ASX RELEASE 24th February 2021

Paradigm Announces 1HY21 Financial Results

KEY HIGHLIGHTS

- Paradigm reports NPAT loss AUD $20.7m 1H21 loss compared to $5.1m loss 1H20.
- Paradigm has contracted Premier Research as the Clinical Research Organisation (CRO) for the Phase 3 clinical program. Premier Research is a leading CRO in managing pain trials, having performed more than 870 trials across acute and chronic pain.
- The Company has also contracted with Cytel for the Phase 3 clinical program to provide statistical and data management services.
- Site selection and study infrastructure is being finalised for the PARA_OA_002 Pivotal study with a plan for 65 sites (approximately 58 sites in the US and 7 in Australia). Due to overwhelming interest in study participation Paradigm will be able to select the best sites for participation.
- Key OA Consultants retained in US and Europe and Lead Investigators selected for OA Pivotal Study in the US, EU and Australia.
- Data and Safety Monitoring Board (DSMB) being assembled to review unblinded data to conduct interim analysis to select treatment regimen based on criteria set to evaluate efficacy and safety and to monitor the safety of participants throughout the trial.
- Site selection completed and preparation is underway to enrol the first participants in Para_008 study evaluating synovial fluid effects of PPS in knee OA prior to the end Q1 CY21 with treatment commencing in Q2 CY21.
- Extensive non-clinical and pharmacokinetic studies completed to support OA clinical development program and meet FDA requirements for IND submission and subsequent drug development.
- New batch of iPPS (Zilosul®) has been manufactured to ensure sufficient product for Paradigm's clinical trial and user-pays TGA SAS.

Paradigm Biopharmaceuticals Limited (ASX: PAR) is pleased to provide additional detail on the ramp up in activities to accompany its Half Yearly Accounts. Paradigm reports a NPAT loss of $20.7MAUD for 1HY21, compared to a NPAT loss of $5.1MAUD for 1HY20. The increase in NPAT loss of $15.6MAUD compared to the prior corresponding period reflects the significant progress made with the Osteoarthrosis (OA) and Mucopolysaccharidosis (MPS) clinical programs, in addition to some increased general and administration and commercial expenses in line with organisation growth.

Osteoarthritis (OA)

During the six months to December 31, 2020, Paradigm Biopharmaceuticals progressed the clinical program for Osteoarthritis (OA) after holding key meetings with global regulators to develop a harmonised clinical program. The Company has been focused on actioning this clinical program during the first half of FY21 to submit an IND with US FDA by the end of Q1 CY21. This has resulted in a spend of $11.6MAUD in pre-clinical and clinical activities for 1HY21 period on OA in preparation of commencing the PARA-OA-002 Phase 3 Pivotal Study in Q2 CY21, in addition to supporting the initiation of the PARA-OA-008, a Phase 2 exploratory study on synovial fluid biomarkers.

PARA_OA_002

Paradigm has commenced several key activities in preparation for its IND submission due this quarter to the FDA and initiation of the PARA_OA_002 pivotal study.

Clinical Research Origination (CRO)

The company has appointed two leading CRO's to assist with the execution of the PARA_OA_002 study in the US and Australia. Premier Research is a world leader in chronic and acute pain clinical trial management having performed over 870 clinical trials spanning all areas of pain. Premier brings significant knowledge and training to sites that will be treating trial participants on approaches researchers use to minimise the placebo response. Cytel is the second CRO the company has contracted to assist with the Phase 3 clinical program. Cytel is a provider of statistical programming, adaptive clinical trial design and consulting solutions for pharmaceutical and biotechnology companies.

Site Section

Paradigm, in partnership with its CRO's, is currently finalising site selection in the US and Australia. 65 sites will be initiated for the PARA_OA_002 pivotal trial, with Paradigm receiving strong interest from a large number of sites in the US. Approximately 58 sites have/will be selected from the US with the remaining 7 sites initiated in Australia.

Key Consultants and Lead Investigators Secured

To ensure Paradigm has continuity and access to the most experienced scientists and clinical researchers in the field, we have retained leading specialists in the US, Australia and EU as consultants to the program.

Data and Safety Monitoring Board (DSMB)

A key component of the PARA_OA_002 is the adaptive trial design which allows for dose selection prior to commencing the Phase 3 pivotal and confirmatory studies. The DSMB is an independent and multidisciplinary group established by Paradigm to conduct the interim analysis for dose selection and to review, at pre-defined intervals, accumulating trial data to monitor the progress of the trial. While Paradigm and the trial investigators will monitor the day-to-day conduct of the trial, the DSMB will monitor safety and the overall trial conduct of the trial and issue recommendations to Paradigm.

PARA_OA_008

Paradigm recently announced ethics approval had been received for Phase 2 exploratory study to evaluate the treatment effect of Pentosan Polysulfate Sodium (PPS) (Zilosul®) compared with Placebo on Synovial Fluid Biomarkers in participants with Knee Osteoarthritis (OA) Pain. In preparation for imminent subject screening and first participant treatment during Q2 CY21, Paradigm has selected the CROs for managing the PARA_OA_008 study. The study will evaluate 60 participants randomised 1:1 to receive either PPS (n=30) or placebo (n=30).

Non-Clinical and PK Studies

Following feedback from the FDA during the Pre-IND meeting on the 21st February 2020, Paradigm completed several non-clinical studies and a PK study in healthy volunteers in Australia, focussed on evaluation of sub-cutaneous administration of PPS. The program has addressed specific FDA requirements to support the IND submission. The non-clinical studies confirmed no changes to the established safety profile of the drug. The additional PK study confirmed no differences in the kinetics of the drug between the Japanese subjects and western subjects and confirmed information on drug half-life and clearance.

Mucopolysaccharidoses (MPS)

PAR has commenced a Phase 2 open label study in patients with MPS-1 to better understand the ability of PPS to relieve persistent chronic pain in subjects with this rare genetic disease. Paradigm announced in November 2020, the initiation of a Phase 2 open-label clinical trial of PPS, in patients with the ultra-rare orphan disease Mucopolysaccharidosis Type 1 (MPS-I). The study is being conducted at the Adelaide Women's and Children's Hospital (WCH) with 3 patients currently undergoing treatment.

The Mucopolysaccharidosis Type VI (MPS-VI) clinical program is also progressing with Paradigm requesting Ethics Committee approval in Brazil to conduct a placebo-controlled study to determine the effect of PPS to relieve chronic pain in patients with MPS-VI. The CRO and Principal Investigator have been appointed. Paradigm is working with the local CRO in preparation for a submission to the Brazil regulator. The spend on MPS activity in 1HY21 was $2.2MAUD.

Dr Donna Skerrett, Paradigm's Chief Medical Officer said, "*During CY 2020 Paradigm conducted a number of non-clinical and clinical studies to provide updated information regarding drug characteristics, pharmacokinetics, and non-clinical toxicity as requested by the FDA in the Company's first meeting with the Agency in February 2020. Paradigm has worked diligently to ensure it has all the necessary supporting non-clinical and clinical data and clinical development plan to support its IND submission in Q1 CY 2021***."**

About injectable PPS

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 currently only available by inclusion into a Paradigm Sponsored clinical trial.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Limited (ASX: PAR) is a late-stage development company with the mission to develop and commercialise Pentosan Polysulfate Sodium for the treatment of pain, inflammation, and modification of pathogenesis of disease driven by inflammation, aging, degenerative disease, infection or genetic predisposition.

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

Authorised for release by Paul Rennie, CEO & Interim Chair.

Zilosul® is a registered Trademark of Paradigm Biopharmaceuticals Limited (ASX: PAR).

To learn more please visit: www.paradigmbiopharma.com

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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 2020
Previous reporting period:	31 December 2019

2. Results for announcement to the market

	$	**$ and % increase/(decrease) over previous corresponding period**
Revenue from continuing activities	254,475	(571,478) (69.19%)
(Loss) from continuing activities after tax attributable to members	(20,730,495)	15,626,491 306.16%
Net (loss) for the period attributable to members	(20,730,495)	15,626,491 306.16%
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	

Paradigm Biopharmaceuticals Limited
Appendix 4D
Half-year report

2. Results for announcement to the market continued

Brief explanation of any of the figures reported above necessary to enable the figures to be understood:
During the six months to 31 December 2020, Paradigm Biopharmaceuticals committed significant resources to progressing its clinical program for Osteoarthritis (**OA**) which included convening meetings with the US FDA and European Medicines Agency. Based on these meetings, the company has been able to develop a globally harmonised clinical program that will enable it to combine data generated from the planned clinical trials in each of the US and Europe, thereby supporting more statistically robust outcomes. Since those meetings, the Company has been incorporating the agencies' feedback into its clinical program towards submitting an IND with US FDA by the end of Q1 2021 for a phase III trial. In preparation for the commencement of that trial, the company has engaged with service providers that will project manage the trial and the trial data, and continues to progressively engage with trial sites. The increase in NPAT loss compared to the prior corresponding period reflects the significant increase in the costs and expenses that the company needed to incur in order to be able to launch a phase III trial as well as a phase II trial for the treatment of Mucopolysaccharidosis (**MPS**). These costs and expenses included payments that have been made to the clinical trial service providers. In addition there are some increased general administration and commercial expenses in line with organisation growth. (refer to Section 2 significant state of affairs).

3. Net tangible assets

	Current Period	**Previous corresponding period**
Basic loss per ordinary security (cents per share)	(9.10) cents	(2.60) cents
Diluted loss per ordinary security (cents per share)	(9.10) cents	(2.60) cents
Net tangible asset backing per ordinary security (cents per share)	37.75 cents	38.75 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 reviewed	✓	The accounts are in the process of being reviewed	
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 2020 is attached.

8. Signed

Signed _____

Mr. Paul Rennie
Interim Chair and Managing Director
24th February 2021

Paradigm Biopharmaceuticals Limited

ABN 94 169 346 963

Half Year Report - 31 December 2020

Paradigm Biopharmaceuticals Limited
Directors' report
31 December 2020

The directors present their report, together with the financial statements, on the Consolidated Entity consisting of Paradigm Biopharmaceuticals Limited (**Paradigm or the Company**) and the entities it controlled at the end of, or during, the half-year ended 31 December 2020.

Directors

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

Paul Rennie
Christopher Fullerton (resigned on 19 November 2020)
John Gaffney
Donna Skerrett (appointed on 03 July 2020)
Amos Meltzer (appointed on 09 December 2020)

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 2020 of $20,730,495 (2019: Loss of $5,104,004).

Significant changes in the state of affairs

- A clear Regulatory path for Zilosul® registration has been developed with feedback from key regulatory agencies the EMEA and the US FDA following successful meetings with both regulatory bodies in February (Pre-IND, US FDA), September 2020 (Scientific Advice, EMEA) and December (Type C, US FDA). This enabled Paradigm to harmonise its clinical trial design with the key regulatory bodies, de-risking the clinical program.
- In September an amendment to the exclusive supply agreement with bene pharmaChem was completed. The amendment resulted in expanded territories being added to the agreement in addition to an increase in the number of indications covered by the agreement. The agreement was updated to reflect a 25-year period of exclusivity in supply with bene pharmaChem effective from the date of marketing approval.
- In November Paradigm announced the initiation of a Phase 2 open label clinical trial of injectable Pentosan Polysulfate Sodium (**PPS**), in patients with the ultra-rare orphan disease Mucopolysaccharidosis Type 1 (**MPS-1**).
- Paradigm has secured **PPS** product to support the commencement of the pivotal phase 3 study PARA-002 and the PARA-008 study to measure synovial fluid impact in the knee. Enough product has been obtained to support resumption of the Special Access Scheme (**SAS**) program in Australia.
- During the first 6 months of the year two new Directors were appointed to the Board, Dr Donna Skerrett and Mr Amos Meltzer. Mr Chris Fullerton resigned from the Board at the company's AGM.

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 

Mr. Paul Rennie
Interim Chair & Managing Director
24th February 2021

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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 2020, 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

J S CROALL
Partner

Dated: 24 February 2021
Melbourne, Victoria

Paradigm Biopharmaceuticals Limited
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General information

The financial statements cover Paradigm Biopharmaceuticals Limited as a Consolidated Entity, consisting of Paradigm Biopharmaceuticals Limited and its controlled entities (together referred to as the “Consolidated Entity”) at the end of the half-year ended 31 December 2020. 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:

Registered office

Level 15, 500 Collins Street
Melbourne VIC 3000

Principal place of business

Level 15, 500 Collins Street
Melbourne VIC 3000

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 24th February 2021.

PARADIGM BIOPHARMACEUTICALS LIMITED
CONSOLIDATED INTERIM STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
For the half year ended 31 December 2020

	Notes	31 December 2020 $	31 December 2019 $
Other income		254,475	825,953
Research and development expenses		(17,195,123)	(4,315,825)
General and administration expenses		(3,651,532)	(1,600,031)
Commercial expenses		(119,482)	-
Finance costs		(18,833)	(14,101)
Loss before income tax		**(20,730,495)**	**(5,104,004)**
Income tax expense / (benefit)		-	-
Loss for the year		**(20,730,495)**	**(5,104,004)**
Other comprehensive income		**-**	**-**
Total comprehensive loss attributable to members of the consolidated entity		**(20,730,495)**	**(5,104,004)**
Loss per share (cents)	**8**	(9.1) cents	(2.6) cents

There is no material difference between basic and diluted loss 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 2020

	Notes	31 December 2020 $	30 June 2020 $
ASSETS			
Current assets			
Cash and cash equivalents		85,206,421	103,922,241
Trade and other receivables	2	3,497,824	3,509,777
Prepaid expenses		1,908,959	192,380
Financial assets held at amortised cost		746,200	746,200
Total current assets		**91,359,404**	**108,370,598**
Non-current assets			
Intangible assets	3	2,947,589	2,947,588
Plant and equipment		118,967	109,913
Right-of-use assets	4	752,313	832,917
Security deposits receivable		102,616	102,616
Total non-current assets		**3,921,485**	**3,993,034**
Total assets		**95,280,889**	**112,363,632**
LIABILITIES			
Current liabilities			
Trade and other payables	5	4,380,362	2,784,324
Employee benefits		547,962	455,510
Lease liabilities		130,787	124,731
Total current liabilities		**5,059,111**	**3,364,565**
Non-current liabilities			
Employee benefits		89,435	68,390
Lease liabilities		683,455	748,958
Total non-current liabilities		**772,890**	**817,348**
Total liabilities		**5,832,001**	**4,181,913**
Net assets		**89,448,888**	**108,181,719**
EQUITY			
Issued capital	6	146,510,921	145,865,076
Share based payments reserve	7	4,774,371	3,585,189
Accumulated losses		(61,836,404)	(41,268,546)
Total equity		**89,448,888**	**108,181,719**

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 2020

	Issued Capital $	Share Option Reserve $	Accumulated Losses $	Total $
Balance at 1 July 2019	**109,468,292**	**4,072,844**	**(30,734,818)**	**82,806,318**
Loss for the period	-	-	(5,104,004)	(5,104,004)
Costs in relation to shares issued	(320,130)	-	-	(320,130)
Fair value of shares issued to eligible employees under the plan	-	490,936	-	490,936
Fair value of shares issued to third party under the share-based payment arrangement	-	(533,535)	533,535	-
Exercise of unlisted options	1,403,078	-	-	1,403,078
Balance at 31 December 2019	**110,551,240**	**4,030,245**	**(35,305,287)**	**79,276,198**
Balance at 1 July 2020	**145,865,076**	**3,585,189**	**(41,268,546)**	**108,181,719**
Loss for the period	-	-	(20,730,495)	(20,730,495)
Fair value of shares issued to eligible employees under the plan	-	1,351,819	-	1,351,819
Transfer from share based payments reserve on exercise of options	-	(162,637)	162,637	-
Shares issued relating to repayment of limited recourse loan for ESP	103,675	-	-	103,675
Exercise of unlisted options	542,170	-	-	542,170
Balance at 31 December 2020	**146,510,921**	**4,774,371**	**(61,836,404)**	**89,448,888**

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 2020

	Notes	31 December 2020 $	31 December 2019 $
Cash flows from operating activities			
Research and development and other tax incentive received		50,000	373,198
Payments to suppliers and employees (inclusive of GST)		(19,541,798)	(6,957,394)
Interest received		229,392	694,904
Interest repayment of lease liabilities		(18,833)	(14,101)
Net cash outflow from operating activities	**9**	**(19,281,239)**	**(5,889,292)**
Cash flows from investing activities			
Payments for intangible assets	**3**	(850)	(5,705)
Payments for equipment		(20,130)	(93,178)
Payments for financial assets held at amortised cost		-	3,803,800
Net cash inflow from investing activities		**(20,980)**	**3,704,917**
Cash flows from financing activities			
Proceeds from exercise of share options		542,170	1,403,078
Payment of share issue costs		-	(570,130)
Limited recourse loan repaid under ESP		103,675	-
Principal repayment of lease liabilities		(59,446)	(36,994)
Net cash inflow from financing activities		**586,399**	**781,853**
Net decrease in cash and cash equivalents		**(18,715,820)**	**(1,402,522)**
Cash and cash equivalents at the beginning of the financial period		**103,922,241**	**72,336,173**
Cash and cash equivalents at the end of the financial period		**85,206,421**	**70,933,651**

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 2020 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 2020 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 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 or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

	31-Dec-20 $	30-Jun-20 $
2. TRADE AND OTHER RECEIVABLES		
GST receivable	47,035	34,070
Interest receivable	26,595	51,513
*R&D tax incentive receivable	3,424,194	3,424,194
	3,497,824	**3,509,777**

**The R&D Tax incentive receivable was a best estimate as at 30 June 2020 prior to completion of the FY20 Income Tax Return. A refund of $3,380,776, has now been received by Paradigm on 19 February 2021.*

3. INTANGIBLE ASSETS	**31-Dec-20**	**30-Jun-20**
	$	**$**
Patents	9,926,367	9,925,516
Less: Accumulated amortisation and impairment losses	(6,978,778)	(6,977,928)
Total Intangible Assets	**2,947,588**	**2,947,588**
Reconciliation		
Carrying amount at the beginning of the period	2,947,588	2,981,359
Additions during the period	850	3,353
Disposals	-	-
Amortisation expense	(850)	(37,124)
Impairment losses	-	-
Balance at the end of the financial year	**2,947,588**	**2,947,588**

4. RIGHT-OF-USE ASSETS		
Land and buildings - right-of-use	967,258	967,258
Less: Accumulated depreciation	(214,945)	(134,341)
	752,313	**832,917**

5. TRADE AND OTHER PAYABLES		
Trade and other creditors	4,343,773	2,747,735
Shareholder loans	36,589	36,589
	4,380,362	**2,784,324**

6. ISSUED CAPITAL

	31-Dec-20 Number of Shares	30-Jun-20 Number of Shares	31-Dec-20 $	30-Jun-20 $
Ordinary shares - fully paid	229,169,548	224,747,176	146,510,921	145,865,076

Movements in ordinary share capital

Details	**Shares**	**$**
Balance as at 1 July 2020	224,747,176	145,865,076
Shares issued under ESP	3,315,000	-
Shares forfeited	(52,628)	-
Exercise of unlisted options	1,160,000	542,170
Limited recourse loan repaid under ESP	-	103,675
Balance as at 31 December 2020	**229,169,548**	**146,510,921**

7. SHARE BASED PAYMENT RESERVE

	31-Dec-20 $	30-Jun-20 $
Balance as at the beginning of the period	3,585,189	4,072,844
Fair values of shares issued/to be issued to eligible employees under the ESP	1,351,819	490,936
Fair values of options issued to third party under the share-based payment arrangement	-	786,568
Transfer from share based payments reserve on exercise of options	(162,637)	(1,765,159)
	4,774,371	**3,585,189**

7. SHARE BASED PAYMENT RESERVE (cont'd)

Once an offer of shares under the Employee Share Plan (**ESP**) is approved by the Board, monies are loaned by the Consolidated Entity interest free and on a non-recourse basis to employee's to finance the purchase of shares in the Company. The **ESP** shares are registered in the name of participants. Shares offered under the **ESP** are subject to a 3 year vesting period where the shares will vest in 3 equal amounts. The shares are subject to a restriction on disposal for a period of five years (from date of issue) and for further periods whilst they remain financed. On cessation of employment, the entitlement to any shares held for less than three years is pro-rated.

On 10 July 2020, an invitation of **ESP** shares of 2,215,000 based on 2020 performance was approved and issued at a price of $3.24 per share. On 19 November 2020, a further invitation of **ESP** shares of 1,100,000 based on 2020 performance was approved and issued at a price of $3.05 per share. These shares were issued with vesting conditions. Each tranche of shares will vest in 12 months, 24 months and 36 months.

Fair values at loan date are determined using a Binomial Hedley pricing model that takes into account the issue price, the term of the loan, the share price at loan date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the loan.

ESP Shares	**Grant date**	**Vesting condition**	**Number**
Jul-20	10/07/2020	738,331 shares are vested on 10 July 2021, 738,332 shares are vested on 10 July 2022 and 738,337 shares are vested on 10 July 2023	2,215,000
Nov-20	19/11/2020	366,666 shares are vested on 19 November 2021, 366,667 shares are vested on 19 November 2022 and 366,667 shares are vested on 19 November 2023	1,100,000

31-Dec-20

Grant date	**Expiry date**	**Exercise price**	**Balance at the start of the year**	**Granted**	**Exercised**	**Expired/forfeited**	**Balance at the end of the year**
7/11/2019	7/11/2024	$2.93	2,913,518	-	(175,000)	52,628	2,791,146
10/07/2020	10/07/2025	$3.24	-	2,215,000	-	-	2,215,000
19/11/2020	19/11/2025	$3.05	-	1,100,000	-	-	1,100,000
			2,913,518	**3,315,000**	**(175,000)**	**52,628**	**6,106,146**

7. SHARE BASED PAYMENT RESERVE (cont'd)

30-Jun-20

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Expired/forfeited	Balance at the end of the year
7/11/2019	7/11/2024	$2.93	5,805,000	1,320,088	(4,211,570)	-	2,913,518
			5,805,000	**1,320,088**	**(4,211,570)**	**-**	**2,913,518**

For the shares granted during the current financial year, the valuation model inputs used to determine the fair value at the grant date, are as follow:

Grant date	Expiry date	Share price at grant date	Exercise price	Expected volatility	Dividend yield	Risk free rate	Fair value at grant date
10/07/2020	10/07/2025	$3.24	$3.24	85.00%	0.00%	0.40%	$1.91
19/11/2020	19/11/2025	$3.05	$3.05	85.00%	0.00%	0.30%	$1.81

UNLISTED OPTIONS

31-Dec-20

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Balance at the end of the year
24/03/2020	24/03/2023	$1.75	550,000	-	-	550,000
28/02/2020	28/02/2023	$1.75	275,000	-	-	275,000
18/05/2018	18/05/2021	$0.65	861,250	-	(125,000)	736,250
16/11/2017	15/11/2020	$0.31	35,000	-	(35,000)	-
27/09/2017	27/09/2020	$0.45	1,000,000	-	(1,000,000)	-
			2,721,250	**-**	**(1,160,000)**	**1,561,250**

7. SHARE BASED PAYMENT RESERVE (cont'd)

30-Jun-20

Grant date	Expiry date	Exercise price	Balance at the start of the year	Granted	Exercised	Balance at the end of the year
24/03/2020	24/03/2023	$1.75	-	550,000	-	550,000
28/02/2020	28/02/2023	$1.75	-	275,000	-	275,000
18/05/2018	18/05/2021	$0.65	1,000,000	-	(138,750)	861,250
7/05/2018	7/05/2021	$0.45	1,000,000	-	(1,000,000)	-
16/11/2017	15/11/2020	$0.31	192,500	-	(157,500)	35,000
27/09/2017	27/09/2020	$0.45	2,000,000	-	(1,000,000)	1,000,000
19/01/2017	19/01/2020	$0.40	2,000,000	-	(2,000,000)	-
			6,192,500	**825,000**	**(4,296,250)**	**2,721,250**

8. LOSS PER SHARE

	31-Dec-20	31-Dec-19
Net loss for the period attributable to ordinary shareholders	(20,730,495)	(5,104,004)
	Number	**Number**
Weighted average number of ordinary shares used in calculating basic loss per share	227,745,785	193,420,396
Weighted average number of ordinary shares used in calculation diluted loss per share	**227,745,785**	**193,420,396**
	Cents	**Cents**
Basic loss per share	**(9.10)**	**(2.60)**
Diluted loss per share	**(9.10)**	**(2.60)**

1,561,250 unexercised options (2019: 2,821,250) have been excluded from the calculation of the diluted loss per share above as it would have an anti-dilutive impact.

	31-Dec-20 $	30-Dec-19 $
9. RECONCILIATION OF CASH FLOWS PROVIDED BY OPERATING ACTIVITIES		
Loss for the year	**(20,730,495)**	**(5,104,004)**
Depreciation and amortisation	103,183	73,071
Share-based payment	1,351,819	490,936
Change in operating assets and liabilities		
(Increase) decrease in receivables	11,953	226,242
(Increase) decrease in prepayments	(1,716,579)	(172,156)
Increase (decrease) in trade creditors and accruals	1,698,880	(1,403,381)
Net cash used in operating activities	**(19,281,239)**	**(5,889,292)**

The increase in cash out flows during the six months to 31 December 2020 was driven by the progress made in the Company's clinical program.

10. COMMITMENTS

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

11. CONTINGENT LIABILITIES

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

12. EVENTS SUBSEQUENT TO REPORTING DATE

The impact of the Coronavirus (COVID-19) pandemic is ongoing, and it is not practicable to estimate the potential impact, positive or negative, after the reporting date. The situation is evolving and is dependent on measures imposed by the Australian Federal and State Governments and other countries, such as maintaining social distancing requirements, quarantine, travel restrictions and any economic stimulus that may be provided.

Paradigm Biopharmaceuticals Limited
Directors' Declaration
31 December 2020

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 2020 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 _____

Mr. Paul Rennie
Interim Chair and Managing Director
24th February 2021

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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") and its controlled entities ("Consolidated entity") which comprises the consolidated interim statement of financial position as at 31 December 2020, 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 2020 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 2020 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

Dated: 24 February 2021
Melbourne, Victoria