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Paradigm Biopharmaceuticals (ASX:PAR)

Inaugural R&D Day



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BIOPHARMA

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WELCOME



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Paradigm Chief Executive Officer and Interim Chairman

Paul Rennie



INTRODUCTION

PARADIGM BIOPHARMA...*UNLOCKING POTENTIAL*



COO, Dr Jeannie Joughin

Paradigm Biopharma is a commercially focused drug repurposing company.

Our approach:

- Take an existing, approved drug with demonstrated safety in its approved indication,
- Repurpose to a new patented therapeutic application with high unmet need.
 - **Reduced time, cost and risk.**

(Re) Pioneers of PPS
by developing the injectable form

Zilosul®
OA

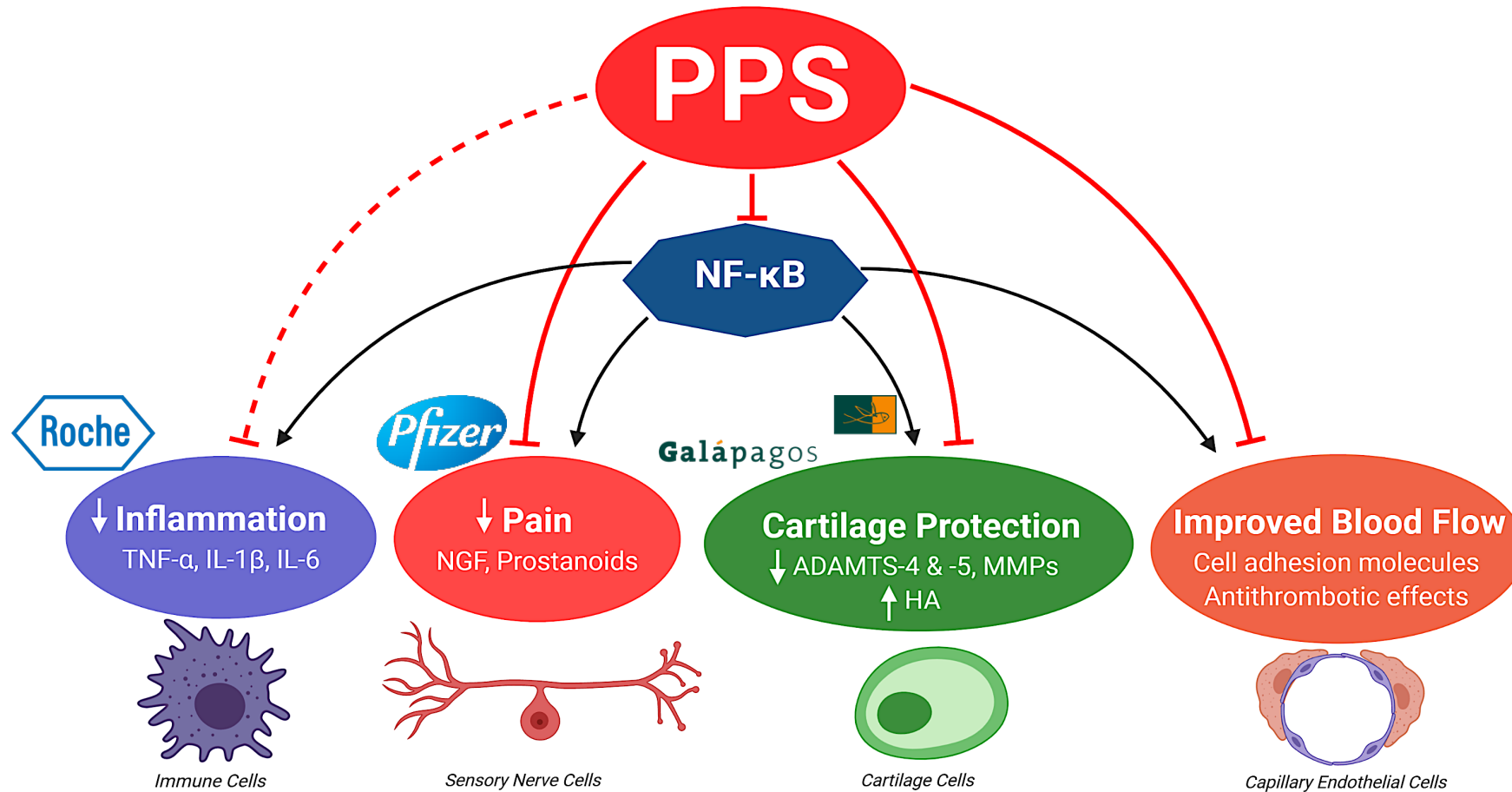
MPS

Alpha-
Virus

Chronic
Heart
Failure

ARDS

CONFIDENT OF CLINICAL SUCCESS



- Multiple modes of action
- Previous Phase IIb, SAS and EAP experience
- Global harmonised clinical trial consultation

AGENDA

Topic	Presenter
OA Clinical Program Update – Trial Outputs and Milestones	Dr Donna Skerrett
Safety and MPS Update	Dr Michael Imperiale
R&D Pipeline	Dr Ravi Krishnan
Revenue Timeline & Summary	Dr Jeannie Joughin
Q&A	Panel



Dr Donna Skerrett,
Chief Medical
Officer



Dr Michael
Imperiale,
Global Head Safety



Dr Ravi Krishnan,
Chief Science Officer

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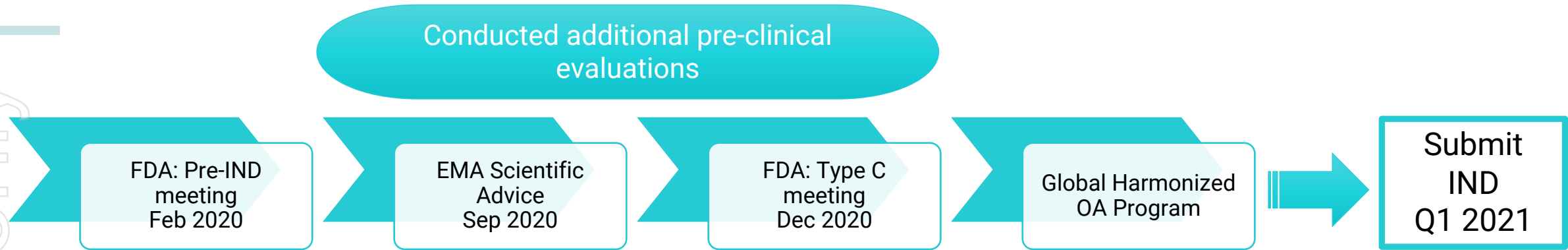
OA CLINICAL PROGRAM UPDATE

DR DONNA SKERRETT



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FEEDBACK FROM EMA + FDA = GLOBAL HARMONISATION



Revised Clinical Trial Program will:

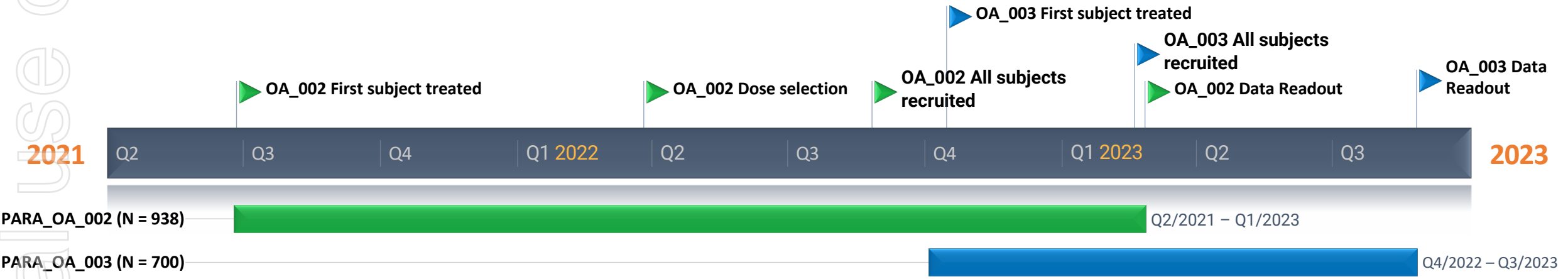
- Confirm minimally effective dose
- Evaluate increased patient numbers to account for potential dropouts related to COVID-19 and aged population, and meet regulatory requirements to collect adequate safety data of iPPS
- Measure confirmed clinical endpoints of WOMAC pain & function
- Confirm Phase III pivotal & confirmatory study
- Improve and expand label for simultaneous registration globally

De-risks overall project

Phase 3 Clinical Program for OA

Treatment of Pain associated with Knee OA

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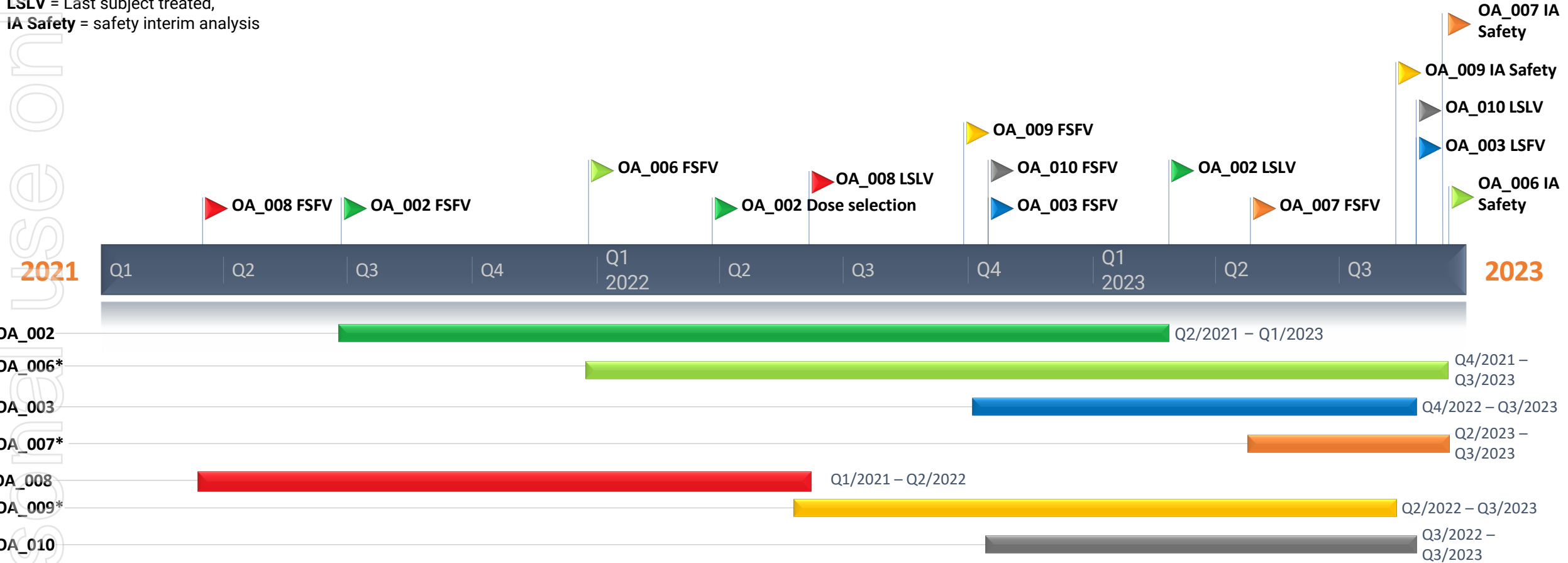


Overall Clinical Program for OA

NB: This reflects current plans and is subject to change



FSFV = First patient treated,
 LSLV = Last subject treated,
 IA Safety = safety interim analysis



PIVOTAL STUDIES FOR REGISTRATION



Study	Region	N	PPS Selected Dose (initial course)	Placebo	Subjects for Safety DB
PARA_OA_002 (Phase 2b/3)	US/AU	938	352	352	352
PARA_OA_006 (2b/3 Extension)	US/AU	750*	282	-	282
PARA_OA_003 (PH3 confirm)	EU/US	700	350	350	350
PARA_OA_007 (PH3 Extension)	EU/US	560*	280	-	60
PARA_OA_008 (Synovial Fluid)	AU	60	30	30	60
PARA_OA_009 (Retreatment)	TBD	270	180	90	225
Previous Studies	AU/US	243	99	72	99
Total			1573	894	1428
PARA_OA_010 (Hip)	TBD	TBD	TBD	TBD	TBD

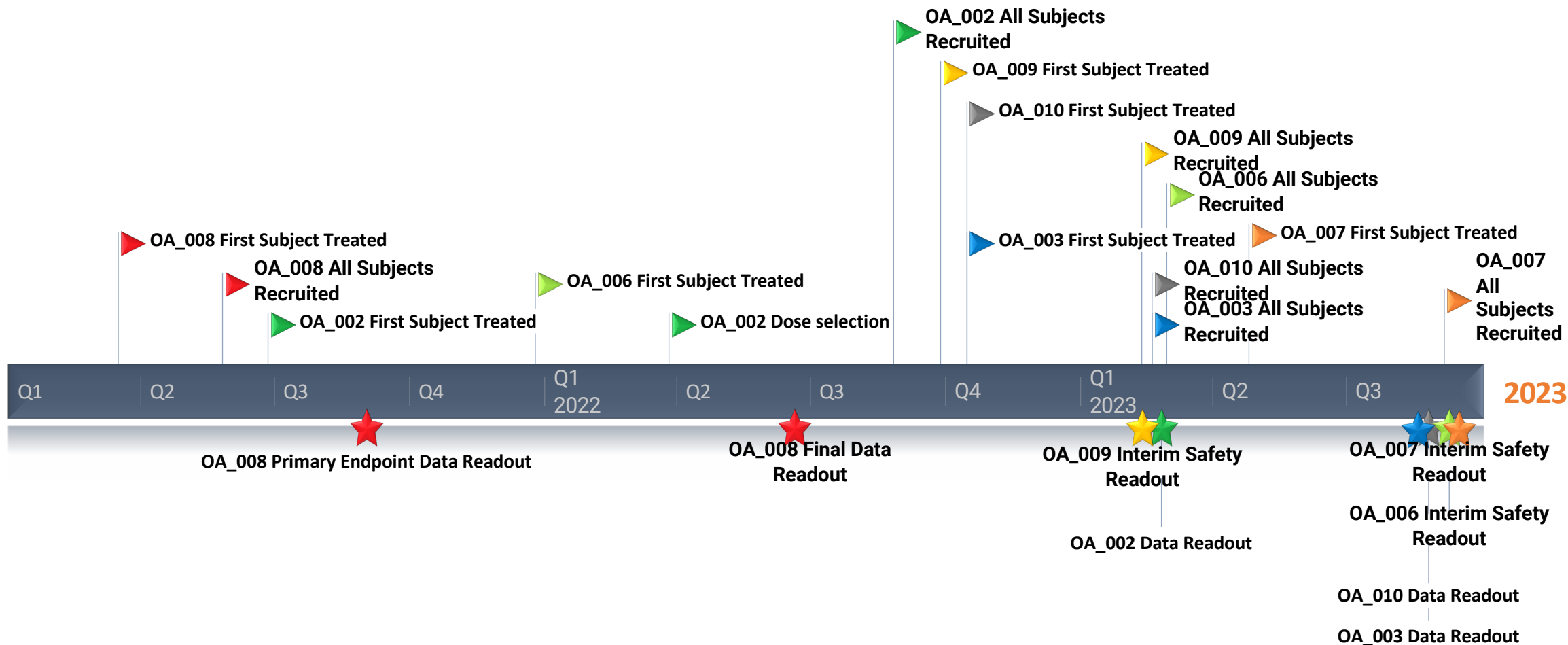
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PIVOTAL STUDIES FOR REGISTRATION*

NEWS FLOW



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SAFETY AND MPS

DR. MICHAEL IMPERIALE



PHARMACOVIGILANCE / SAFETY AT PARADIGM



Michael Imperiale

Head of Global Safety

Inga Greblikiene
Safety Physician

Synteract
Safety Vendor

This will insure accurate and consistent safety data to manage our patients and support a successful NDA submission.

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UPDATE ON MPS

ORPHAN DESIGNATION IN EU AND US

MPS 1 - Australia

- Women's and Children's Hospital Adelaide
- An open label trial currently enrolling up to 10 subjects. Dosed 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.
- 2 subjects currently in treatment: subject 1 at 7 weeks and subject 2 at 3 weeks.
- PPS has been well tolerated with no safety concerns reported.

MPS 6 - Brazil

- A double-blind placebo-controlled trial with 12 subjects. Dosed weekly for 24 weeks.
- Primary endpoint is safety, key secondary endpoints are pain and function, as well as PK.
- The Brazilian regulatory agency, ANVISA, confirmed acceptability of Paradigm's clinical program and study endpoints.

Taken together Paradigm will have a robust data package to inform future MPS activities and partnering discussions.

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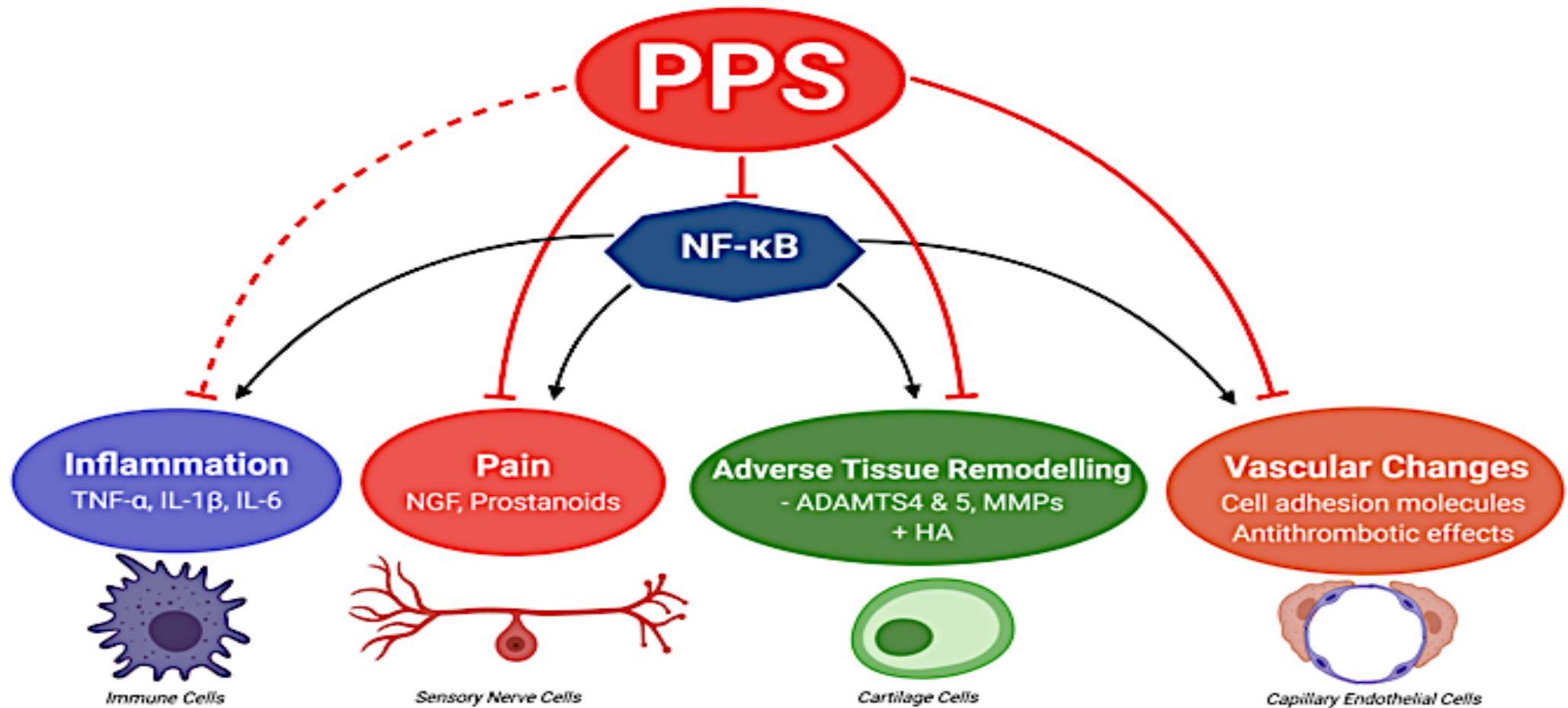
R & D PIPELINE

DR RAVI KRISHNAN



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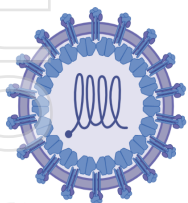
THE MULTIPLE MECHANISMS OF ACTION OF PPS



Multiple mechanisms of action allow the repurposing of PPS across a number of acute and chronic medical indications with unmet needs.

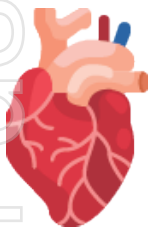
Indication / Action of PPS

Stage of Development



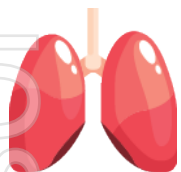
Alphavirus induced arthralgia

- Anti-inflammatory target: NF-kB
- Pain target: NGF
- Cartilage degeneration target: ADAMTS-5; MMPs



Heart Failure

- Adverse tissue remodeling target: ADAMTS-4
- Anti-inflammatory target: NF-kB
- Vascular endothelial inflammation target: CAM (Cell Adhesion Molecules)



Acute Respiratory Distress Syndrome (viral-induced)

- Cytokine storm anti-inflammatory target: NF-kB
- Inhibition of Complement activation

- Preclinical Proof-of concept for CHIK-V: (Institute for Glycomics; Queensland)
- Preclinical Dose translational study: (Center for Heart Failure Research & Institute for Experimental Research, Oslo University, Oslo)
- Preclinical Proof-of-concept study: (Menzies Health Institute, Queensland)

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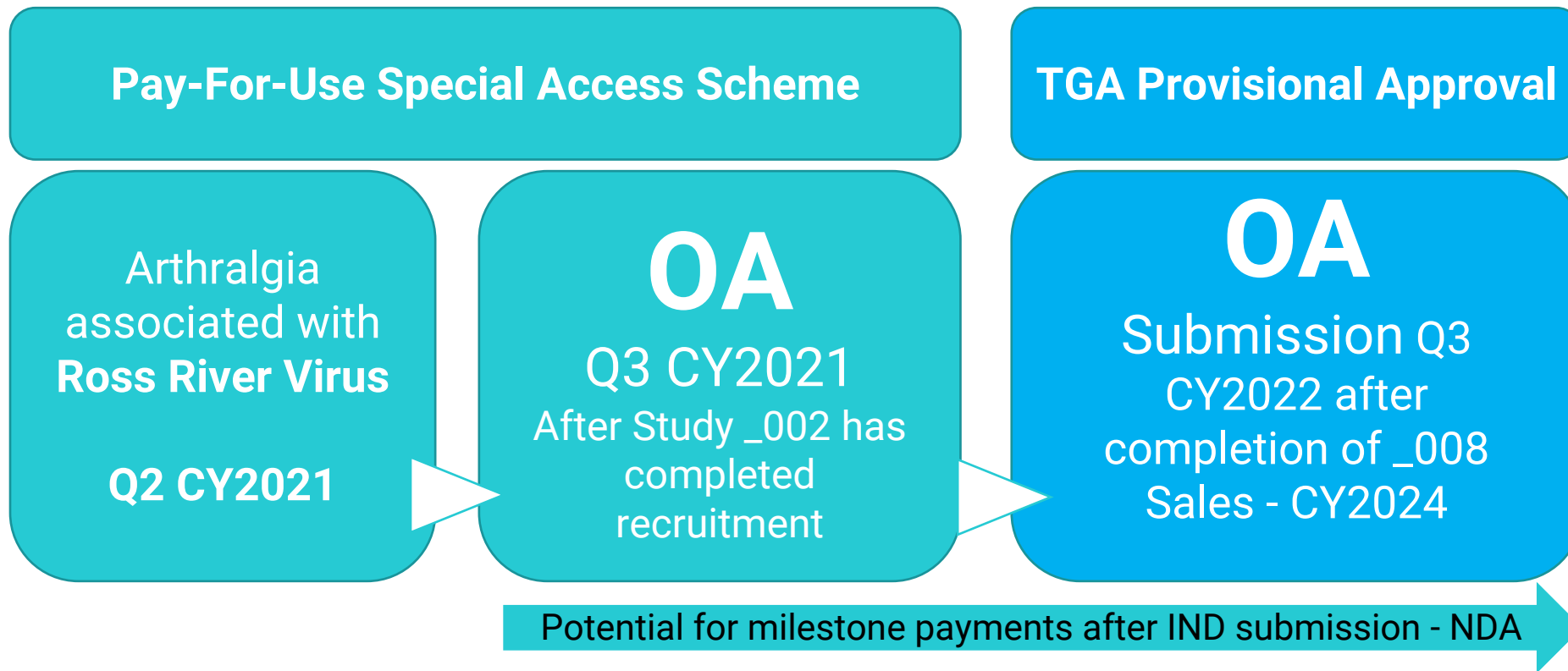
REVENUE TIMELINE & SUMMARY

DR JEANNIE JOUGHIN



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TIMELINE TO FIRST REVENUE - AUSTRALIA



Commercial SAS/Pay for use:

- Price – TBD
- Anticipate modest patient numbers

Advantages:

- Potential to achieve sales ahead of global launch
- Unlocks further investment options for PAR

SUMMARY

- ✓ Highly confident that we will receive global registration once the pivotal Phase 3 clinical trials are successfully completed.
- ✓ Highly qualified and experienced team to design and execute on our Phase 3 program.
- ✓ When IND is open, we have a Phase 3-desirable asset for partnering, for OA of knee and hip.
- ✓ We are focussed on improving the value of Zilosul® by improving the label, pricing potential and patient convenience.
- ✓ Path to revenue in 2021 and maintain optionality in future funding and investment decisions.
- ✓ Establishing exciting pipeline to further unlock the potential of iPPS.

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Q&A OPPORTUNITY

PANEL



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For more information please visit: www.paradgimbiopharma.com
or email any queries to
investorrelations@paradigmbiopharma.com



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