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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

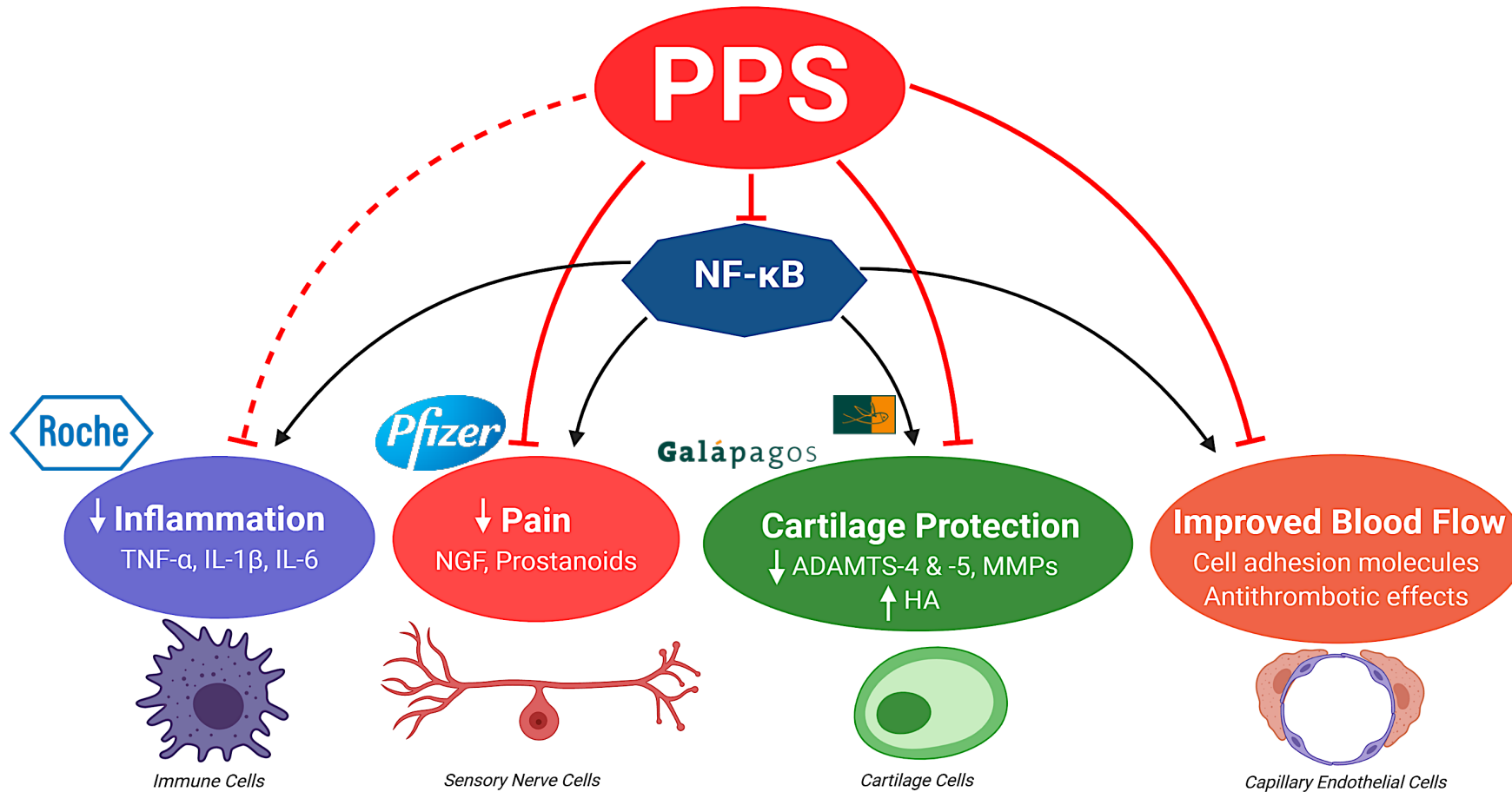
Alpha-  
Virus

Chronic  
Heart  
Failure

ARDS



# CONFIDENT OF CLINICAL SUCCESS



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

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# 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

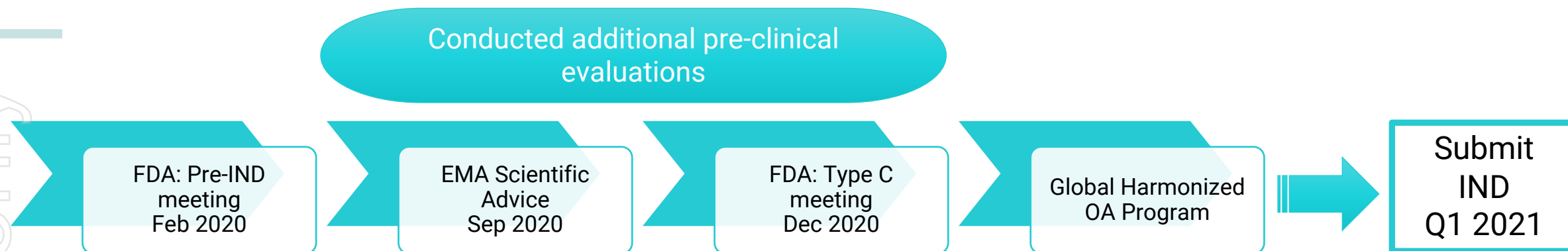
DR DONNA SKERRETT



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# FEEDBACK FROM EMA + FDA = GLOBAL HARMONISATION



## Revised Clinical Trial Program will:

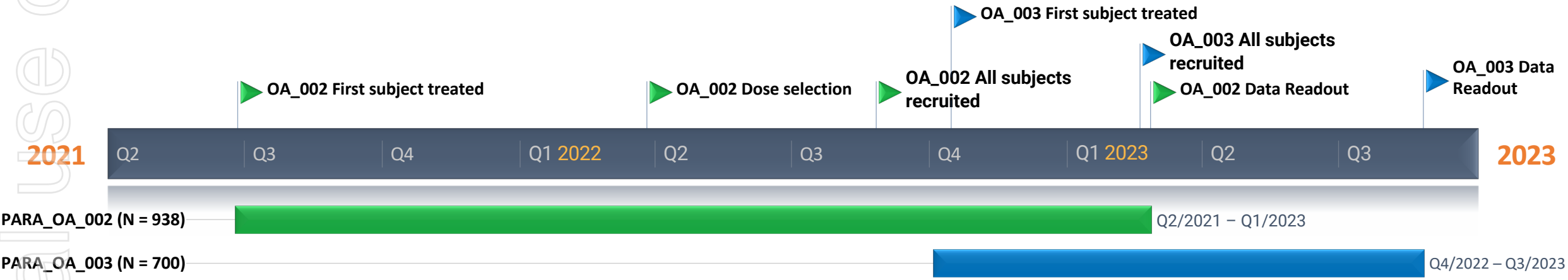
- Confirm minimally effective dose
- Evaluate increased patient numbers to account for potential dropouts related to COVID-19 and aged population, and meet regulatory requirements to collect adequate safety data of iPPS
- Measure confirmed clinical endpoints of WOMAC pain & function
- Confirm Phase III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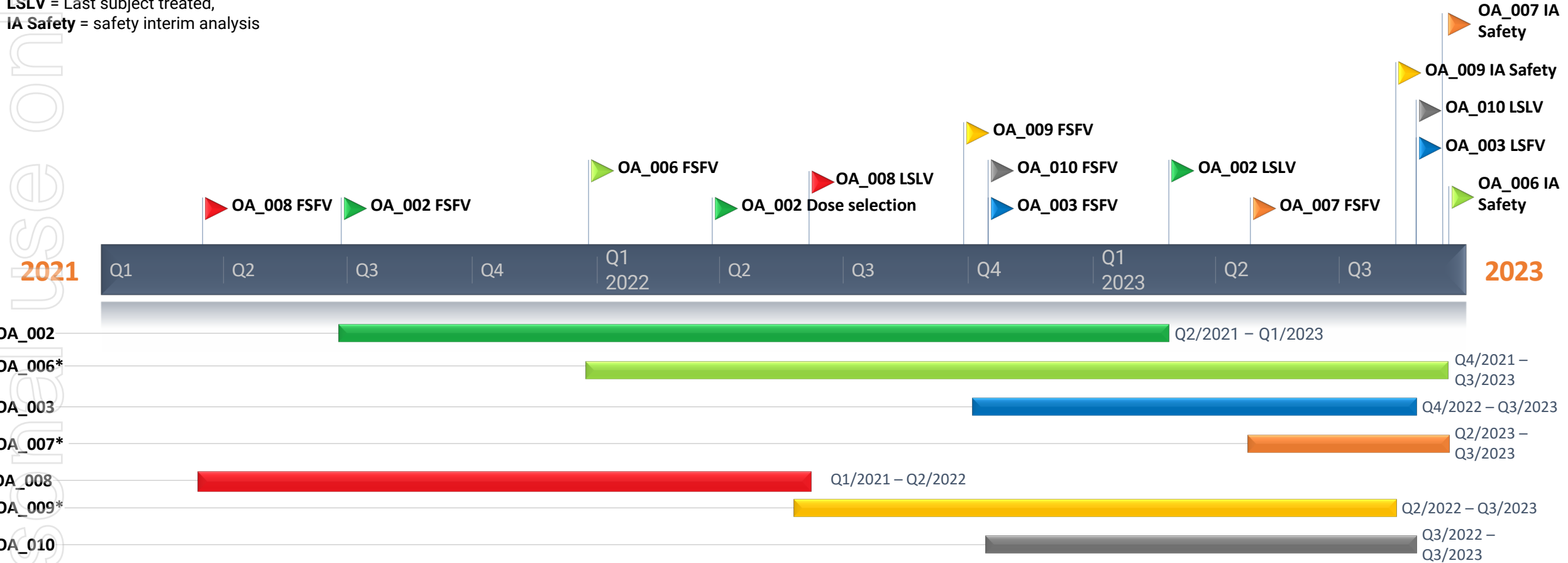


# Overall Clinical Program for OA

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

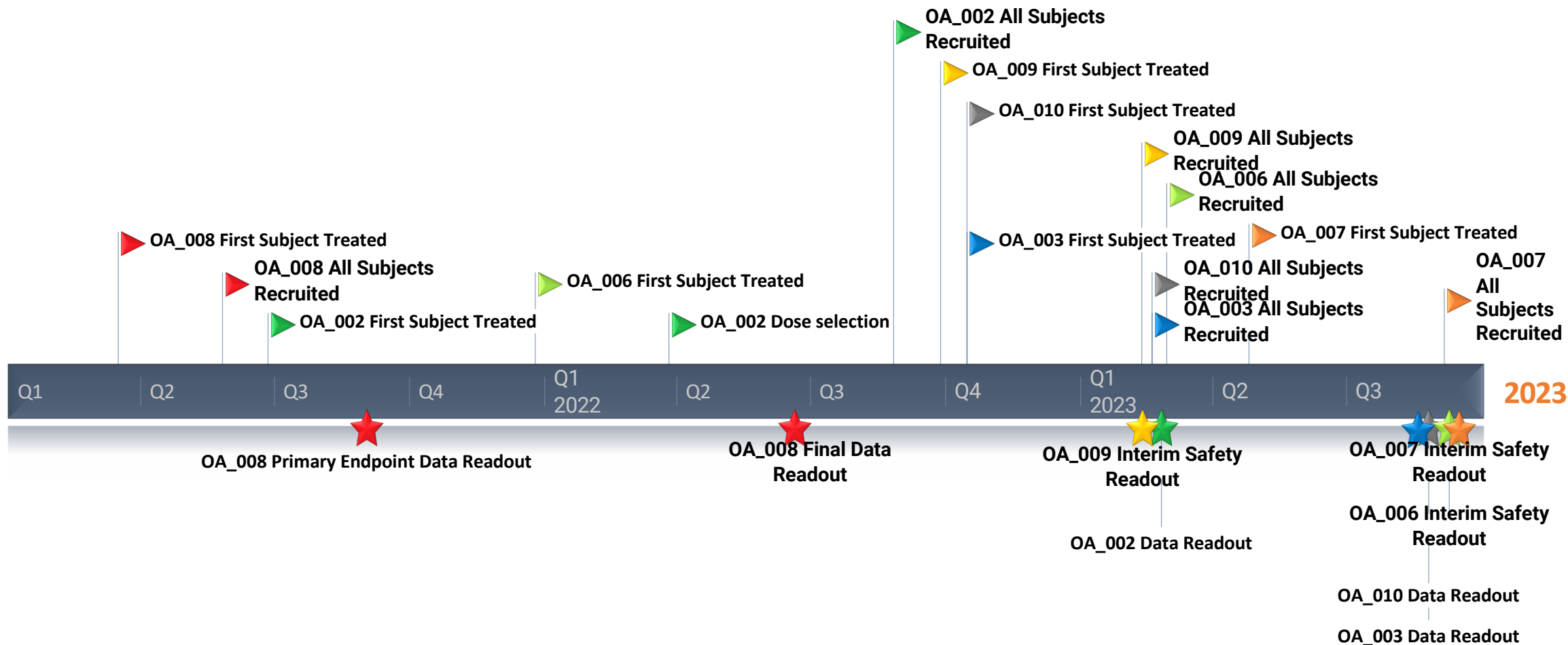
Study	Region	N	PPS Selected Dose (initial course)	Placebo	Subjects for Safety DB
PARA_OA_002 (Phase 2b/3)	US/AU	938	352	352	352
PARA_OA_006 (2b/3 Extension)	US/AU	750*	282	-	282
PARA_OA_003 (PH3 confirm)	EU/US	700	350	350	350
PARA_OA_007 (PH3 Extension)	EU/US	560*	280	-	60
PARA_OA_008 (Synovial Fluid)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

# 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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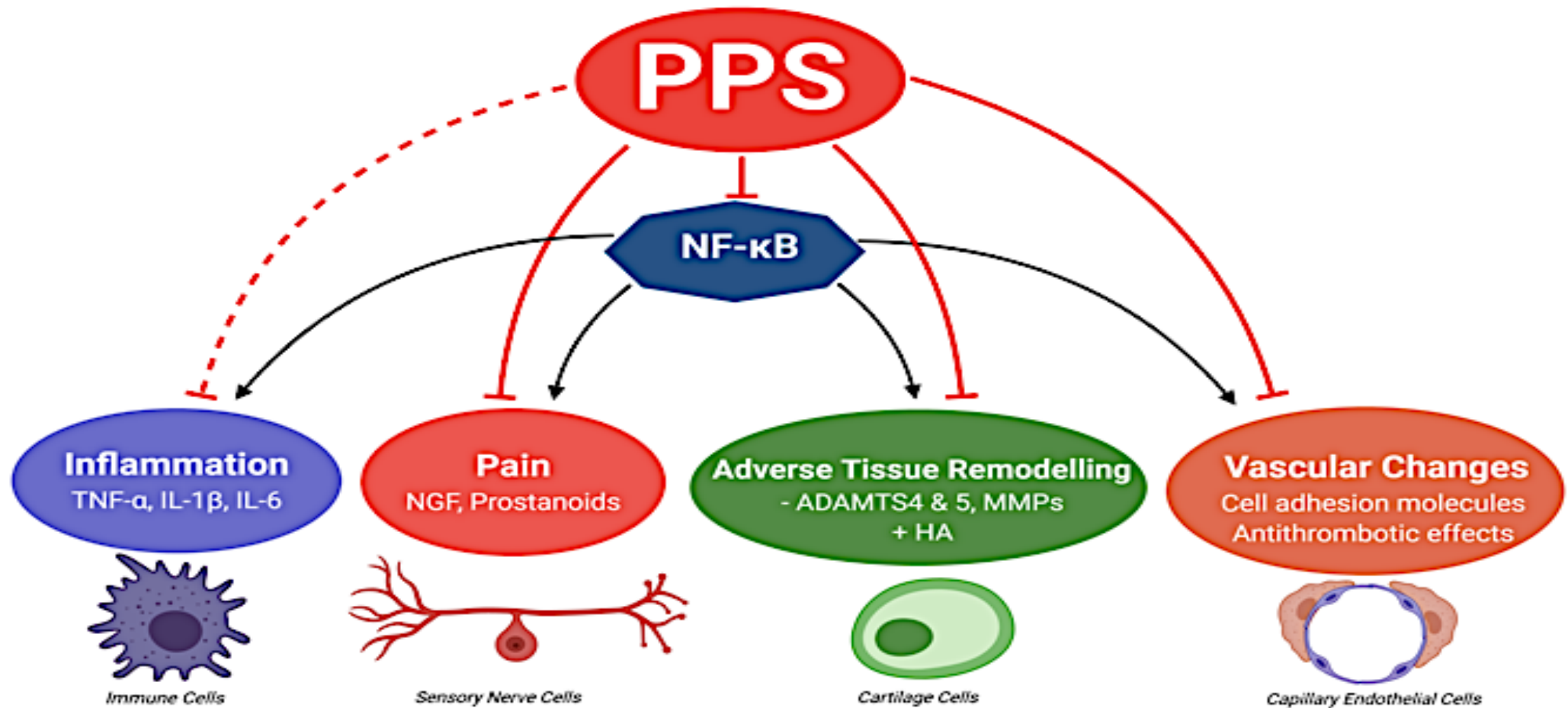
# R & D PIPELINE

DR RAVI KRISHNAN



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# THE MULTIPLE MECHANISMS OF ACTION OF PPS

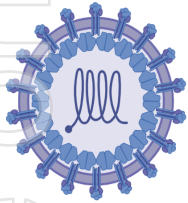




**Multiple mechanisms of action allow the repurposing of PPS across a number of acute and chronic medical indications with unmet needs.**

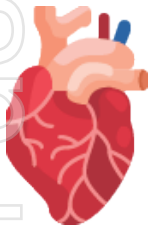
## Indication / Action of PPS

## Stage of Development



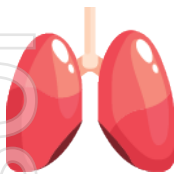
### **Alphavirus induced arthralgia**

- 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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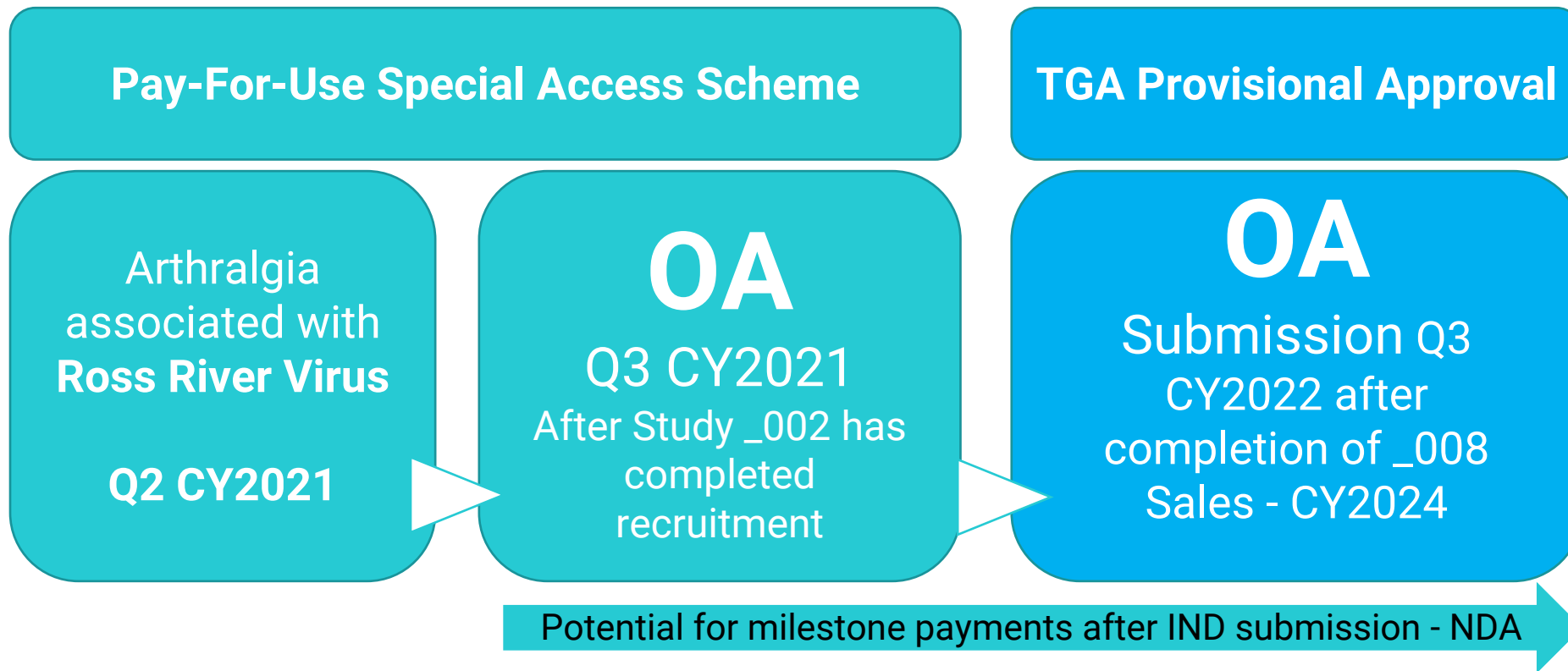
# REVENUE TIMELINE & SUMMARY

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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or email any queries to  
[investorrelations@paradigmbiopharma.com](mailto:investorrelations@paradigmbiopharma.com)



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