PARADIGM BIOPHARMA

2022 ANNUAL GENERAL MEETING

MD & Business Update

Paul Rennie, Managing Director

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Executive Team

PAUL RENNIE
Founder & Chairman

DR. DONNA SKERRETT
Chief Medical Officer

DR RAVI KRISHNAN
Chief Scientific Officer

JUSTIN CAHILL
Chief Financial Officer

Key Milestones Achieved FY22

Osteoarthritis (OA)

- IND open for phase 3 clinical trial and Fast Track Designation granted by US FDA
- Actively screening and enrolling participants in US, AU, UK
- Globally harmonised clinical program will support: registration in multiple jurisdictions, a broad label, maximise reimbursed price and market penetration from launch

Mucopolysaccharidosis (MPS)

MPS-VI

- Phase 2 clinical trial commenced evaluating the safety and tolerability of iPPS compared to placebo (2:1)

MPS-I

- Presentation of interim 6-month data at the International Congress of Inborn Errors of Metabolism

Company

- Continued development of two early-stage pipeline assets, HFpEF and ARDS
- Partnership with NFL Alumni Health
- Actively engaged in discussions with potential partners

Osteoarthritis

OA

Osteoarthritis - Global Phase 3 Achievements

Harmonised clinical protocol to achieve simultaneous registration in key jurisdictions

PARA_OA_002 Global Progress

United States

- Fast Track Designation
- 50+ sites activated
- Enrolling participants

Australia

- 8 sites activated
- Enrolling participants

UK and Europe

- 12 sites selected
- UK reg & ethics approval received
- First UK site activated and commenced screening activities
- First UK subject randomised

Canada

- Regulatory and ethics approval received
- Up to 10 sites to be activated
- First subject expected to be randomised Q4

Lead Program

Osteoarthritis

KEY OBJECTIVES FY23

Data Safety Monitoring Board Review (DSMB)

- Formal review by the DSMB for the PARA_OA_002 trial in December
- Review and evaluation of the accumulated PARA_OA_002 study data

PARA_OA_002 Stage 1

- 100% recruitment of stage 1 during 1H CY23
- Stage 1 aims to identify the minimum effective dose of iPPS to be carried into stage 2 and the confirmatory PARA_OA_003 study

Activities to Accelerate Recruitment for PARA_OA_002

- Protocol Modification to reduce patient and site burden
- Increase total number of sites
- Recruitment and retention activities

DMOAD Program

Osteoarthritis

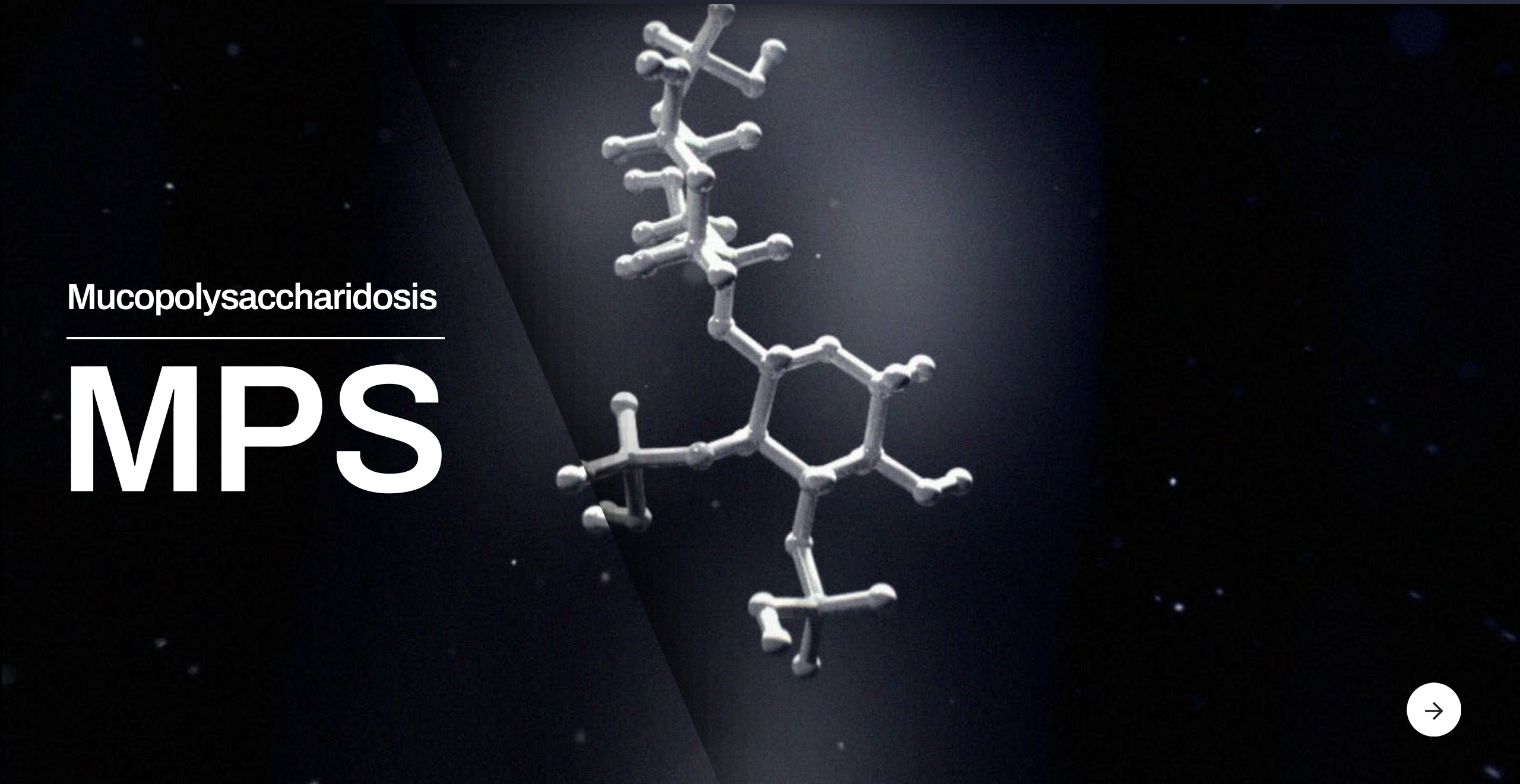
EXPLORING THE POTENTIAL OF PPS AS A DISEASE MODIFYING OA DRUG (DMOAD)

PARA_OA_008

- Global market research detailed US$6000+ achievable for Zilosul® if DMOAD label achieved
- Outstanding top-line results reported at day 56:
  - iPPS impacted multiple biomarkers measured in the synovial fluid
  - iPPS treatment showed statistically significant improvements at day 56 in pain, function, stiffness, and overall WOMAC scores for twice-weekly iPPS compared to the placebo arm

Next Steps

- Day 168 (~6-month) top-line data readout
- Data from day 56 & 168 will be prepared for peer review and journal submission
- Regulatory discussions on DMOAD pathway (FDA & EMA)
- TGA Provisional Approval application to be assessed following 6-month data, FDA and EMA discussions



Mucopolysaccharidosis

MPS

Mucopolysaccharidosis (MPS)

Phase 2 asset in rare disease associated with inflammation & ongoing musculoskeletal pain: iPPS has FDA & EMA orphan designation for MPS

MPS I - Australia

- Open-label trial SC dosing subjects weekly for 12 weeks, then every other week for a total of 52 weeks
- Primary endpoint is safety, key secondary endpoints are pain and function, as well as PK
- Interim top-line data presented at ICEIM 2021 by primary investigator Dr Drago Bratkovic showed iPPS is well tolerated, demonstrating reduction in pain and GAGs, and improvement in function

MPS VI - Brazil

- A double-blind placebo-controlled trial with 12 subjects. Dosed weekly SC for 52 weeks
- Primary endpoint is safety, key secondary endpoints are pain and function
- Safety Monitoring Physician confirmed two successful safety reviews in participants aged 9 to 16 and in the 16+ cohort, with the clinical trial now assessing the youngest cohort (aged 5 to 9 years)

Mucopolysaccharidosis

MPS

KEY OBJECTIVES FY23

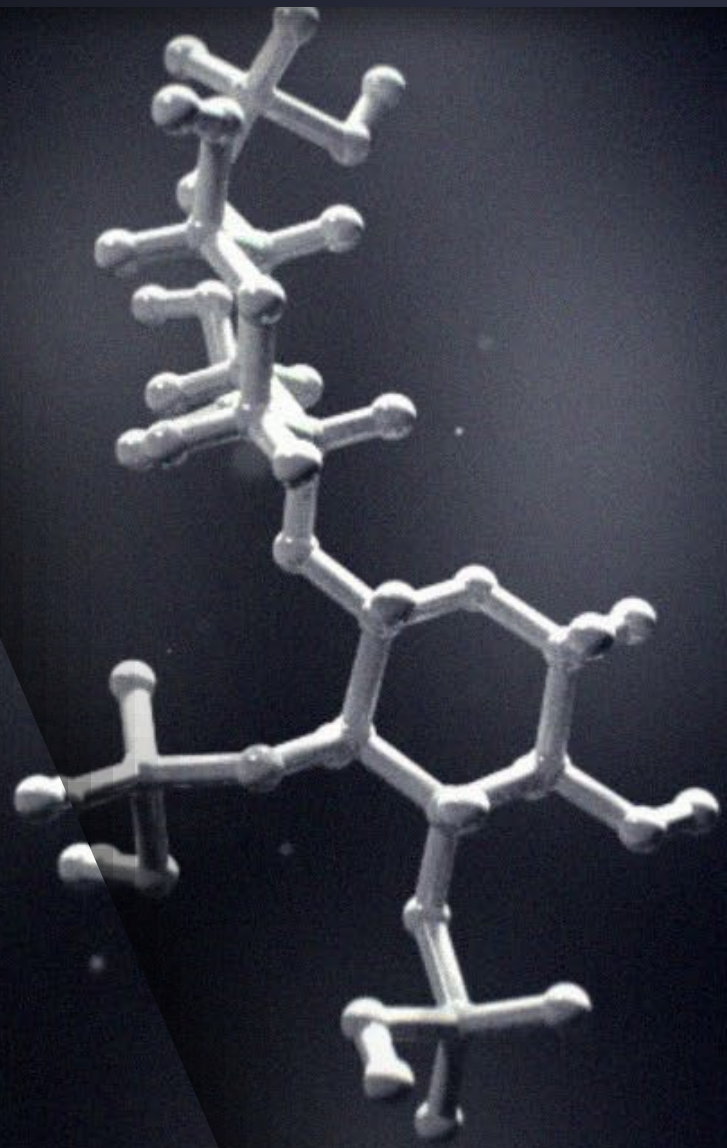
MPS-I

- Data for the phase 2 study to be presented by Dr Bratkovic at ICLD 2023 and will cover information on pain, function, urinary GAGs, and change in biomarkers
- Preparation for completion of study and final data read out

MPS-VI

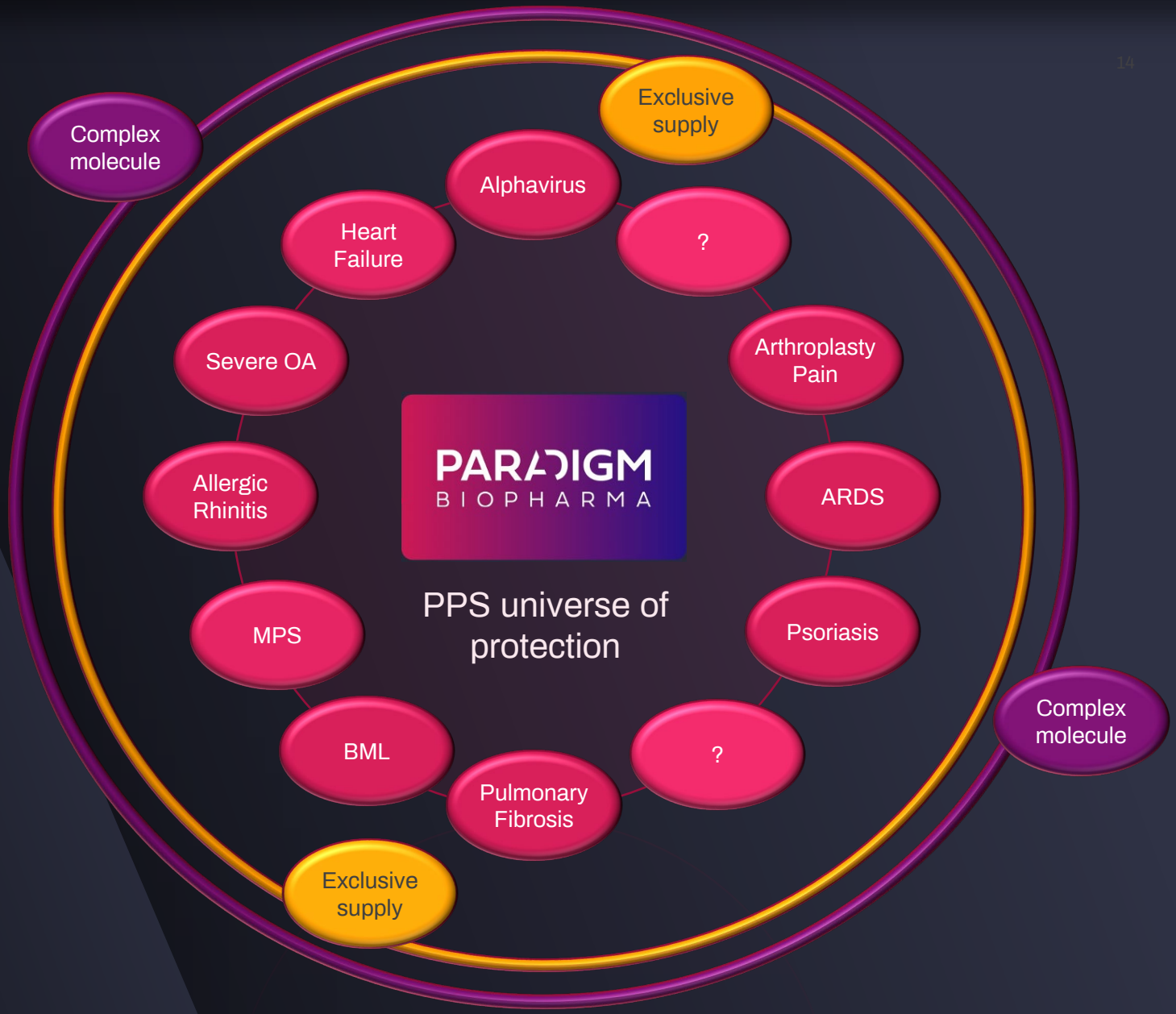
- 100% recruitment of phase 2 study, n=12 participants
- Poster presentation to the 19th annual *WORLD*Symposium in Orlando, Florida in February. Dr Roberto Giugliani will be presenting the poster, providing an update on enrolment & baseline characteristics of MPS-VI participants in the trial
- Endpoint evaluation and feasibility assessment for potential pivotal phase 3 MPS-VI study

Company UPDATE



Extensive Market Protection

- Multiple method of use patents, continually refined and expanded with additional patents being pursued
- IP portfolio expansion as new data is obtained from clinical and pre-clinical studies being undertaken



Business Development

Engaged business development consultants to assist with partnering discussions

Plexus Ventures

- Leading global business development firm serving the pharmaceutical industry for over 30 years
- Plexus Ventures has a long track record of deal successes for or with many of the pharmaceutical industry's largest firms as well as among emerging companies
- Focus on global partnering activities for Paradigm
- Process designed to create competitive tension between potential partners to produce the best partnering outcome

Angel Pond

- Angel Pond is a China based facilitator of pharma partnering activities
- Primary focus partnering activities for Paradigm in China

Global Presence

Global and AU Conference Presentations past 12-months:

JP Morgan Healthcare Conference, Evercore ISI HealthCONx, Truist Life Sciences Conference, Goldman Sachs SMID Cap Conference, BIO Europe and International Partnering Conferences, Bell Potter, MST Access, and other broker Healthcare days

Publications

- ChikV pre-clinical study, peer reviewed and published in PLoS One Journal
- "Pentosan Polysulfate Inhibits Attachment and Infection by SARS-CoV-2 In Vitro: Insights into Structural Requirements for Binding" published in Journal of Thrombosis & Haemostasis. Collaboration between Ronzoni, Bene & Paradigm

Upcoming presentations at key global conferences during Q1 CY23 :

- JP Morgan Global Healthcare Conference presentation, January 2023
- MPS-I data presentation at International Conference on Lysosomal Diseases, February 2023
- MPS-VI clinical program presentation at WORLD*Symposium* February 2023
- OARSI 2023 World Congress on OA, March 2023

FY23 Key Milestones

1. Secure funding to advance the development of Paradigm's programs.
2. PARA_OA_002 Stage 1, 100% recruitment.
3. OA manuscript following day 56 PARA_OA_008 readout, detailing biomarker and clinical outcomes completed for peer review and publishing.
4. OA manuscript following 6-month PARA_OA_008 data (MRI and clinical outcomes) completed for peer review and publishing.
5. Presentation of PARA_OA_008 data at major orthopedic conference
6. Activities implemented to accelerate phase 3 clinical trial recruitment.
7. Commercial in Confidence.

Commercial in confidence milestone will be detailed retrospectively in the company's FY23 Annual Report

Expected News Flow

Next 6 - months

- ✓ PARA_OA_006 extension study commencement Q4 CY2022
- ✓ FY22 tax rebate of $7.4m Q4 CY2022
- PARA_OA_002 update – First data safety monitoring board review Q4 CY2022
- MPS-VI phase 2 clinical trial – 100% recruitment Q4 CY2022
- PARA_OA_008 – 6-month data Q1 CY2023
- Canine OA model – 20-week follow-up (3-year human equivalent) data 1H CY2023
- PARA_OA_002 – Stage 1 100% recruitment 1H CY2023
- Preclinical proof-of-concept study mouse model of ARDS mediated by influenza infection peer-reviewed publication 1H CY2023
- Further IP generation and protection
- Progress commercial discussions on MPS asset

Appendix

Corporate Snapshot

Key Financial Details

Ticker Symbol	ASX:PAR
Trading Range (12mth)	A$0.855 – $2.33
Share Price (25.11.22)	~A$ 1.465
Total Ordinary Shares on Issue	285m
Market Capitalisation (25.11.22)	~A$417.5m
Cash Balance (30.09.22)	A$92.4m
Enterprise Value	~A$325.5

Top Holders

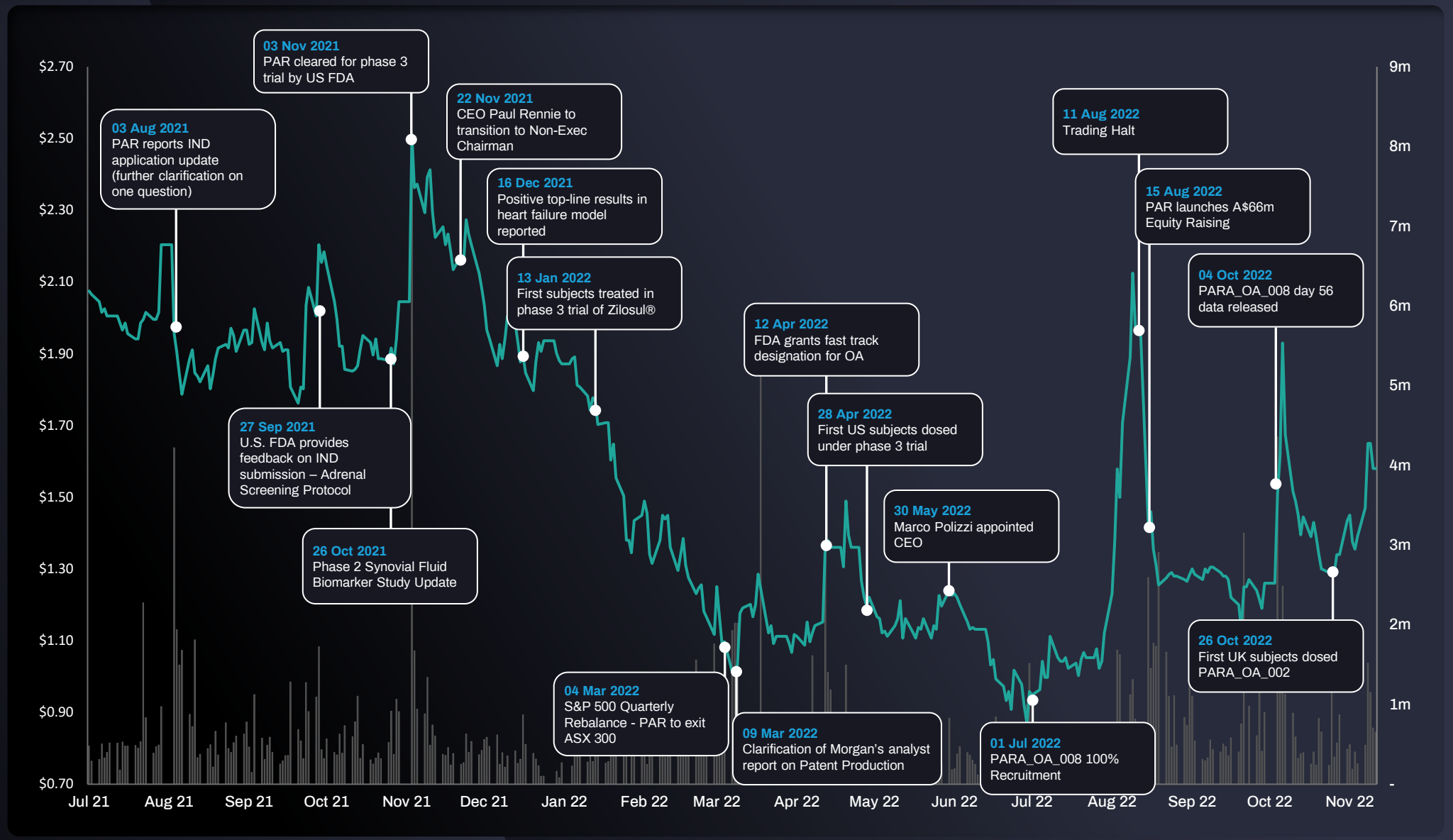
Rank	Name	Units #	Units %
1	CITICORP NOMINEES PTY LIMITED	22,318,994	7.83
2	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	16,465,182	5.78
3	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	11,499,288	4.03
4	KZEE PTY LTD <KZEE SUPERANNUATION FUND A/C>	10,767,843	3.78
5	PAUL JOHN RENNIE	7,548,567	2.65

Substantial Holders

Rank	Name	Units #	Units %
1	MR PAUL RENNIE	20,391,234	7.15
2	ALLIANZ GLOBAL INVESTORS	16,378,604	6.08

*As of last public disclosure

Key News Events



For more information please visit:
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