2017. In-life human data on ten patients with painful bone marrow edema and osteoarthritis have already been treated with the PPS drug. Impressive clinical findings have been made and they have been submitted to the skeletal radiology Journal for publication. The Company expects to receive ethics approval within the next 3 months for the first pilot study, which will be a double-blinded multi-site study to treat 60 patients with early OA and expects to commence the trial in July/August 2017. An additional pilot study on rheumatoid arthritis, which will be randomised, double-blinded and placebo-controlled, will also commence in late 2017.

“We have made excellent progress with all our indications over the first half and are confident of achieving further milestones in the remainder of 2017. We are looking forward to the read-out of our two phase 2 trials in the second half CY2017. The completion of two Phase 2 trials represents major financial catalytic events for the Company. We aim to have results published in our first two Phase clinical trials published in peer-reviewed journals later this year. We remain on track with our clinical development timeline and expenditure and look forward to updating investors on our progress,” said Paradigm Biopharma Director and Chief Executive Officer, Paul Rennie.

FOR FURTHER INFORMATION PLEASE CONTACT:

Paul Rennie
Director & CEO
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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 2016
Previous reporting period: 30 June 2016

2. Results for announcement to the market

	\$	\$ and % increase/(decrease) over previous corresponding period
Revenue from continuing activities	57,615	11,519 25.00%
(Loss) from continuing activities after tax attributable to members	(2,818,409)	(1,395,857) (98.12%)
Net (loss) for the period attributable to members	(2,818,409)	(1,395,857) (98.12%)
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)	(3.05) cents	(1.85) cents
Diluted earnings per ordinary security (cents per share)	(3.05) cents	(1.85) cents
Net tangible asset backing per ordinary security (cents per share)	4.79 cents	3.99 cents

4. Control gained over entities

Not applicable.

5. Loss of control over entities

Not applicable.

6. Audit qualification or review

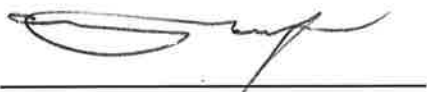
This report is based on accounts to which one of the following applies: (Tick one)			
The accounts have been audited	<input checked="checked" type="checkbox"/>	The accounts are in the process of being audited	<input type="checkbox"/>
If the accounts are subject to audit dispute or qualification, a description of the dispute or qualification: N/A			

7. Attachments

The report of half year ended 31 December 2016 is attached.

8. Signed

Signed



Graeme Kaufman
Chairman
23 February 2017

Signed



Paul Rennie
Chief Executive Officer and Managing Director
23 February 2017

Paradigm Biopharmaceuticals Limited

ABN 94 169 346 963

Half Year Report - 31 December 2016

Paradigm Biopharmaceuticals Limited
Directors' report
31 December 2016

The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the "Group") consisting of Paradigm Biopharmaceuticals Limited (referred to hereafter as the "Company") and the entities it controlled at the end of, or during, the half-year ended 31 December 2016.

Directors

The following persons were directors of Paradigm Biopharmaceuticals Limited 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 Group are researching and developing therapeutic products for human use.

Results

The Group made a loss for the period ended 31 December 2016 of \$2,818,409 (2015: Loss of \$1,422,552).

Significant changes in the state of affairs

In October 2016, the company raised capital of \$6,210,000 by way of private placement.

In December 2016, the company raised capital of \$294,000 by way of a Share Purchase Plan.

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
23 February 2017

Signed 

Paul Rennie
Chief Executive Officer and Managing Director
23 February 2017

RSM Australia Partners

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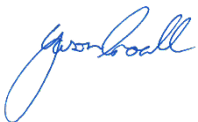
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AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the financial report of Paradigm Biopharmaceuticals Limited for the half year ended 31 December 2016, 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.

A stylized, handwritten signature of "RSM" in blue ink.**RSM AUSTRALIA PARTNERS**A handwritten signature in blue ink, appearing to read "J S Croall".

J S CROALL
Partner

23 February 2017
Melbourne, Victoria

Paradigm Biopharmaceuticals Limited

Contents

31 December 2016

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General information

The financial statements cover Paradigm Biopharmaceuticals Limited as a consolidated entity consisting of the Company and its subsidiaries (together referred to as the "Group") 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
Facsimile: (61-3) 9629 5466

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 23 February 2017.

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF PROFIT OR LOSS
AND OTHER COMPREHENSIVE INCOME
For the half year ended 31 December 2016

	31 December 2016	31 December 2015
Notes	\$	\$
Other Income	57,615	46,096
Research & Development	(1,716,166)	(932,085)
Employee Expenses	(322,511)	(231,295)
General and Administration expenses	(837,347)	(305,268)
Loss before income tax	(2,818,409)	(1,422,552)
Income tax expense / (benefit)	-	-
Loss for the year	(2,818,409)	(1,422,552)
Other comprehensive income	-	-
Total comprehensive income attributable to members of the consolidated entity	(2,818,409)	(1,422,552)
Earnings per share (cents)	(3.05) cents	(1.85) 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 2016

		31 December 2016	30 June 2016
	Notes	\$	\$
ASSETS			
Current assets			
Cash and cash equivalents		5,024,918	2,998,352
Trade and other receivables		1,351,857	1,342,224
Prepaid Insurance/Others		102,299	8,040
Total current assets		6,479,074	4,348,616
Non current assets			
Intangible assets	2	9,838,808	7,987,552
Equipment		20,386	10,635
-			
Total non current assets		9,859,194	7,998,187
Total assets		16,338,268	12,346,803
LIABILITIES			
Current liabilities			
Trade and other payables		1,498,869	1,026,308
Employee benefits		133,821	90,376
Total current liabilities		1,632,690	1,116,684
Net assets		14,705,578	11,230,119
EQUITY			
Issued capital	3	21,057,603	15,071,813
Share Options reserve	4	1,107,980	799,902
Accumulated losses		(7,460,005)	(4,641,596)
Total equity		14,705,578	11,230,119

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 2016

	Issued Capital \$	Share Option Reserve \$	Accumulated Losses \$	Total \$
Balance at 1 July 2015	1,577,497	748,800	(1,717,171)	609,126
Accumulated loss from Xosoma			(6,194)	(6,194)
Loss for the period	-	-	(1,422,552)	(1,422,552)
Shares issued	14,823,334	-	-	14,823,334
Costs in relation to shares issued	(1,327,170)	-	-	(1,327,170)
Fair value of shares issued to eligible employees under the plan	-	-	-	-
Balance at 31 December 2015	15,073,661	748,800	(3,145,917)	12,676,544
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	308,078	-	6,812,078
Costs in relation to shares issued	(518,210)	-	-	(518,210)
Balance at 31 December 2016	21,057,603	1,107,980	(7,460,005)	14,705,578

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 2016

	31 December 2016	31 December 2015
Notes	\$	\$
Cash flows from operating activities		
Payments to suppliers and employees	(3,185,412)	(859,876)
Interest received	14,284	36,429
Net cash outflow from operating activities	(3,171,128)	(823,447)
Cash flows from investing activities		
Payments for intangible assets	2 (779,593)	(153,218)
Acquisition of business assets	-	(410,228)
Payments for equipment	(15,898)	(3,153)
Net cash outflow from investing activities	(795,491)	(566,599)
Cash flows from financing activities		
Proceeds from the issue of share capital	6,504,000	8,000,000
Payment of share issue costs	(510,815)	(1,327,170)
Net movement in related party loans	-	(141,346)
Net cash inflow from financing activities	5,993,185	6,531,484
Net increase in cash and cash equivalents	2,026,566	5,141,438
Cash at the beginning of the financial period	2,998,352	124,857
Cash at the end of the financial period	5,024,918	5,266,295

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 2016 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 2016 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.

2. INTANGIBLE ASSETS

Patents and development costs	9,838,808	7,987,552
Less: Accumulated amortisation	-	-
Total Intangible Assets	<u>9,838,808</u>	<u>7,987,552</u>
Reconciliation	\$	\$
Carrying amount at the beginning of the period	7,987,552	356,288
Additions during the period	1,851,256	7,631,264
Disposals	-	-
Amortisation expense	-	-
Balance at the end of the financial year	<u>9,838,808</u>	<u>7,987,552</u>

Additions for the period relate to one-time payments due to milestones achieved in respect to clinical trials and marketing approval as outlined by the Asset Sale Agreement with Glycan Biosciences LLC.

Paradigm Biopharmaceuticals Limited
Notes to the financial statements
31 December 2016

3. ISSUED CAPITAL

	31-Dec-16		30-Jun-16	
	Number	\$	Number	\$
Ordinary Shares				
Balance as at the beginning of the period	87,580,220	15,071,813	37,368,333	1,577,497
Ordinary shares issued	13,550,000	6,504,000	42,352,381	14,823,334
Ordinary shares issue costs (Net of GST)		(518,210)		(1,329,018)
Subdivision of shares	-	-	-	-
Shares issued under ESP	370,000	-	-	-
Preference shares issued during the period	-	-	-	-
Preference shares issue costs (Net of GST)	-	-	-	-
Cancellation of Preference shares	-	-	(1,835,000)	(1,835,000)
Preference shares conversion to Ordinary shares	-	-	9,694,506	1,835,000
Balance as at the end of the period	101,500,220	21,057,603	87,580,220	15,071,813

	31-Dec-16	30-Jun-16
	\$	\$
4. SHARE OPTIONS RESERVE		
Balance as at the beginning of the period	799,902	748,800
Fair values of shares issued to eligible employees under the ESP	37,553	51,102
Fair values of options issued to third party under the share-based payment arrangement	270,525	-
	1,107,980	799,902

5. COMMITMENTS

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

6. CONTINGENT LIABILITIES

The Group 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 Group's operations, results and state of affairs in future financial years.


Paradigm Biopharmaceuticals Limited
Directors' declaration
31 December 2016

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 2016 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
23 February 2017

Signed 

Paul Rennie
Chief Executive Officer and Managing Director
23 February 2017

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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 2016, 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 2016 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.

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 2016 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



J S CROALL
Partner

23 February 2017
Melbourne, Victoria