

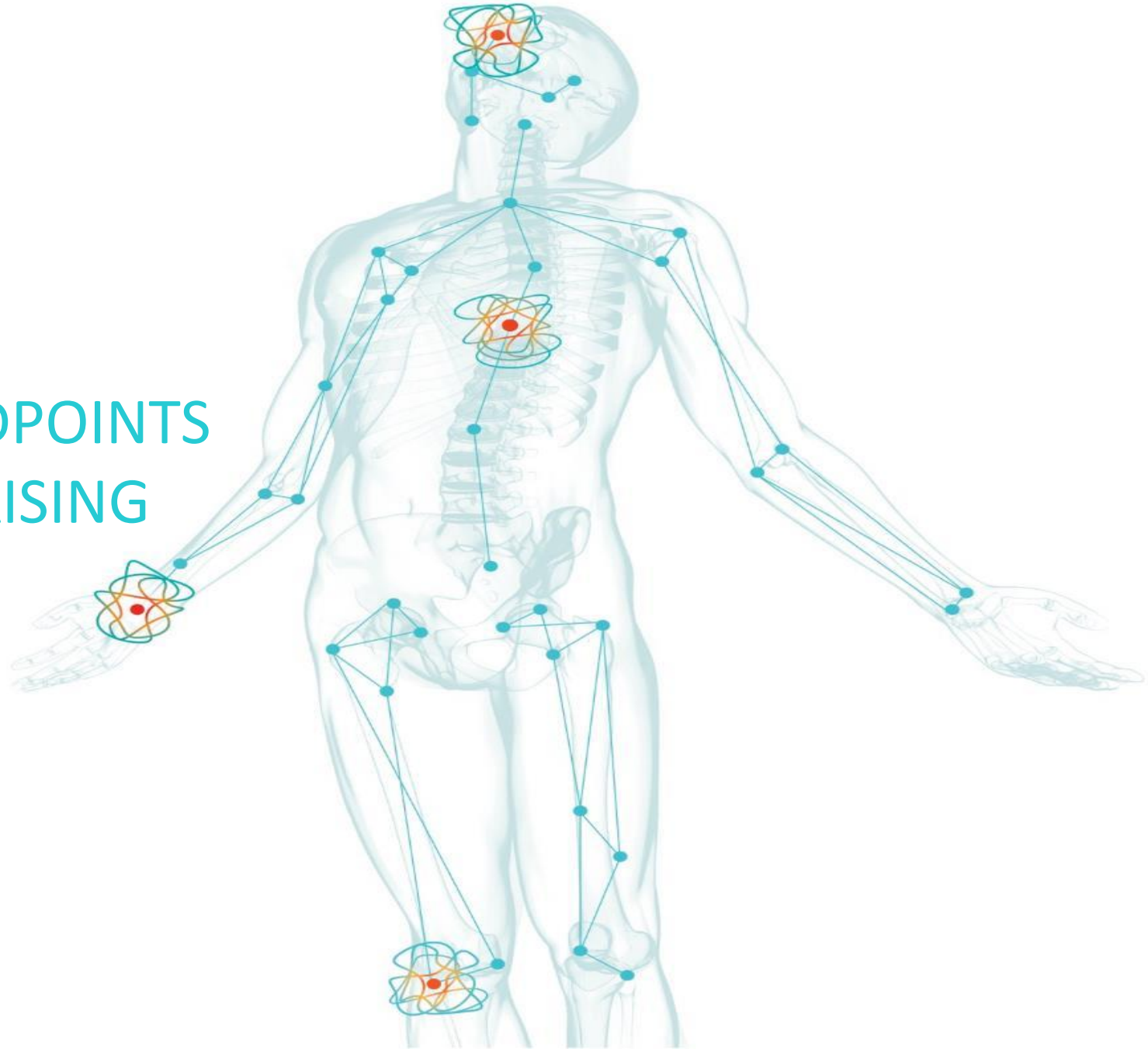


PHASE 2B SECONDARY ENDPOINTS MET & \$77.9M CAPITAL RAISING

- OBJECTIVE MRI/BML DATA
- ACTIVITIES OF DAILY LIVING
- KOOS PAIN DAY 165

Paul Rennie, CEO & MD

15 April 2019



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EXECUTIVE SUMMARY



- **Paradigm Biopharmaceuticals Ltd (PAR.ASX)** is an ASX-listed biotechnology company focused on repurposing Pentosan Polysulfate Sodium (PPS), an **FDA-approved drug** that has a **long track record** of safely treating inflammation over sixty years.
- Initial focus is on repurposing PPS (under the name ZILOSUL®) to treat **Osteoarthritis (OA) – market with over 31m sufferers in the US alone**
- **Phase 2b trial in OA of the knee has now met primary and secondary endpoints** and will move to pivotal phase 3 in the US in 2019
 - Primary endpoint (released Dec 18) - 50% reduction in pain
 - Secondary endpoint (released today) – 6 month duration of effect and reduction in volume/size/grade of BML confirmed by MRI
- Phase 2b trial demonstrated the **combination of safety, subjective efficacy, objective efficacy, indicative regression of disease via reduced BML and mechanism of action**
 - Competing treatments (NGF, steroid, opioid) have not demonstrated all in combination
 - **Potential blockbuster drug may attract significant commercial interest**
- Raising A\$77.9m to fund the Company for a minimum of 3 years and through to completion of pivotal trials and new drug applications in OA and MPS, **putting the Company in a strong financial position**
- **Additional news flow and catalysts expected in next 6 months** (MPS, NFLPA, TGA provisional approval etc.)

CORPORATE SNAPSHOT



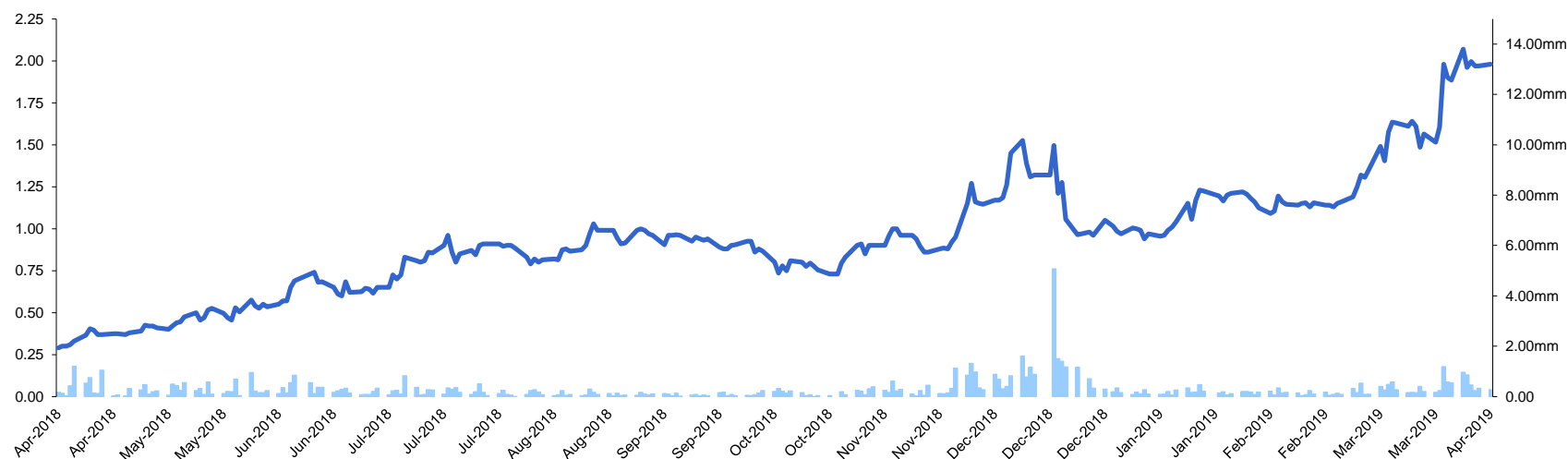
Financial information

Share price (8-April-2019)	A\$1.98
Number of shares	140m
Number of Options	6.2m
Market capitalisation	A\$278m
Cash Mar-19	A\$8.1m
Pro-Forma Cash Post Transaction	A\$82.0m

Top Shareholders

	Shares (m)	%
Paul Rennie (Managing Director)	21.6	15.4%
Other Board and management	7.1	5.1%
Irwin Biotech (<i>technology vendor</i>)	6.3	4.5%
MJGD Nominees (<i>technology vendor</i>)	5.8	4.1%
J.P. Morgan Nominees Aust Pty Ltd	4.2	3.0%
Citicorp Nominees Pty Ltd	4.1	3.0%

Share Price (\$)



Paradigm Biopharmaceuticals Limited (ASX:PAR) - Volume

Paradigm Biopharmaceuticals Limited (ASX:PAR) - Share Pricing

BACKGROUND ON PENTOSAN POLYSULFATE SODIUM (PPS)



PPS has a long safety history and is currently being sold in the US and Europe

Pentosan Polysulfate Sodium

- Pentosan polysulfate sodium (PPS) is a semi-synthetic drug manufactured from beech-wood hemicellulose
- PPS has been used in humans for more than 60 years
- The oral formulation is FDA approved and sold under the name Elmiron, by Janssen Pharmaceuticals (Johnson & Johnson), for the treatment of interstitial cystitis (painful bladder syndrome). Also used to treat deep vein thrombosis
- Paradigm has been granted patents to use PPS for new indications

Potential biological characteristics

- ✓ Anti-inflammatory
- ✓ Prevents cartilage degeneration
- ✓ Anti-histamine
- ✓ Anti-clotting
- ✓ Prevents necrosis (premature cell death)
- ✓ Non performance enhancing (WADA & ASADA Cleared)
- ✓ Non-addictive

Excellent Safety Profile

- PPS has a well established safety profile with no reported serious adverse events
- Approved by FDA over 30 years ago for oral use, over 100 million injectable doses of PPS have been administered
- PPS is a semi-synthetic, complex carbohydrate, which makes it well tolerated by the human body
- PPS is a weak anti-coagulant compared to Heparin. PPS has 1/15th – 1/20th the anti-coagulant activity of Heparin. Data on file with US FDA
- The clearance of PPS from the body, as measured by activated partial thromboplastin time (aPTT), is 300 minutes (5 hours).
- Suggested sports physician treatment protocol:
 - Administration at least 48 – 72 hours before any contact sport is played
 - Blood test prior to contact sport to test coagulation parameters are within the normal range
- Paradigm believes that the weak anti-coagulant properties of PPS should not present any notable issues

STRONG PATENTS & IP POSITION



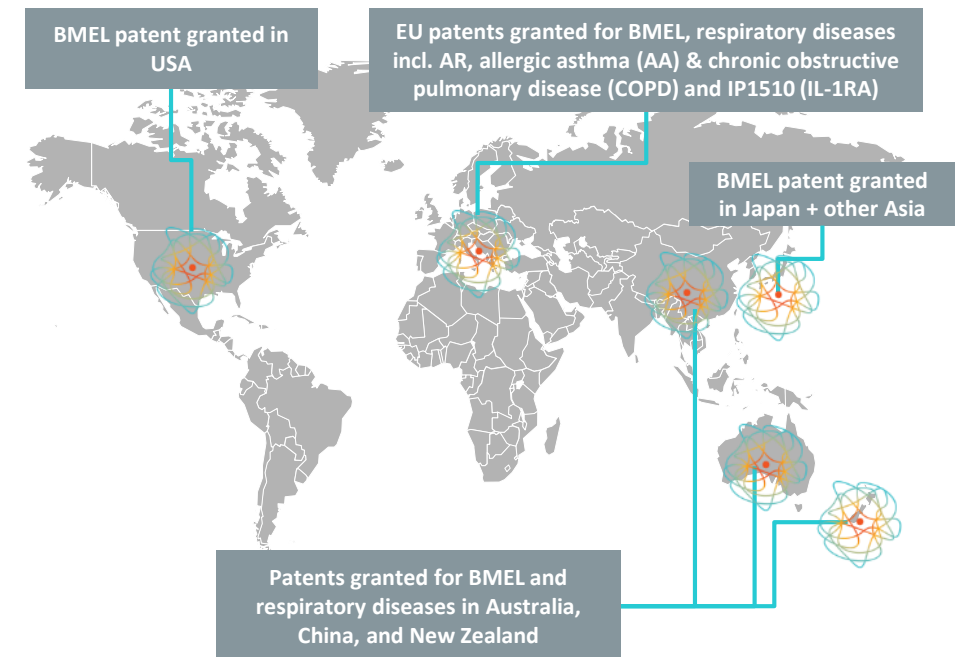
Multi-faceted IP protection increases barriers to entry for potential competitors

Valuable patent portfolio

- Paradigm has patent protection because it is using PPS for new indications
- Minimum life on patents is 2030 and beyond for more recent patents - **i.e. 2035 - 2040**
- Established regulatory exclusivity and trademarks
- Patents for MPS (ex Japan) + Orphan Status
- Patent applications for Ross River virus and Chikungunya virus
- Patent applications for osteoarthritis and concurrent BMEL
- Patent for Heart Failure indication
- Prosecuting new patent applications

Secure manufacturing and supply

- Exclusive long term supply agreement with bene PharmaChem¹
- bene pharmaChem makes the only FDA-approved form of PPS
- **Manufacturing methods are highly complex and a well kept trade secret**
- **bene pharmaChem has been supplying J&J for over 20 years for oral use**

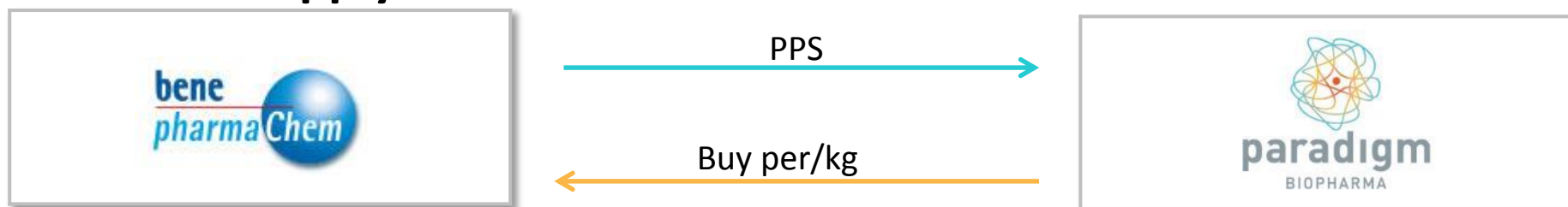


1. bene pharmaChem is a private company located in Germany and manufactures the only officially approved and clinically tested medicinal PPS in the USA, Europe and Australia

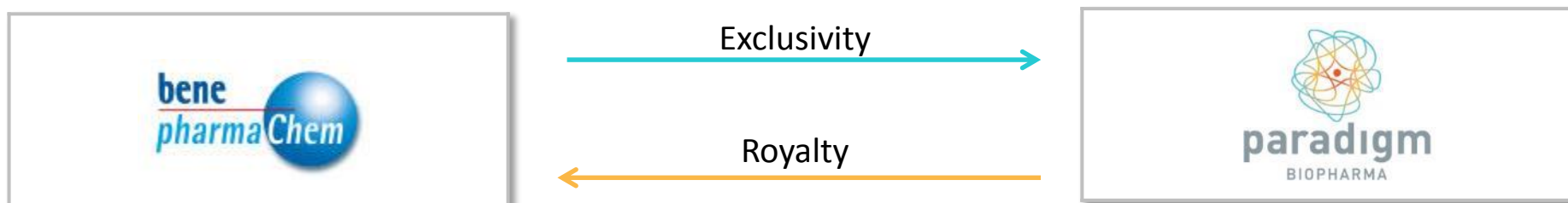
EXCLUSIVE SUPPLY & MANUFACTURING



Exclusive Supply



License

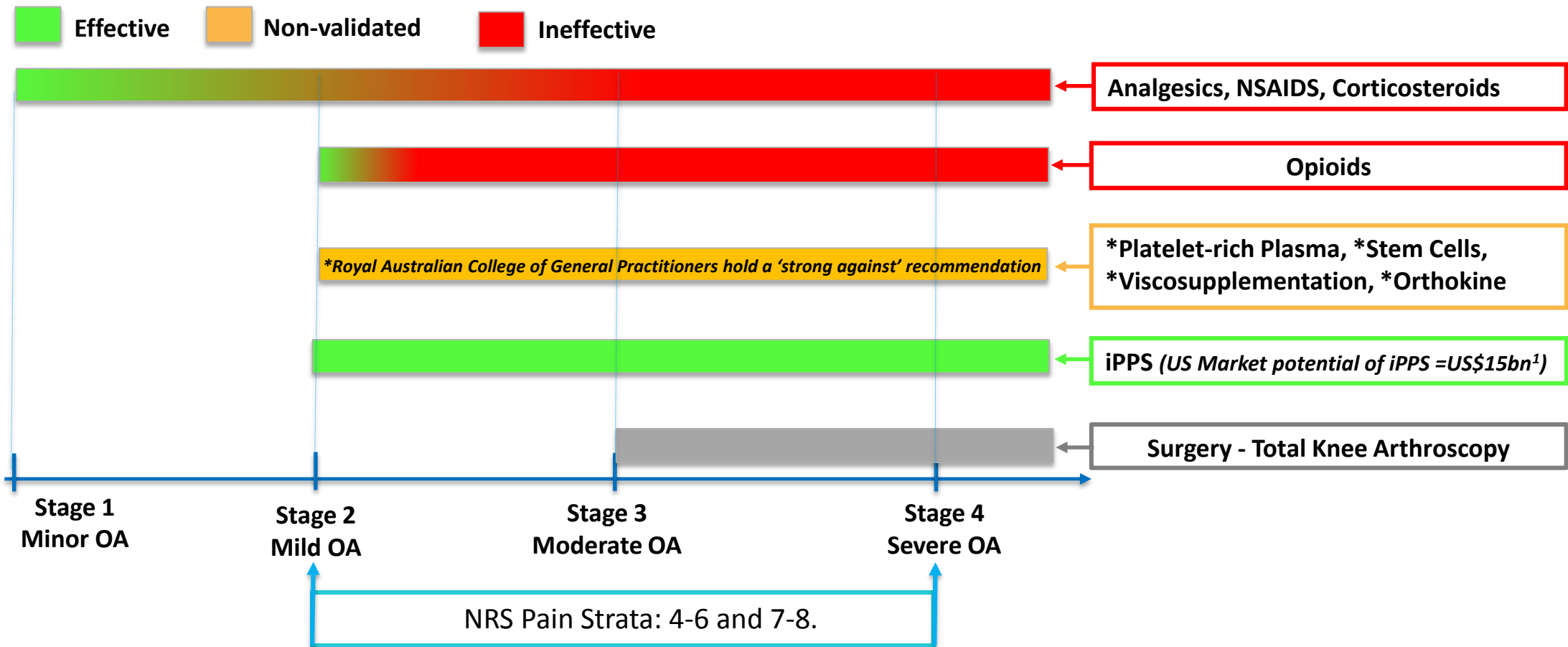


- **Paradigm has executed a long term exclusive supply agreement** with bene pharmaChem GmbH & Co. KG
- Bene pharmaChem are the original developer of PPS and the only FDA-approved manufacturer
- Leading Big Pharma Co (J&J) source their PPS from bene for a different application (bladder pain).
- Agreement grants exclusive supply of only FDA approved PPS for Paradigm's orthopaedic and respiratory programs.
- Paradigm to pay bene pharmaChem small single digit royalty on commercial sales

MARKET DEMAND – OA STAGES AND TREATMENTS



There are no effective treatments for Moderate to Severe OA



1. 14m American have symptomatic knee OA – 7m are eligible for knee replacement (late stage 3/stage 4) – PAR Estimate - 5m x US\$3,000 per iPPS treatment = US\$15bn p.a. - <https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf>



BLOCKBUSTER POTENTIAL US MARKET REVENUE P.A

Key Assumptions:

- 31m OA sufferers in the US
- Annual dosing/treatment – assumed 12 month duration of effect as observed in TGA special access scheme
- Indicative and potential pricing of US\$2-3k per treatment















		MARKET PENETRATION (31m OA sufferers)		
		10% Market Penetration	20% Market Penetration	30% Market Penetration
INDICATIVE POTENTIAL PRICING	US\$1.5k p.a	US\$6.2bn p.a	US\$12.4bn p.a	US\$18.6bn p.a
	US\$2.0k p.a	US\$7.7bn p.a	US\$15.5bn p.a	US\$23.2bn p.a
	US\$2.5k p.a	US\$9.3bn p.a	US\$18.6bn p.a	US\$27.9bn p.a

DEALS – GLOBAL BIG PHARMA INTEREST IN OA



Safety Issues

Recent transactions highlight big pharma interest in OA

COMPANIES	COMPOUND	REGION	UPFRONT	TOTAL VALUE	STATUS
 	Anti-NGF	Global	US\$200m	US\$1.8bn	Phase 3
 	Anti-NGF	Global	US\$250m	US\$1.25bn	Phase 3
 	Corticosteroid	Global	Take-over*	US\$1.0bn*	Commercialised
 	Anti-NGF	Global (ex Japan)	US\$50m	US\$435m	Discontinued
GLOBAL AVERAGE			US\$166m	US\$1.12bn	
 	ADAMTS-5 Inhibitor	EU	Unknown	US\$346m	Phase 1
 Mitsubishi Tanabe Pharma	Gene therapy	Japan	US\$24m**	US\$434m**	Handed Back
 	Gene therapy	Japan	US\$27m	US\$591m	Phase 3
 Mitsubishi Tanabe Pharma	Anti-NGF	Asia	US\$55m	US\$325m	Phase 3
REGIONAL AVERAGE			US\$35m	US\$424m	

Sources: Bloomberg, company filings; *Sanofi-Flexion take-over rumoured – Fierce Biotech; **Mitsubishi handed back rights to TissueGene who executed deal with MundiPharma

SUCCESSFUL RE-PURPOSED DRUGS



Re-purposed drugs have become true blockbusters

BRAND NAME	ORIGINAL INDICATION	NEW INDICATION	PHARMA COMPANY	PEAK ANNUAL SALES
SPRAVATO	Anaesthetic (Ketamine)	Treatment Resistant Depression	Janssen/J&J	Approved March 2019
REVLIMID	Structural Analogue of THALOMID (below)	Multiple Myeloma	Celgene	\$9.7B (2018)
TECFIDERA	Psoriasis	Multiple Sclerosis	Biogen/IDEC	\$4.0B (2017)
VIAGRA	Angina	Erectile Dysfunction	Pfizer	\$2.05B (2008)
GEMZAR	Anti-viral	Various Cancers	Lilly	\$1.72B (2008)
RITUXAN	Various Cancers	Rheumatoid Arthritis	Biogen & Roche	\$7.1B (2015)
EVISTA	Osteoporosis	Invasive Breast Cancer	Lilly	\$1.07B (2011)
PROSCAR	Hypertension	BPH	Merck	\$741.4M (2005)
THALOMID	Anti-Nausea	Leprosy Multiple Myeloma	Celgene Celgene	\$535.2M (2008)
REVATIO	Angina/ED	PA Hypertension	Pfizer	\$525.0M (2008)
PROPECIA	Hypertension	Male Pattern Baldness	Merck	\$429.1M (2008)
ELMIRON (PPS)	DVT	Interstitial cystitis	Janssen/J&J	US\$280m (2015)

Source: Therapeutic Drug Repurposing, Repositioning and Rescue, Drug Discovery World Spring 2015; * Elmiron Use Patents ended in 2012, despite this no generic has been approved in US



OA PHASE 2B TRIAL RESULTS PRIMARY & SECONDARY ENDPOINTS MET



PHASE 2B OA/BML CLINICAL TRIAL – SECONDARY ENDPOINTS

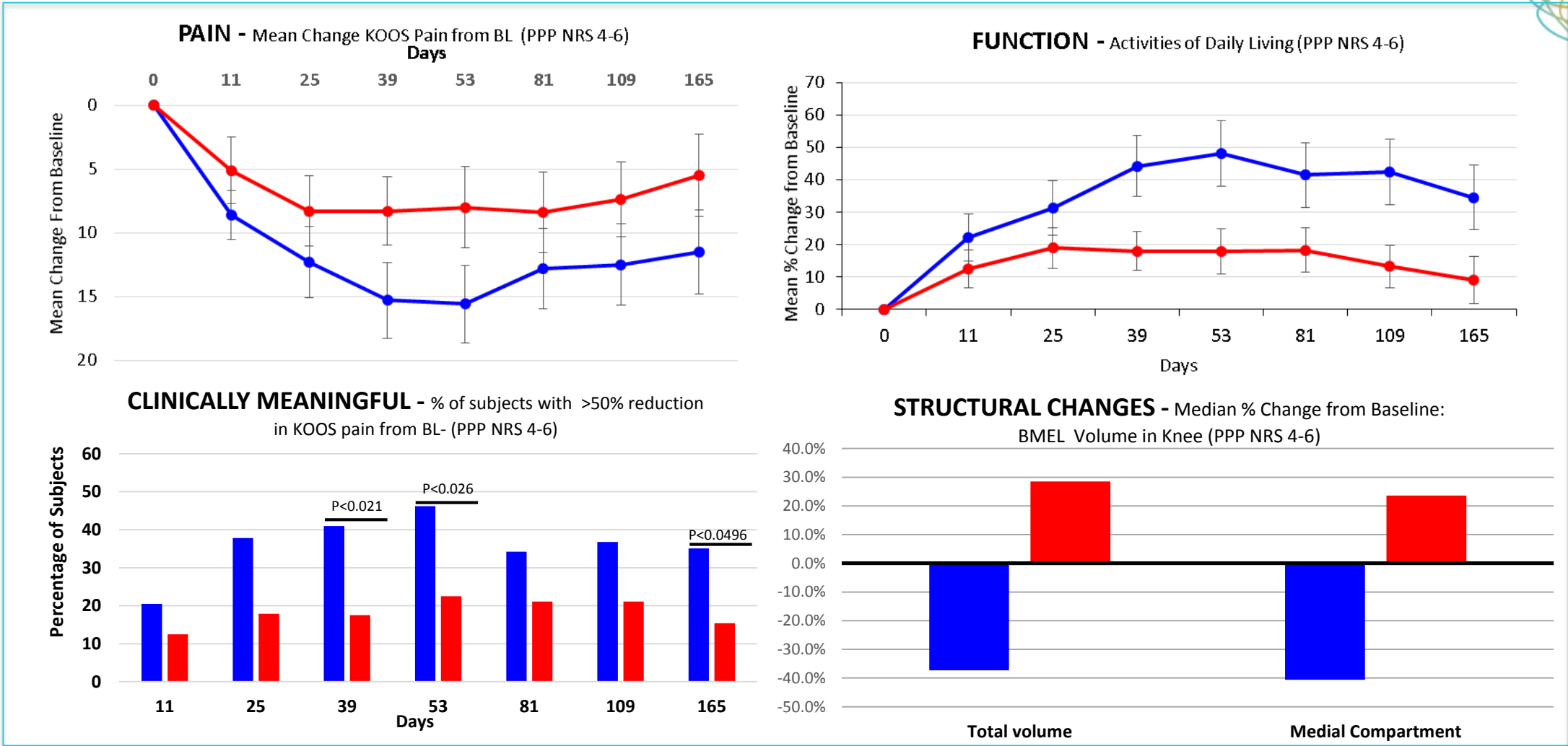


iPPS demonstrated efficacy on both Objective and Subjective and Measures

OBJECTIVE DATA MEASURES		OUTCOME
1.	Reduction in Bone Marrow Edema lesions determined by MRI – NEW DATA	Achieved ✓
SUBJECTIVE DATA MEASURES		OUTCOME
2.	A mean change in KOOS pain scores from baseline to day 165 - NEW DATA	Achieved ✓
3.	Number subjects that had a greater than 50% reduction in KOOS Pain score from baseline to day 165 – NEW DATA	Achieved ✓
4.	Patient Global Impression of Change (PGIC)	Achieved ✓
5.	A mean % change from baseline – KOOS Activities of Daily Living – NEW DATA	Achieved ✓

*Very strong trends and statistical significance in the medial compartment that indicate iPPS is having an effect on BML volume and area

SUMMARY – PHASE 2B DATA – PPP NRS 4-6 (PHASE 3 TARGET POPULATION)



■ Paradigm also achieved a statistically significant and clinically meaningful result in Patient Global Impression of Change (PGIC) (p=0.0062)

■ iPPS ■ Placebo

BONE MARROW LESIONS (BML): CLINICAL IMPLICATIONS FOR KNEE OA AND DISEASE REGRESSION WITH iPPS THERAPY



BML appear as increased signal intensity within the bone marrow



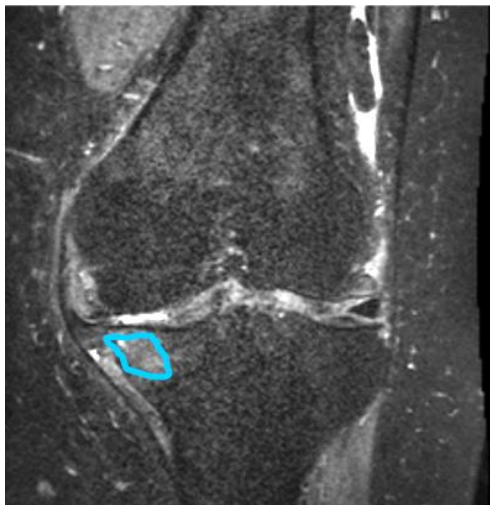
Grade 3 medial tibial BML at baseline

INCREASING PAIN¹

INCREASED CARTILAGE LOSS²

HIGH RISK OF JOINT DESTRUCTION³

HIGH RISK OF TOTAL KNEE REPLACEMENT^{4,5}



Grade 2 medial tibial BML at follow-up

REDUCED PAIN¹

REDUCED CARTILAGE LOSS²

REDUCED RISK OF JOINT DESTRUCTION³

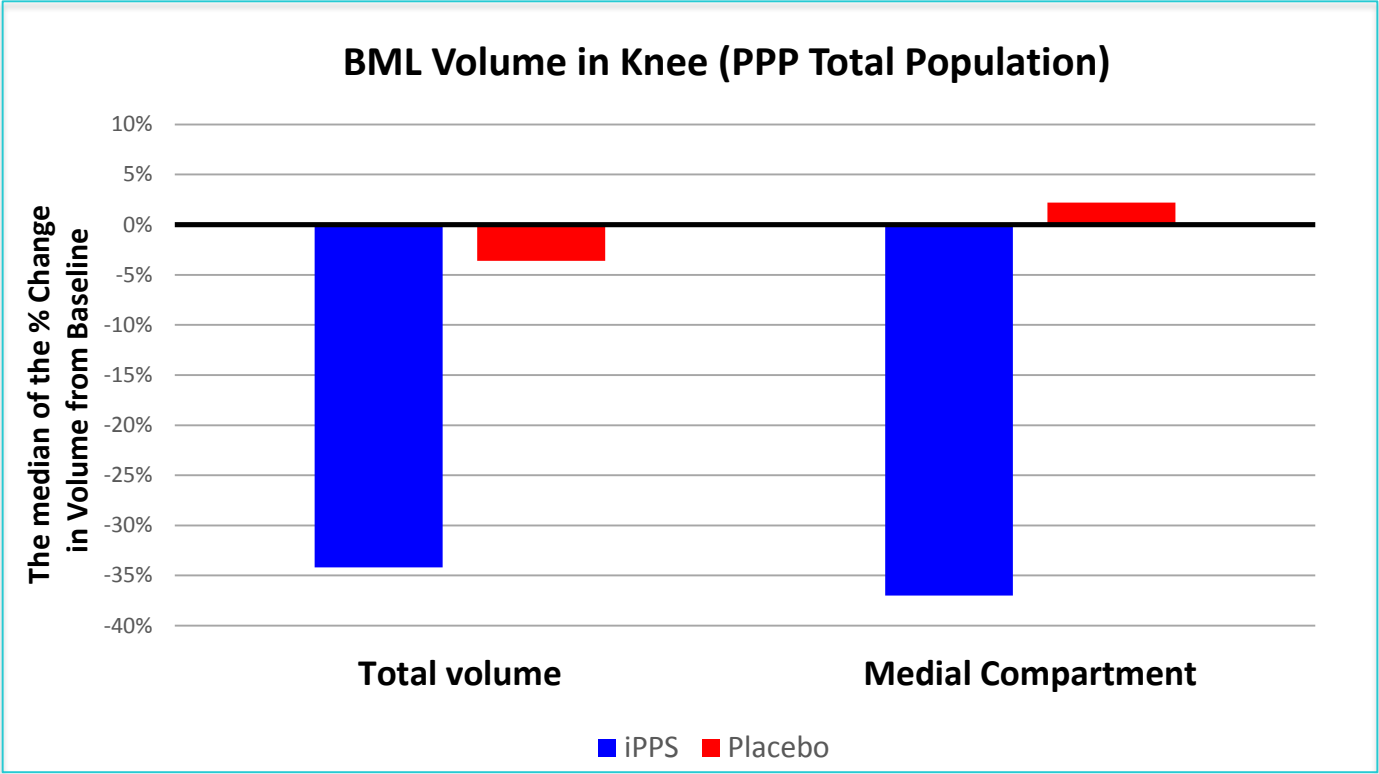
REDUCED RISK OF TOTAL KNEE REPLACEMENT^{4,5}

PHASE 2B OBJECTIVE DATA – REDUCTION IN BML VOLUME (TOTAL POPULATION)



PPP Total Population: The median of the percentage change from Baseline: BML Volume in Knee

BML Volume is a 3D analysis of the total BML within the bone



BML Volume in Knee (3D analysis)

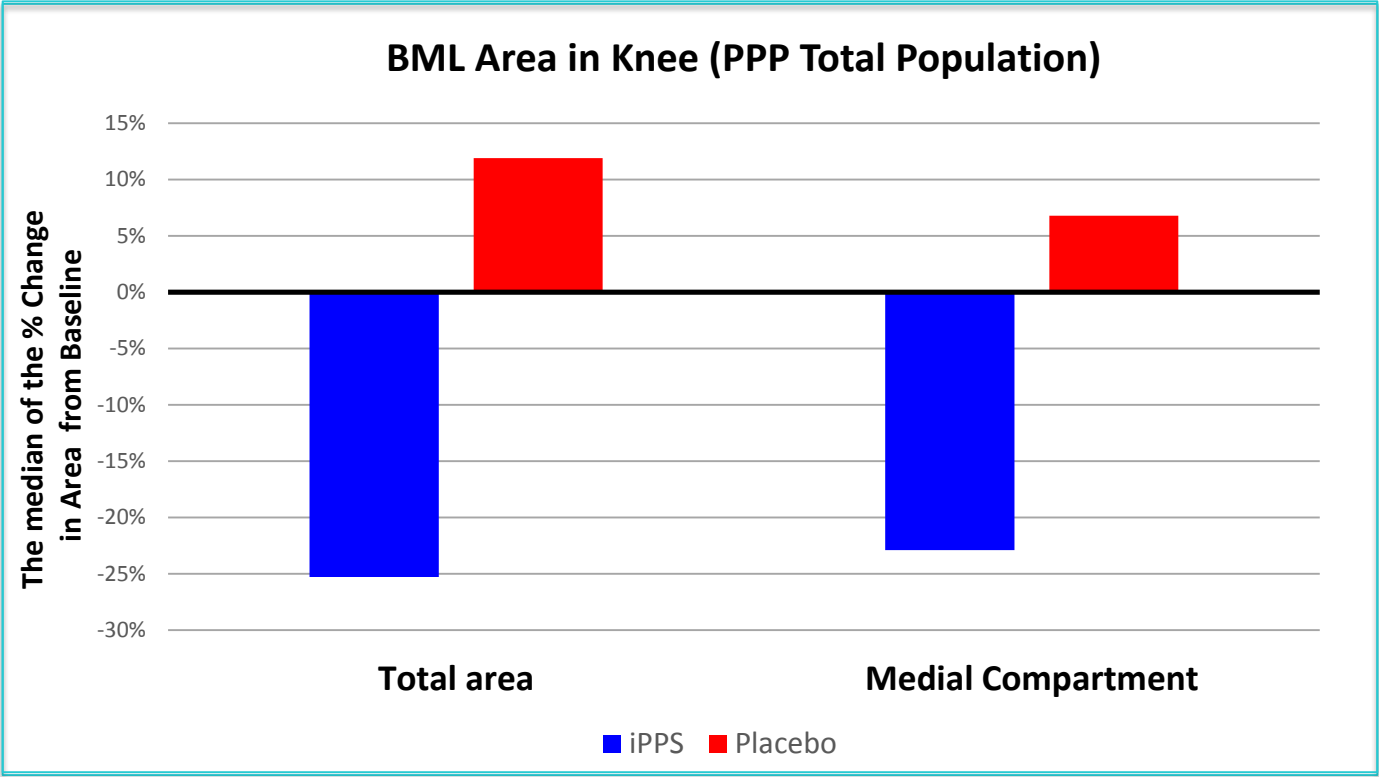
- In both Total Knee and Medial Compartment, iPPS demonstrated a strong trend of efficacy from baseline to day 53

PHASE 2B OBJECTIVE DATA – REDUCTION IN BML AREA (TOTAL POPULATION)



PPP Total Population: The median of the percentage change from Baseline: BML Area in Knee

BML Area in Knee is a 2D analysis of a MRI, to determine the size of a BML.



BML Area in Knee (2D analysis)

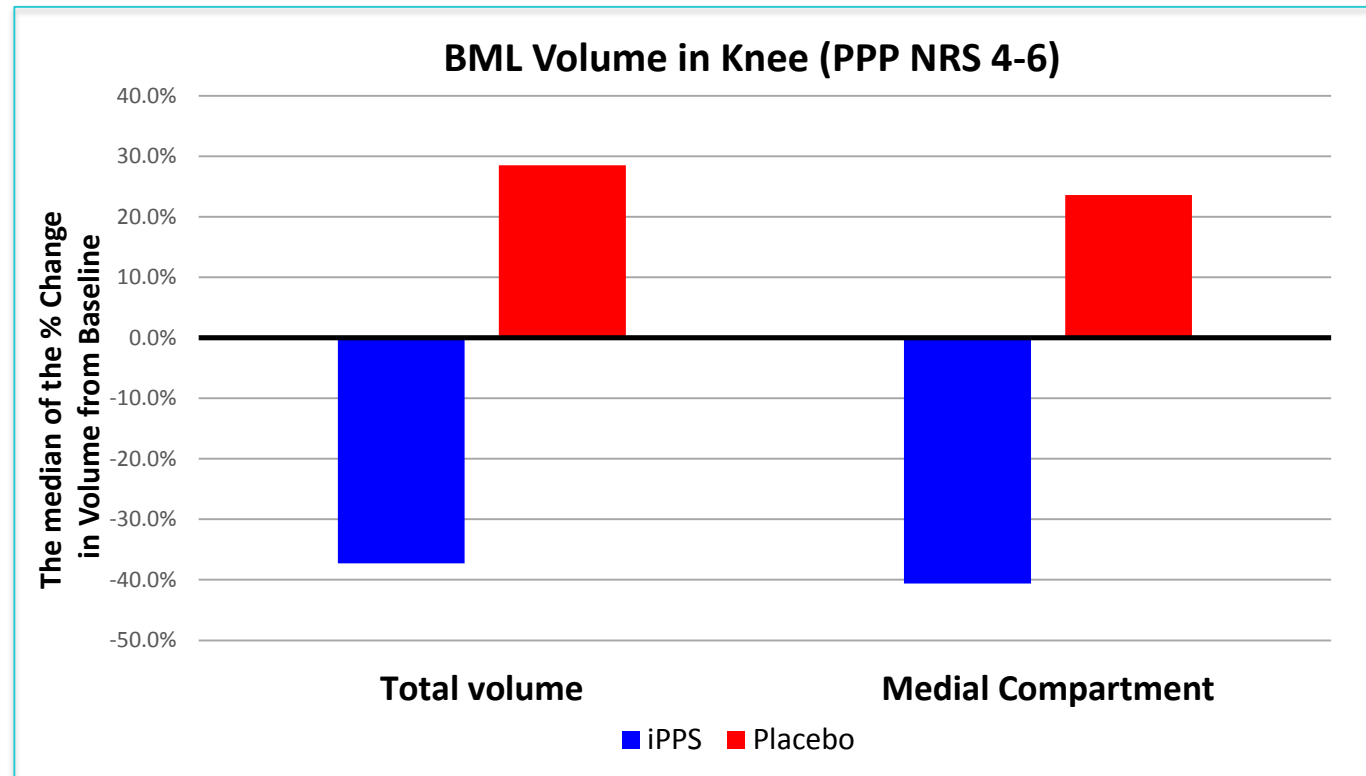
- In both Total Knee and Medial Compartment, iPPS demonstrated a strong trend of efficacy from baseline to day 53

PHASE 2B OBJECTIVE DATA – REDUCTION IN BML VOLUME (PPP NRS 4-6)



PPP NRS 4-6 – The median of the percentage change from Baseline: BML Volume in Knee

BML Volume is a 3D analysis of the total BML within the bone



BML Volume in Knee (3D analysis)

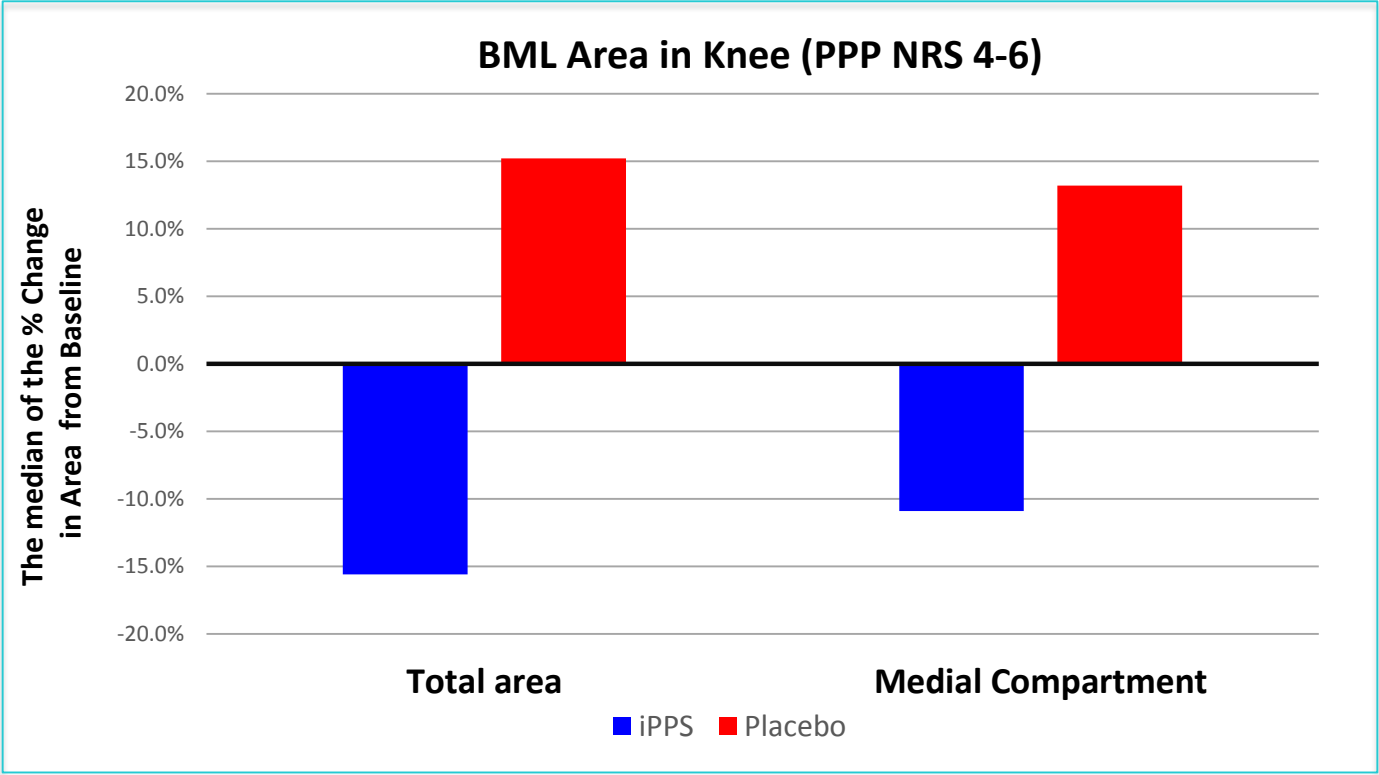
- In both Total Knee and Medial Compartment, iPPS demonstrated a strong trend of efficacy from baseline to day 53

PHASE 2B OBJECTIVE DATA – REDUCTION IN BML AREA (PPP NRS 4-6)



PPP NRS 4-6 – The median of the percentage change from Baseline: BML Area in Knee

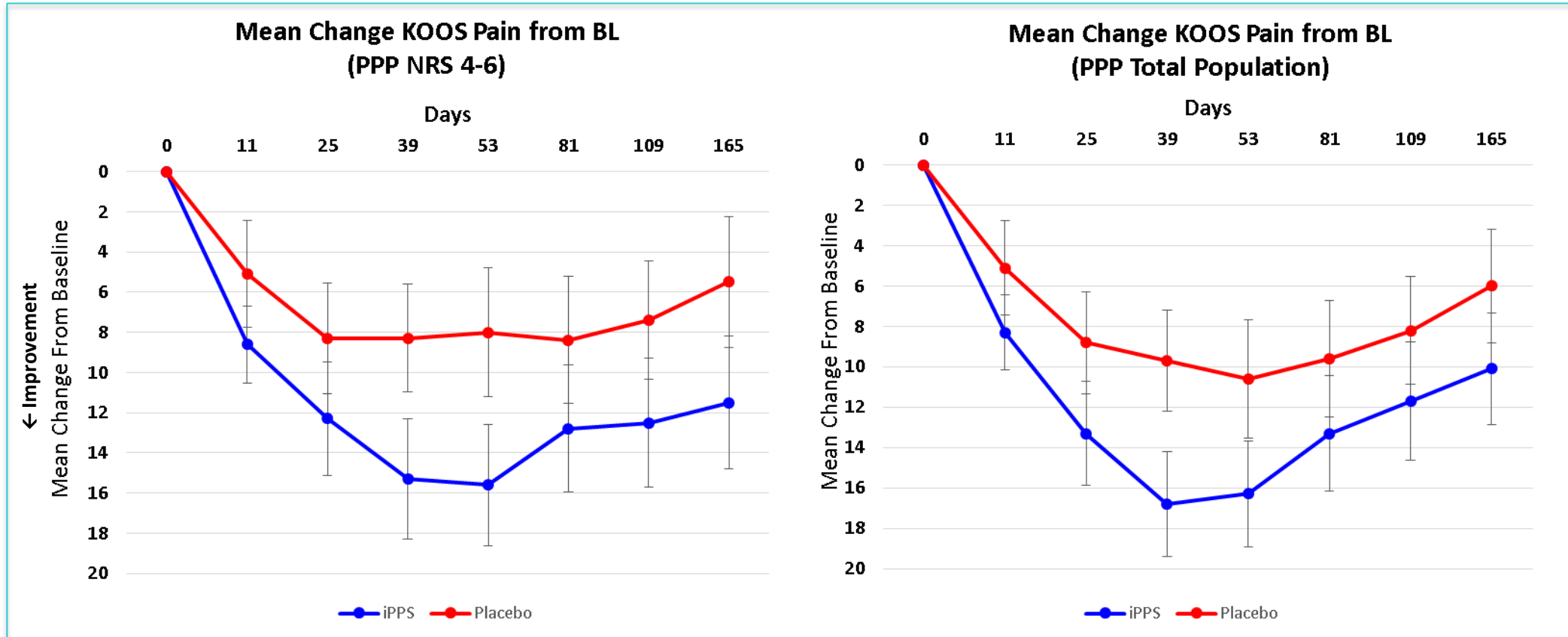
BML Area in Knee is a 2D analysis of a MRI, to determine the size of a BML.



BML Area in Knee (2D analysis)

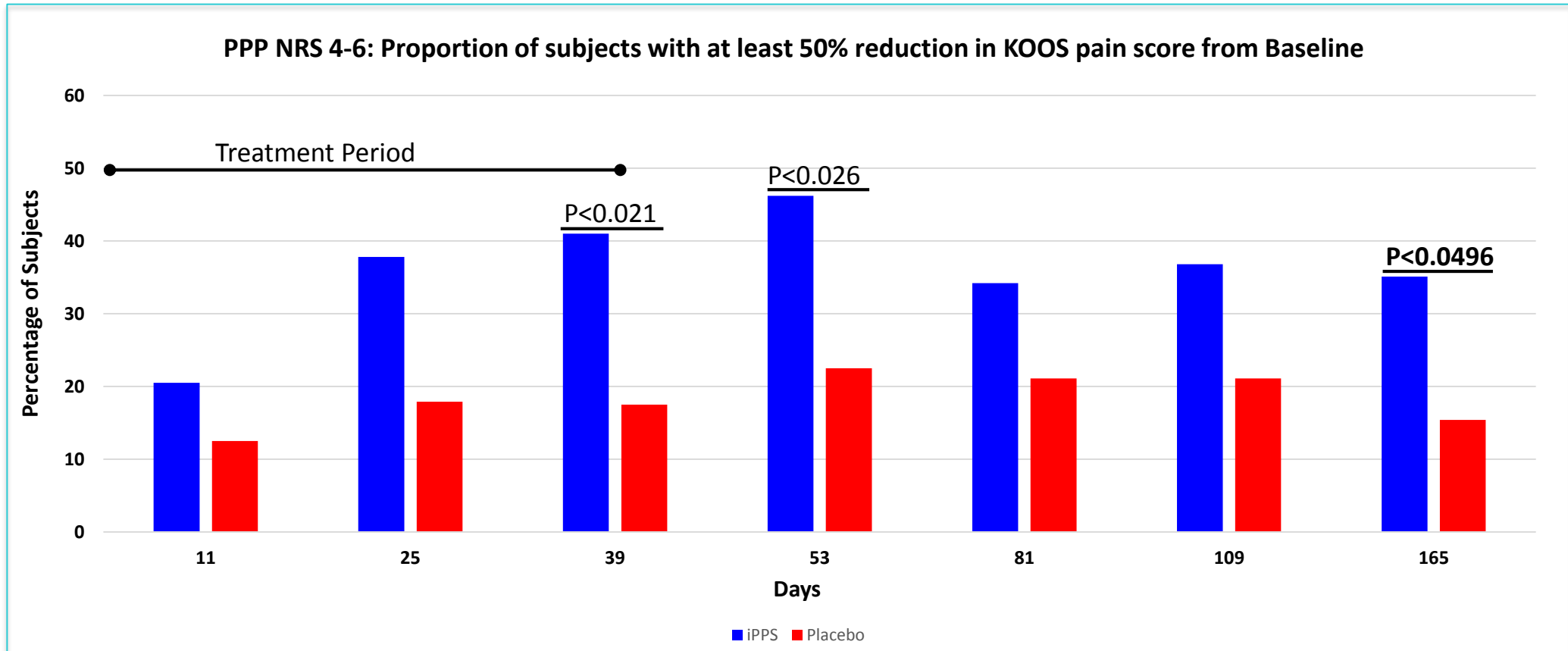
- In both Total Knee and Medial Compartment, iPPS demonstrated a strong trend of efficacy from baseline to day 53

MEAN CHANGE IN KOOS PAIN SCORE FROM BASELINE



- In the **PPP Total Population and PPP NRS 4-6 Stratum** Paradigm demonstrated a statistically significant mean change in KOOS Pain from Baseline versus Placebo at **day 39 and day 53**
- A mean change in KOOS Pain from Baseline greater than 10 is considered clinically meaningful, this was achieved the PPP Total Population and PPP NRS 4-6 Stratum from day 25 onward

GREATER THAN 50% REDUCTION IN KOOS PAIN FROM BASELINE (PPP NRS 4-6)



- Statistically greater proportions of subjects with >50% reductions in pain from Baseline after iPPS as measured by **KOOS Pain subscale** (chi-square analysis) at **day 39, day 53 and day 165**
- >50% pain reduction corresponds to high reduction in pain (OARSI definition)

CLINICALLY MEANINGFUL IMPROVEMENT IN PHYSICAL FUNCTION

– KOOS ACTIVITIES OF DAILY LIVING



What is KOOS Activities of Daily Living (Secondary Endpoint)?

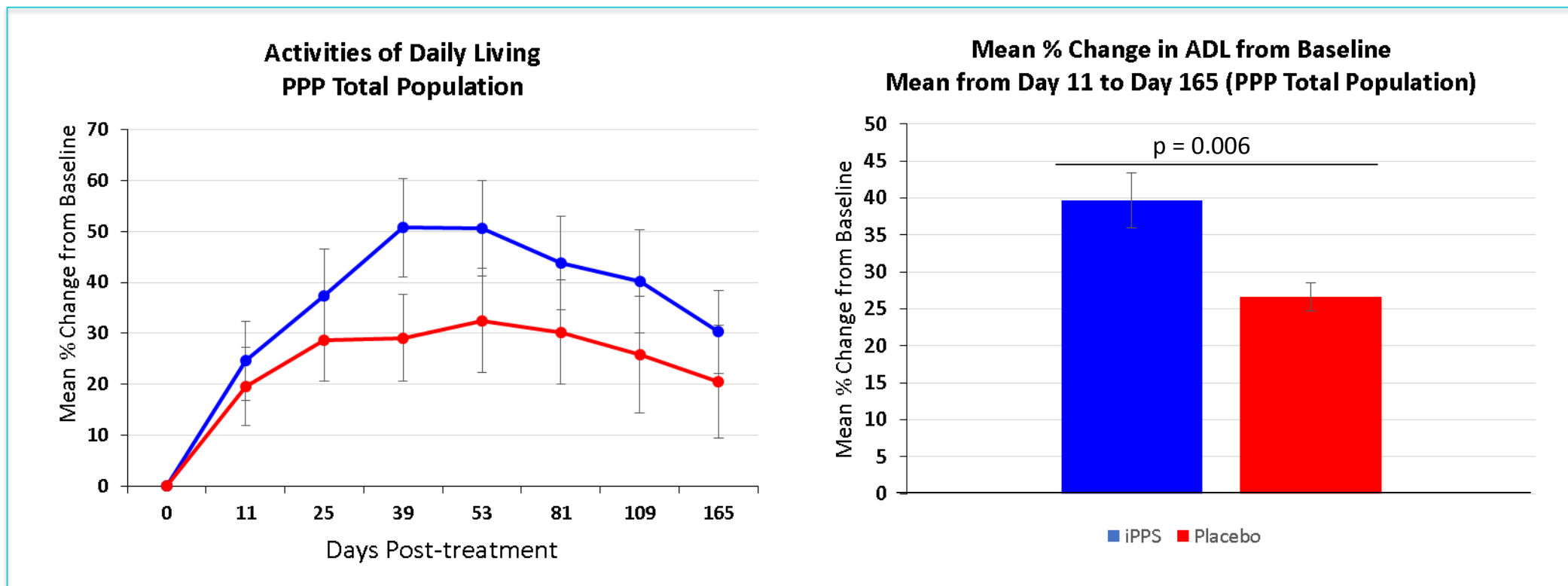
- KOOS Activities of Daily Living (ADL) is a secondary endpoint and measures physical function while performing daily activities.
- It includes 17 different items, which patients score the degree of difficulty experienced in the last week on a scale of 0-4 (None, Mild, Moderate, Severe, Extreme). The items include, ascending/descending, standing, going shopping, putting on/taking off socks etc.
- A normalized score (100 indicating no symptoms (positive) and 0 indicating extreme symptoms (negative)) is determined in subjects during the course of treatment and post-treatment.

CLINICALLY MEANINGFUL IMPROVEMENT IN PHYSICAL FUNCTION

– KOOS ACTIVITIES OF DAILY LIVING (PPP TOTAL POPULATION)



PPP Total Population - iPPS shows improvement in Activities of Daily Living compared to Placebo



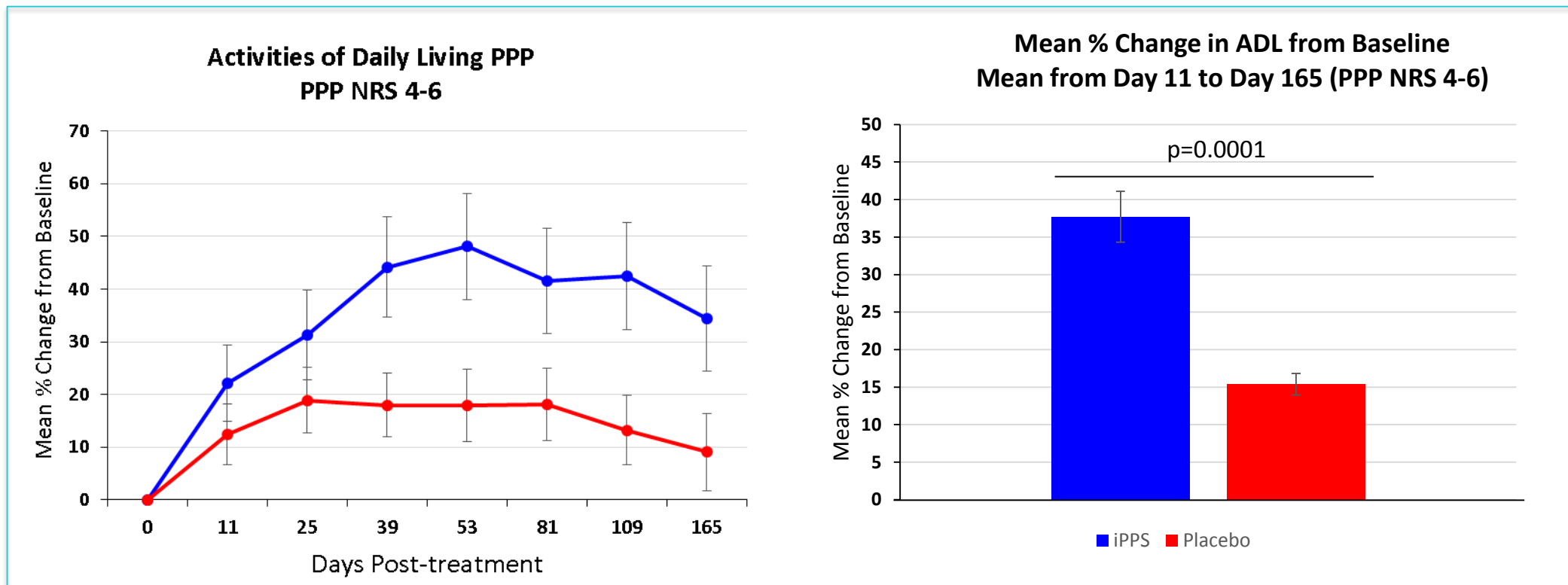
- In **PPP Total Population** iPPS demonstrated a statistically significant mean percentage change in KOOS Activities of daily living from Baseline versus Placebo at day 39
- In **PPP Total Population** iPPS demonstrated a statistically significant mean percentage change from baseline (p=0.006)

CLINICALLY MEANINGFUL IMPROVEMENT IN PHYSICAL FUNCTION

– KOOS ACTIVITIES OF DAILY LIVING (PPP NRS 4-6)



PPP NRS 4-6 - iPPS shows improvement in Activities of Daily Living compared to Placebo



- In **PPP NRS 4-6 Stratum** iPPS demonstrated a statistically significant mean percentage change in KOOS Activities of daily living from Baseline versus Placebo at **day 39, day 53, day 81, day 109 and day 165**
- In **PPP NRS 4-6 Stratum** iPPS demonstrated a statistically significant mean percentage change from baseline (p=0.0001)

PHASE 2B OA/BML CLINICAL TRIAL – PRIMARY ENDPOINTS PREVIOUSLY REPORTED 18 DECEMBER 2018.



- Clinical trial met the primary endpoint - change in the KOOS pain score from baseline at Day 53 for the total trial population ($p < 0.0001$);
- Mean Change in KOOS pain score from Baseline – Total Population and NRS:4-6 Strata - Clinically meaningful and statistically significant results.
- Number of subjects with a >50% Reduction from Baseline in KOOS Pain Score at Day 53 – NRS:4-6 Strata. Clinically meaningful and statistically significant results ($p < 0.026$)
- Mean Percentage Change in NRS Pain from Baseline – NRS:4-6 Strata. Clinically meaningful and statistically significant results ($p < 0.028$).
- A key measure in pain outcomes is the Patient Global Impression of Change (PGIC) the total population and placebo was statistically (PGIC, $p = 0.0062$);
- All data will be the subject of a peer-review publication in CY2019;
- Safety of drug confirmed.

CAPITAL RAISING & POTENTIAL NEWSFLOW



CAPITAL RAISING STRUCTURE



- **A\$77.9m capital raising at A\$1.50 per share comprising**
 - **A\$51.6m Placement to Sophisticated and Professional investors under Listing Rule 7.1 and 7.1a**
 - **A\$26.3m 1 for 8 Fully Underwritten Accelerated Entitlement Offer to existing eligible shareholders. Placement shares will not be eligible to participate in the Entitlement Offer**
- **Bell Potter Securities Ltd is Sole Lead Manager and Underwriter to the Offer**

Current Shares on issue	140.3m
Placement Shares Issued	34.4m
Shares on issue post Placement	174.7m
Entitlement Offer Shares Issued	17.5m
Shares on issue post Entitlement Offer and Placement	192.2m
Market capitalisation at A\$1.90	A\$365.2m
Pro-forma cash position 31-March-19 (incl proceeds of offer minus costs)	A\$82.0m
Pro-forma Enterprise Value	A\$283.2m

USE OF FUNDS



- **A\$77.9m anticipated to fund the Company's OA and MPS programs through to end of their pivotal phase 3 studies and new drug applications. A\$82.0m cash position post capital raising will put the Company in a strong negotiating position on commercial transaction.**

	Amount	Comments
<u>Complete</u> Phase 2/3 MPS(Rare Disease) Pivotal Clinical Trial	A\$7.0m	<ul style="list-style-type: none"> Complete Phase 2/3 pivotal clinical trial. Randomise, double-blind, placebo-controlled, multi-national clinical trial. (n=100)
<u>Complete</u> Phase 3 Osteoarthritis Pivotal Clinical Trial	A\$30.0m	<ul style="list-style-type: none"> Commence Phase 3 Pivotal Clinical Trial in the USA, EU and AUS with 70% of subjects from the USA (n=100). Forecast maximum of A\$30M (n=500).
Employ additional 2x US based staff	A\$3.0m	<ul style="list-style-type: none"> Two FT Clinical Research Associates and Two FT project managers to work with US Based CMO.
Working capital, costs of the offer, further preclinical studies and IP acquisitions	A\$37.9m	<ul style="list-style-type: none"> Ongoing working capital and costs of the offer Future acquisitions of Intellectual Property outside of PPS to further broaden portfolio Further preclinical work to expand pipeline
Total	A\$77.9m	

ANTICIPATED AND POTENTIAL CATALYSTS & NEWS FLOW



- **Successful OA Phase 2b trial secondary endpoints released** with capital raising
- **Ongoing partnering discussions with big pharma**
- **Release of scientific journal detailing mechanism of action via NGF – Q2 2019**
- **Appointment of highly regarded US based CMO – Q2 2019**
- **Potential to treat to MPS patients in Australia via the SAS – Q2 CY2019**
- **Up to 50 ex-NFL players in the US to be treated with iPPS for OA pain - Potential for significant media attention if treatment is successful – Q2 CY2019**
- **File IND for Phase 2/3 for Mucopolysaccharidosis (MPS) - Q2 CY2019**
- **Further release of patients OA data** under the TGA special access scheme throughout 2019
- **File TGA Provisional Approval** to sell ZILUSOL (iPPS) in Australia, potential for near term revenue – Q2 CY2019
- **Ross River Phase 2a (safety study) trial results release – Q2/Q3 CY2019**
- **File IND and meet with FDA re Phase 3 trial in OA - Q3 CY2019**
- **Possibility of being granted “Fast Track status” for Phase 3 OA trial**

INDICATIVE TIMETABLE



Release of OA Phase2b Secondary Endpoints	Pre-Market Monday 15 April 2019
Trading Halt	Monday 15 April – Tuesday 16 April 2019
Company resumes trading and Offer announced Record date for eligibility under the Entitlement Offer	Wednesday 17 April 2019
Settlement of New Shares issued under the Placement Entitlement Offer Opens	Wednesday 24 April 2019
Allotment of New Shares issued under the Placement	Friday 26 April 2019
Entitlement Offer closes	6 May 2019
Entitlement Offer shares are allotted	14 May 2019



Risk Factors

This section outlines some (but not all) of the key risks associated with an investment in Paradigm. Paradigm's assets and business is subject to a number of risk factors both specific to its assets / business and of a general nature which may impact on its future performance and forecasts. This is not an exhaustive list of the relevant risks and the risks set out below are not in order of importance. The risks set out below and other risks not specifically referred to below may in the future materially adversely affect the value of Paradigm shares and their performance. Accordingly, no assurance or guarantee of future performance or profitability is given by Paradigm in respect of Paradigm shares.

Before subscribing for Paradigm shares, prospective investors should carefully consider and evaluate Paradigm, its assets and its business and whether Paradigm shares are suitable to acquire having regard to their own investment objectives and financial circumstances and taking into consideration the material risk factors, as set out below.

In deciding whether to participate in the Offer, you should read this presentation in its entirety and carefully consider the risks outlined in this section. Prospective investors should also consider publicly available information on Paradigm, examine the full content of this presentation and consult their technology, financial, tax and other professional advisers before making an investment decision.

Research and Development Activities: Paradigm's future success is dependent on the performance of Paradigm in clinical trials and whether it proves to be a safe and effective treatment. Paradigm's lead product is an experimental product in clinical development and product commercialisation resulting in potential product sales and revenues is likely to be years away, and there is no guarantee that it will be successful. It requires additional research and development, including ongoing clinical evaluation of safety and efficacy in clinical trials and regulatory approval prior to marketing authorisation. Drug development generally is often associated with a high failure rate and until Paradigm is able to provide further clinical evidence of the ability of Paradigm's product to improve outcomes in patients, the future success of the product in developed remains speculative. Research and development risks include uncertainty of the outcome of results, difficulties or delays in development and generally the uncertainty that around surrounds the scientific development of novel pharmaceutical products.

Dilution Risk: Eligible shareholders that do not take up all or part of their entitlements will be diluted by not participating to the full extent in the Entitlement Offer and by the Institutional Placement, but will not be exposed to future increases or decreases in Paradigm's share price in respect of those shares which would have been issued to them had they taken up all of their entitlement.



Risk Factor Continued

Economic Risks: Paradigm is exposed to economic factors in the ordinary course of business. A number of economic factors / conditions, both domestic and global, affect the performance of financial markets generally, which could affect the price at which Paradigm Shares trade on ASX. Among other things, adverse changes in macroeconomic conditions, including movements on international and domestic stock markets, interest rates, exchange rates, cost and availability of credit, general consumption and consumer spending, input costs, employment rates and industrial disruptions, inflation and inflationary expectations and overall economic conditions, economic cycles, investor sentiment, political events and levels of economic growth, both domestically and internationally, as well as government taxation, fiscal, monetary, regulatory and other policy changes may affect the demand for, and price of, Paradigm Shares and adversely impact Paradigm's business, financial position and operating results. Trading prices can be volatile and volatility can be caused by general market risks such as those that have been mentioned. New Shares in Paradigm may trade at or below the price at which they are currently commence trading on ASX including as a result of any of the factors that have been mentioned, and factors such as those mentioned may also affect the income, expenses and liquidity of Paradigm. Additionally, the stock market can experience price and volume fluctuations that may be unrelated or disproportionate to the operating performance of Paradigm.

Dividend Guidance: No assurances can be given in relation to the payment of future dividends. Future determinations as to the payment of dividends by Paradigm will be at the discretion of Paradigm and will depend upon the availability of profits, the operating results and financial conditions of Paradigm, future capital requirements, covenants in relevant financing agreements, general business and financial conditions and other factors considered relevant by Paradigm. No assurance can be given in relation to the level of tax deferral of future dividends. Tax deferred capacity will depend upon the amount of capital allowances available and other factors.

Forward-Looking Statements: There can be no guarantee that the assumptions and contingencies on which the forward-looking statements, opinions and estimates contained in this presentation are based will ultimately prove to be valid or accurate. The forward-looking statements, opinions and estimates depend on various factors, including known and unknown risks, many of which are outside the control of Paradigm. Actual performance of Paradigm may materially differ from forecast performance.

Product Safety and Efficacy: Serious or unexpected health, safety or efficacy concerns with Paradigm's (or similar third party) products may expose Paradigm to reputational harm or reduced market acceptance of its products, and lead to product recalls and/or product liability claims and resulting liability, and increased regulatory reporting. There can be no guarantee that unforeseen adverse events or manufacturing defects will not occur. Paradigm will / may seek to obtain adequate product liability insurance at the appropriate time in order to minimise its liability to such claims however there can be no assurance that adequate insurance coverage will be available at an acceptable cost. Any health, safety or efficacy concerns are likely to lead to reduced customer demand and impact on potential future profits of Paradigm.



Risk Factors Continued

Intellectual Property risks: Securing rights in technology and patents is an integral part of securing potential product value in the outcomes of biotechnology research and development. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. Paradigm's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Because the patent position of biotechnology companies can be highly uncertain and frequently involves complex legal and factual questions, neither the breadth of claims allowed in biotechnology patents nor their enforceability can be predicted. There can be no assurance that any patents which Paradigm may own, access or control will afford Paradigm commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that Paradigm will be free to commercialise its drug candidates. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology or products to avoid Paradigm's patented technology. Paradigm's current Patenting strategies do not cover all countries which may lead to generic competition arising in those markets.

Competition: The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change, both in Australia and internationally, and there are no guarantees about Paradigm's ability to successfully compete. Paradigm's products may compete with existing alternative treatments that are already available to customers. In addition, a number of companies, both in Australia and internationally, are pursuing the development of competing products. Some of these companies may have, or may develop, technologies superior to Paradigm's own technology. Some competitors of Paradigm may have substantially greater financial, technical and human resources than Paradigm does, as well as broader product offerings and greater market and brand presence. Paradigm's services, expertise or products may be rendered obsolete or uneconomical or decrease in attractiveness or value by advances or entirely different approaches developed by either Paradigm or its competitors.

Regulatory Approval. Paradigm operates within a highly regulated industry, relating to the manufacture, distribution and supply of pharmaceutical products. There is no guarantee that Paradigm will obtain the required approvals, licenses and registrations from all relevant regulatory authorities in all jurisdictions in which it operates. The commencement of clinical trials may be delayed and Paradigm may incur further costs if the Food and Drug Administration (FDA) and other Regulatory Agencies observe deficiencies that require resolution or request additional studies be conducted in addition to those that are currently planned. A change in regulation may also adversely affect Paradigm's ability to commercialise and manufacture its treatments.

Clinical Development: Clinical trials are inherently risky, and may prove unsuccessful or non-efficacious, impracticable or costly, which may impact profitability and commercial potential. Failure or negative or inconclusive results can occur at many stages in development, and the results of earlier clinical trials are not necessarily predictive of future results. In addition, data obtained from trials is susceptible to varying interpretations, and regulators may not interpret the data as favourably as Paradigm, which may delay, limit or prevent regulatory approval.

Risk Factors Continued



Commercial Risk: Paradigm may, from time to time, consider acquisition, licensing, partnership or other corporate opportunities for Paradigm's product development programs. There can be no assurance that any such acquisition, licensing, partnership or corporate opportunities can be concluded on terms that are, or are believed by Paradigm to be, commercially acceptable. In the case of licensing and partnership opportunities, even if such terms are agreed there is a risk that the performance by and the delivery of contracted outcomes by collaborators may not occur due to a range of unforeseen factors relating to environment, technology and market conditions.

Market penetration: Where Paradigm does obtain regulatory approval, future success will also depend on Paradigm's ability to achieve market acceptance and attract and retain customers, which includes convincing potential consumers and partners of the efficacy of Paradigm's products and Paradigm's ability to manufacture a sufficient quantity and quality of products at a satisfactory price.

Manufacturing: There is a risk that scale-up of commercial quantities or the supply of PPS may present technical difficulties. Any unforeseen difficulty relating to manufacturing or supply of PPS may negatively impact Paradigm's ability to generate profit in future.

Reliance on Key Personnel: Paradigm is reliant on key personnel employed or engaged by Paradigm. Loss of such personnel may have a material adverse impact on the performance of Paradigm. In addition, recruiting qualified personnel is critical to Paradigm's success. As Paradigm's business grows, it may require additional key financial, administrative, investor and public relations personnel as well as additional staff for operations. While Paradigm believes that it will be successful in attracting and retaining qualified personnel, there can be no assurance of such success. The loss of key personnel or the inability to attract suitably qualified additional personnel could have a material adverse effect on Paradigm's financial performance.

Insurance and Uninsured Risks Although Paradigm maintains insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance will not cover all the potential risks associated with its operations and insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. It is not always possible to obtain insurance against all such risks and Paradigm may decide not to insure against certain risks because of high premiums or other reasons.

Litigation: In the ordinary course of conducting its business, Paradigm is exposed to potential litigation and other proceedings, including through claims of breach of agreements, intellectual property infringement or in relation to employees (through personal injuries, occupational health and safety or otherwise). If such proceedings were brought against Paradigm, it may incur considerable defence costs (even if successful), with the potential for damages and costs awards against Paradigm if it were unsuccessful, which could have a significant negative financial effect on Paradigm's business. Changes in laws can also heighten litigation risk (for example, antitrust and intellectual property). Circumstances may also arise in which Paradigm, having received legal advice, considers that it is reasonable or necessary to initiate litigation or other proceedings, including, for example, to protect its intellectual property rights. There has been substantial litigation and other proceedings in the pharmaceutical industry, including class actions from purchasers and end users of pharmaceutical products.

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- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

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United Kingdom

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THANK YOU

