PARADIGM BIOPHARMACEUTICALS LIMITED

ASX RELEASE 31st July 2020

PARADIGM - JUNE 2020 QUARTERLY REPORT

KEY HIGHLIGHTS (INCLUDING SIGNIFICANT EVENTS POST END OF QUARTER)

- **Pre-IND meeting with FDA:** FDA minutes confirmed the complexity and uniqueness of the Bene pharmaChem PPS molecule, being the only FDA approved PPS.
- **Capital raise:** In March 26,923,077 shares were issued and placed with Domestic and International Institutions to raise $35m. The proceeds from the placement will be applied to costs of the second Phase 3 osteoarthritis (OA) clinical trial (confirmatory clinical trial). The company is now fully funded to complete its current clinical programs in OA and MPS through to registration.
- **Real-world evidence:** New data on a cohort of 34 SAS patients was presented using the primary and secondary end points Paradigm will use in its Phase 3 clinical trials. This data showed the chronic pain response as measured by the WOMAC pain score demonstrated a mean reduction of 44.9%. In addition, 85.7% (30 out of 34) of SAS patients had reported Patient global impression of Change (PGIC) of moderately to definite and considerable improvement in their OA condition with iPPS (Zilosul®) treatment.
- **Orphan drug designation:** The company was advised by the FDA that Paradigm's orphan designation request for MPS-I has been granted, joining the previously granted designation for MPS-VI.
- **New staff appointments:** Further strengthening of the Paradigm team with significant additions to the senior management team in Dr Jeannie Joughin (Chief Operations Officer) and Dr Michael Imperiale (Chief Safety Officer).
- **ASX 300:** Addition to the ASX 300 index.
- **FDA EAP data readout:** 65% mean reduction in WOMAC pain from baseline across total patient population (n=10) using WOMAC Pain Subscale in the FDA Expanded Access Program in the USA.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) (Paradigm or the Company) is pleased to provide its quarterly update for the three months ended 30th June 2020 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as at 30th June 2020 was $104.6m (at 31 March 2020: $74.5m) with a net operating cash outflow during the quarter of $4.7m.
- Research & development expenditure for the quarter was $4.2m compared to the previous quarter of $2.4m. Details of the research and development activities are summarised in the continuing activities under Outlook below.
- For the purpose of Listing Rule 4.7C.3, Non-Executive Chairman and Non-Executive Directors were paid director fees of $60,000 for the quarter.

OUTLOOK

- The Company continues to prepare information that was requested by the TGA for the next stage of submission for the Provisional Approval determination. The company will further update the market on the progress of this process in Q4 CY 2020.
    - Additional new data on 67 patients treated under the SAS program. Paradigm expects to report on 35 patients in Q3 with the remaining patient data available in early Q4 CY2020. The data will be presented in a similar manner as the April 6th announcement of 34 patients using the same endpoints and product identified for Paradigm's Phase 3 trials (WOMAC pain and WOMAC function and PGIC). This will take the total number of SAS patients reported on with the proposed Phase 3 endpoints to over 100 patients.
- Paradigm remains focused on its IND submission to the FDA for the remainder of CY20. The Paradigm team and its consultants continue to compile the necessary information and data for the IND submission toward the end of Q4 CY2020. The Company has been made aware of a FDA guideance on timelines and possible delays to meeting requests as a result of COVID-19. The delays for meetings are not significant and may be within the range of weeks rather than months but Paradigm will update the market should COVID-19 impact the timing of Paradigm's IND meeting with the FDA.
- Paradigm expects to receive notification from the Ethics Committee on its Phase 2 MPS -1 clinical program during the current quarter.
- Feedback from the Joint Parallel Scientific Advice meeting with the FDA (US) and EMA (Europe) is expected this quarter which will give Paradigm important feedback and scientific advice from both agencies on questions in regard to clinical trial end points and overall trial design for Paradigm's proposed pivotal/registrational trial in MPS-VI.
- The company is currently in the process of finalising a Commercial Research Agreement with an Australian University. The research program will investigate the safety and efficacy of iPPS in a viral induced respiratory disease model. Paradigm will provide additional detail to the market once this has been completed.
- Paradigm staff and the principal investigators have completed writing the Phase 2b osteoarthritis clinical trial and the Phase 2A Viral Arthritis clinical trial manuscripts. The manuscripts will now be sent to the chosen Journal Editor for peer-review and publication. Paradigm expects both Peer reviewed publications to be released Q4 CY 2020.
- The company expects to have a presence at several domestic and international Virtual Conferences during FY21 to continue to promote Paradigm to new investors as we progress through our clinical development programs.
- Paradigm will be looking to add further strength to its organisation, targeting those with previous Big-Pharma experience.

Addressable Market: Osteoarthritis (OA) is the most common joint disorder in the United States. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic. ABOUT 54.4 MILLION ADULTS IN THE U.S. HAVE DOCTOR-DIAGNOSED ARTHRITIS[1]. OA affects 240 million people globally[2].

About injectable PPS (Zilosul®): 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 only available by inclusion into a Paradigm Sponsored clinical trial or via a treating physician applying for its use in patients via the TGA's SAS - Category B.

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

Authorised for release by Paul Rennie, Managing Director & Interim Executive Chairman.

FOR FURTHER INFORMATION PLEASE CONTACT:
Simon White
Director of Investor Relations
Tel: +61 (0) 404 216 467
Paradigm Biopharmaceuticals Ltd
ABN: 94 169 346 963
Level 15, 500 Collins St, Melbourne, VIC, 3000, AUSTRALIA
Email : investorrelations@paradigmbiopharma.com

[1] https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf (Barbour – MMWR [66] 2017).
[2] https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa_serious_disease_121416_1.pdf