ASX RELEASE

15 May2017

Paradigm Non-Deal Roadshow Presentation

Paradigm Biopharmaceuticals Ltd (ASX:PAR) updates its Corporate Presentation.

Over the next few weeks, Paradigm management will be conducting a number of investor meetings, the updated presentation can be found below.

FOR FURTHER INFORMATION PLEASE CONTACT:

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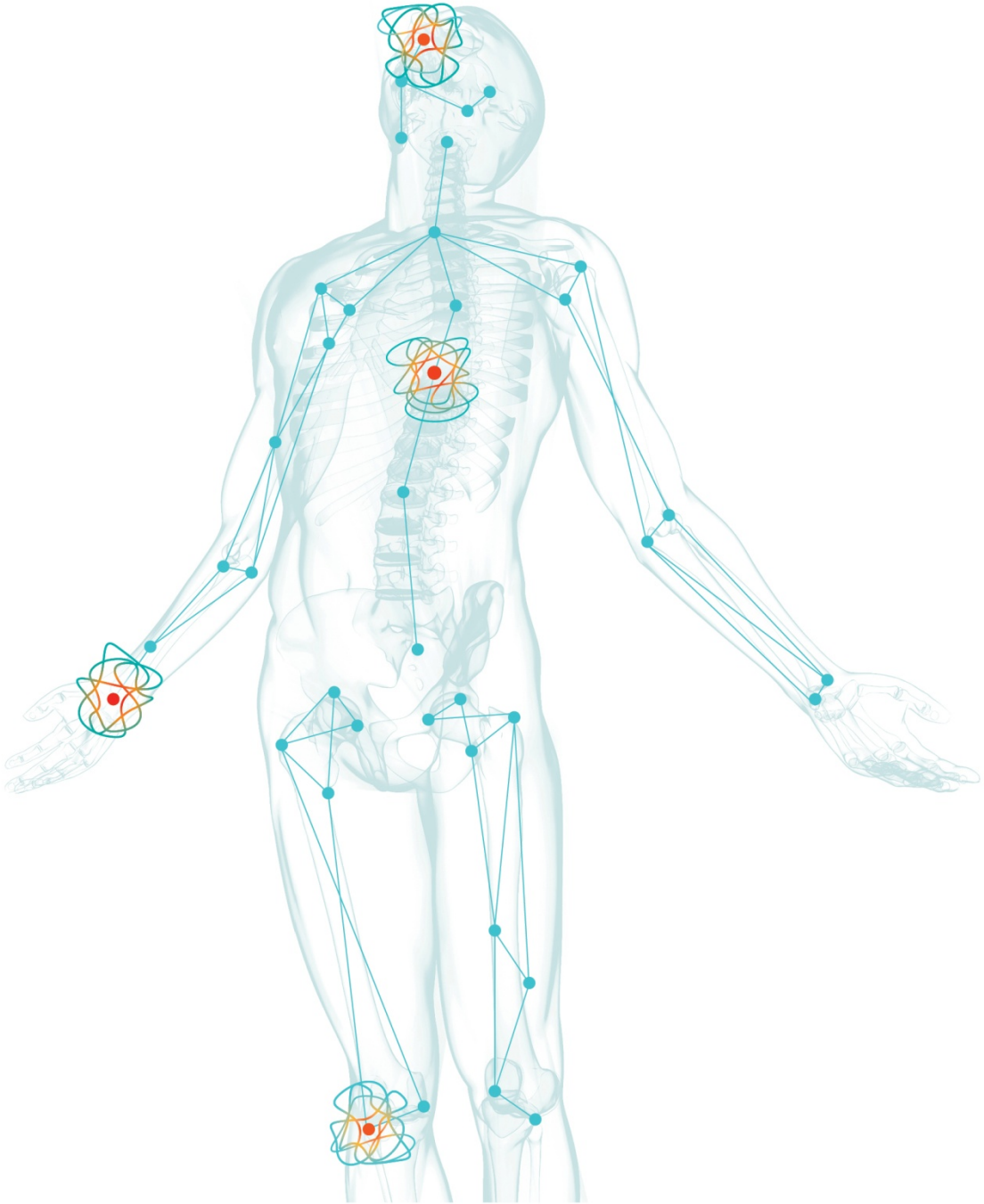
paradigm
BIOPHARMA

Non-deal Roadshow Presentation

Paul Rennie, CEO & MD

15 May, 2017



Company Highlights

- Repurposing a pre-approved drug **to treat conditions associated with inflammation** in a safer way
- Repurposing **reduces clinical risk and costs, whilst accelerating commercialisation**
- Pentosan Polysulfate Sodium (PPS) is a new, multi-acting treatment for hay fever, bone bruising and viral arthritis, all of which have **very large addressable markets (US$14bn+)**
- **Multiple short term share price catalysts –** Positive results from upcoming Phase 2 clinical trials for hay fever and bone bruising to potentially provide significant share price re-rating catalysts
- **Highly credentialed board and management team** with top tier experience at CSL Limited (CSL.ASX) and Mesoblast Limited (MSB.ASX)
- **Fully funded** through to the completion of the Phase 2 open label clinical trial for bone bruising, Phase 2 hay fever and Phase 2 alpha viruses trials
- Multi-faceted IP strategy and ability to leverage relationships to **fast-track time to market**
- Strong focus on prudent cash management to **enhance shareholder returns**

Drug repurposing strategy

Much lower cost, accelerated timeline, lower risk and with higher rates of success

- **Lower cost:** average development cost of US$28m compared to US$1.3bn for “de novo” development[1]
- **Faster:** FDA 505(b)(2) pathway leveraging previous clinical efforts**,** which accelerates the development timeline
- **Lower risk:** safety already established so less chance of failure (safety issues account for 30% of clinical failures[1])
- **Higher success rates:** 25% chance of successful commercialisation compared to 10% for “de-novo” drugs[1]
- **Repurposed drugs have the same potential** to reach ‘blockbuster drug status’ as de novo drugs

Standard clinical development[1,2]

10-17 year process

Discovery & pharmacology	Preclinical testing	Phase I clinical trials	Phase II clinical trials	Phase III clinical trials	Regulatory approval
2 – 3 years	5 – 6 years		2 – 6 years		1 – 2 years

Paradigm’s drug repurposing timeline

3-5 year process to approval, potential for cash flow in 2017 if a partnering opportunity is secured

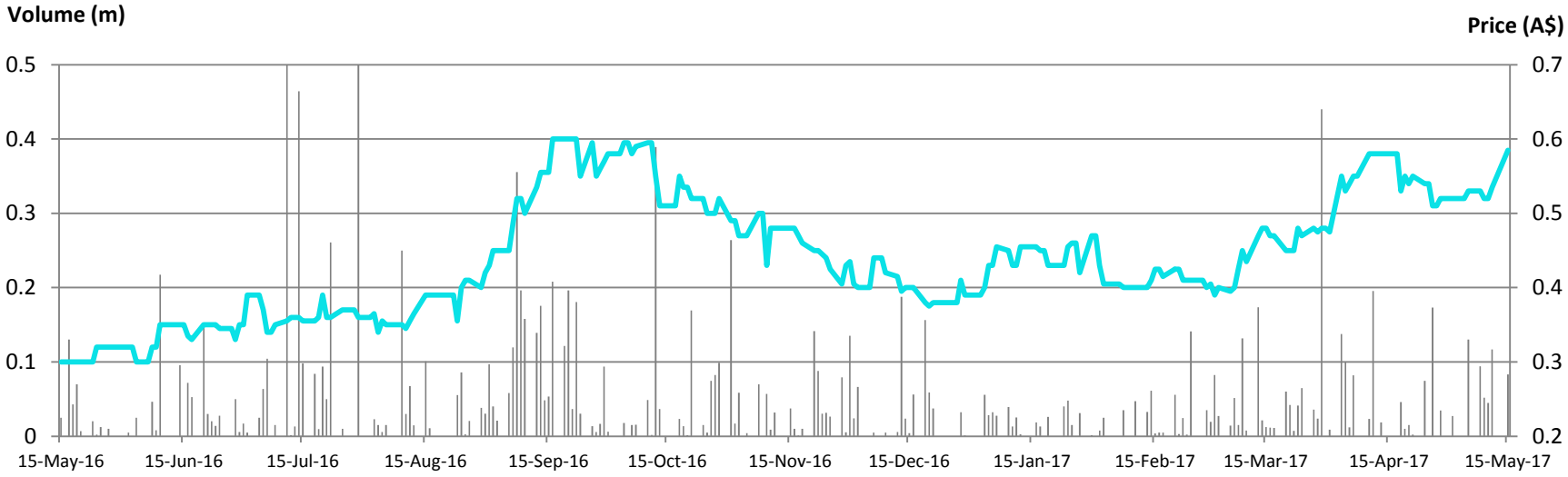
Phase I & Phase II trials (hay fever) 1 pivotal Phase II trial (BME)	1 pivotal Phase III trial for each indication	Regulatory approval
1 year (expected completion early 2017)	1 – 2 years	1 – 2 years

Source:
1. Khanaoure A, Chuki P & De Sousa A (2014)
2. Ashurn T & Thor K (2004)

Company Overview

Financial information	
Share price (15-May-17)	A$0.585
Number of shares[1]	101.5m
Market capitalisation	**A$59.4m**
Cash (31-Mar-17)	~A$4.1m
Debt (31-Mar-17)	No debt
Enterprise value	**A$55.3m**

Top shareholders[2,3]	Shares (m)	%
Paul Rennie *(Managing Director)*	21.2	21.1%
MJGD Nominees *(technology vendor)*	6.9	6.9%
Other Board and management	7.1	7.1%
Irwin Biotech *(technology vendor)*	6.3	6.3%



Source: IRESS

Note:

1. Includes 33.9m escrowed shares 2. Blue shading represents Board and management holdings 3. MJGD Nominees and Irwin Biotech are select vendors of Xosoma, which was acquired by Paradigm prior to listing

Board and Management

High quality Board and management, with top tier pharmaceutical experience

- Board and management are renowned leaders in the biopharmaceutical industry, having held senior management positions with top ASX-listed companies, CSL (CSL.ASX) and Mesoblast (MSB.ASX)
- Extensive experience bringing biopharmaceutical products from clinical development to commercialisation
- Small and highly specialised team focused on product development utilising outsourcing effectively

Board and management

Graeme Kaufman – Non-executive Chairman
- Broad experience in development and commercialisation of pharmaceutical drugs, previously CFO at CSL, executive VP of Mesoblast and Chairman of Bionomics (BNO)

Paul Rennie – Managing Director
- Extensive experience in drug development and commercialisation, previously COO & Executive VP, New Product Development of Mesoblast

John Gaffney – Non-executive Director
- 30+ years experience as a lawyer, previously Director of Patrys (PAB.ASX)

Christopher Fullerton – Non-executive Director
- Chartered Accounting and investment banking expertise, previously Non-executive Chairman of Bionomics and Cordlife (now Life Corporation (LFC.ASX))

Dr Ravi Krishnan – Chief Scientific Officer
- Significant experience in experimental pathology and investigating novel compounds with immune modulatory effects and anti-inflammatory properties

Kevin Hollingsworth – CFO & Company Secretary
- Previously CFO and Co-Sec of Mesoblast and Patrys (PAB.ASX)

Pentosan Polysulfate Sodium

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

Pentosan Polysulfate Sodium

- Pentosan Polysulfate Sodium (PPS) has been used in humans for more than 60 years
- First approved by FDA more than 30 years ago
- Since approval, there have been in excess of 100 million injectable doses of PPS administered
- Paradigm has been granted patents to use PPS for new indications

Current treatment uses

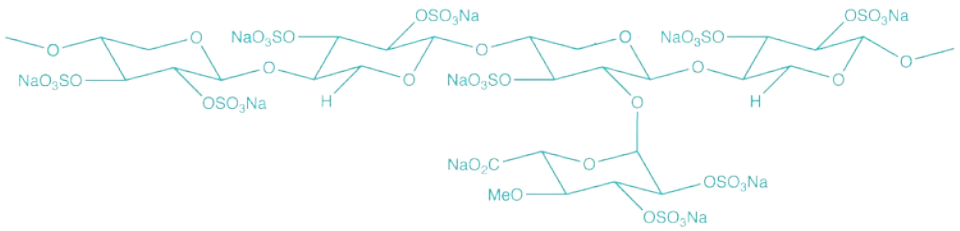
- The oral formulation is FDA approved and sold under the name Elmiron, by Janssen Pharmaceuticals, for the treatment of interstitial cystitis (painful bladder syndrome)
- Also used to treat deep vein thrombosis

Current distributors

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Ideal biological characteristics

- PPS is an anti-inflammatory and an anti-histamine with biological characteristics that make it ideally suited for treating hay fever (allergic inflammation in the nasal passage) and bone marrow edema (inflammation in the bone) & viral arthritis
  - ✓ Anti-inflammatory
  - ✓ Anti-histamine
  - ✓ Anti-clotting
  - ✓ Prevents necrosis (premature cell death)
  - ✓ Prevents cartilage degeneration



Hay Fever

Hay fever is a very common condition that is poorly treated at present

What is hay fever (allergic rhinitis)?

- Allergic inflammation of the nasal airways, when an allergen is inhaled by a sensitised individual

Why focus on hay fever?

- Strong need for more effective treatment options
  - **More than 50% of patients are dissatisfied with current medication and 60% have said they would be interested in new treatments**[1]
  - Long term use of corticosteroids proven to be harmful to certain sufferers
- Clear need for safer, superior and cheaper treatments
- Hay fever associated with growing economic burden

Addressable market for hay fever:

Estimated number of people who suffer from hay fever worldwide[2]

US$11+ BILLION

size of the therapeutic market for hay fever in 2014[3]

Source:
1. 2005 survey conducted by Asthma and Allergy Foundation of America
2. Mullol J, et al. (2008)
3. Visiongain: Allergic Rhinitis Drugs Market Forecast 2015-2025

Hay Fever: The Market for RHINOSUL®

RHINOSUL® has the potential to fill the current gap in hay fever treatment options

- The hay fever market is changing with new players, like Meda (MEDA.STO acquired by Mylan for US$7.2B/A$9.5B), developing a new class of dual acting treatments
- RHINOSUL® is dual acting with multiple mechanisms of action that make it a potentially superior treatment to existing therapies corticosteroid therapies (like Rhinocort ®, Beconase ®) and antihistamines (like Claratyne ® and Zyrtec ®)
- **If FDA approved, RHINOSUL® would be the first dual-acting hay fever treatment with no undesirable side effects**

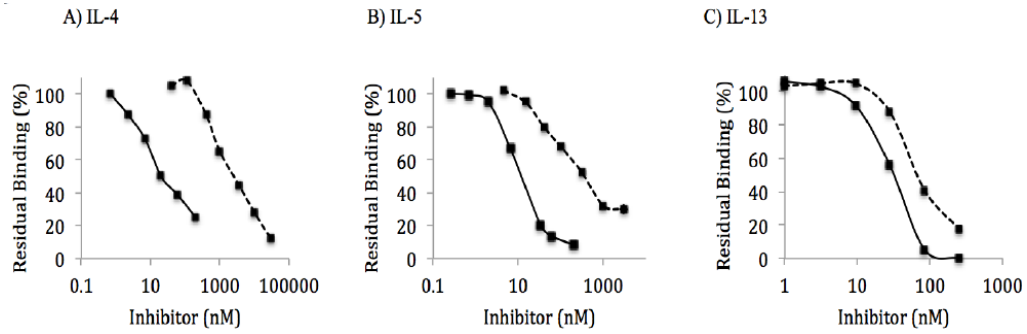
	RHINOSUL®	Anti-histamines (eg. Zyrtec®)	Corticosteroids (eg. Rhinocort®)	Dymista®
Treats acute symptoms (histamine release)	✓	✓	✓[1]	✓
Treats chronic symptoms (inflammation)	✓		✓	✓
No undesirable side effects	✓			
Anti-inflammatory	✓		✓	✓
Simple to manufacture	✓			

Note:
1. Immediate use of corticosteroids do not treat acute hay fever symptoms, however, ongoing use will result in the subsiding of such symptoms

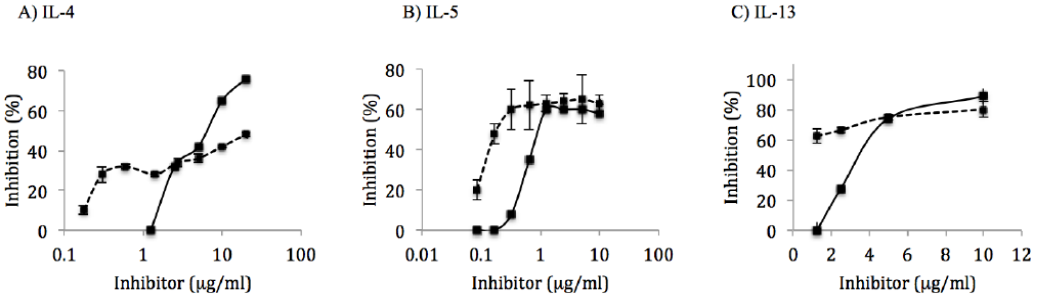
Peer Reviewed Scientific Publication

- *In vitro* studies showing PPS binds to key inflammatory Th2 cytokines

- **PPS shown as a potent Th2 cytokine-binding molecule with biological neutralization capacity and broad anti-inflammatory effects**
- **PPS demonstrated a strong binding affinity to inflammatory cytokines IL-4, IL-5 and IL-13**



- **PPS inhibited the growth of TH2 cytokine-dependent responder cell-lines**

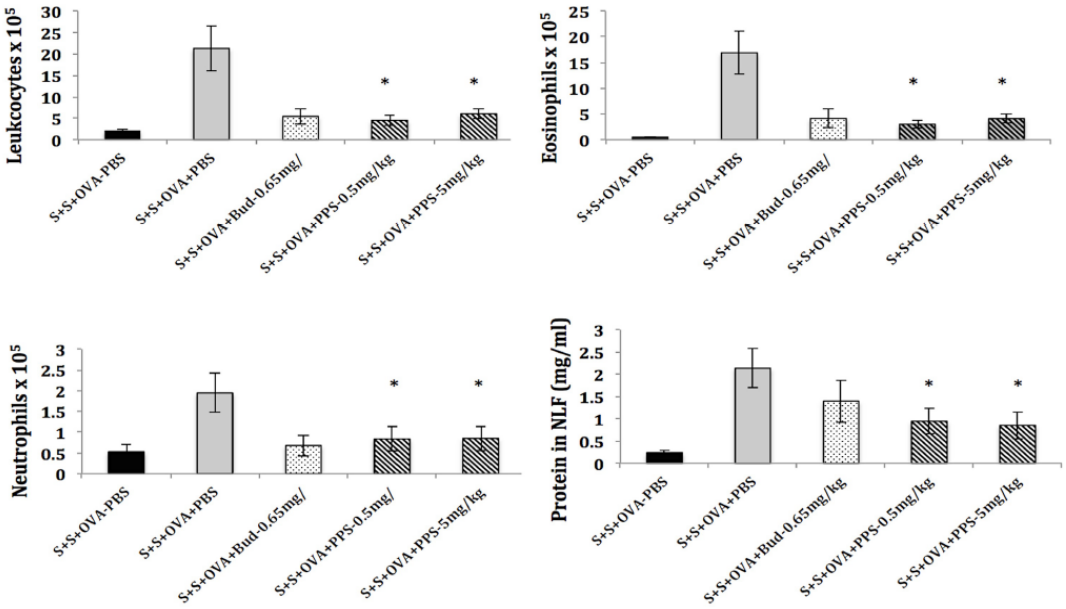


*soluble heparin (dashed lines) and PPS (solid lines)

Peer Reviewed Scientific Publication

- Preclinical (Guinea Pig / Astra Zeneca) Model

- **After OVA challenge (allergen), total leukocyte, eosinophil and neutrophil numbers in the nasal lavage fluid were inhibited by PPS and budesonide (Astra Zeneca Rhinocort)**
- **PPS significantly reduces allergen-induced plasma extravasation and influx of leukocytes into the nasal cavity (the causes of running nose, sneezing itchy eyes and associated inflammation)**



- **Demonstrated PPS has the potential to be a first-in-class, non-steroidal intranasal spray to treat the acute and chronic phases of hay fever**

Phase 2 Hay Fever Challenge Study

Lund University Sweden (ex-Astra Zeneca Respiratory Facility)

- Established model for AR – used by Big Pharma including Astra Zeneca to trial AR drugs
- AR Patients (pollen) in "Off Season"
- 7 day Artificial Challenge Season – Titrated Doses
- Randomised, Double blind, Cross-over with Placebo Control
- Nasal Symptom Scores (am, pm, 10 minute)
- Peak Inspiratory flow
- Optional biomarkers/ biopsy

Hay Fever: Clinical Timeline

Paradigm is on track with clinical development timeline and expenditure

- **Nasal formulation, intra-nasal toxicology and Phase 1 clinical trial – complete**
- **Ethics and Swedish Regulatory approval – complete**
- **Participant screening and recruitment – complete**
- **Final patient treated – complete**
- **Results due late Q2 CY17**
- **Successful Phase II results are expected to result in a significant licensing opportunity**

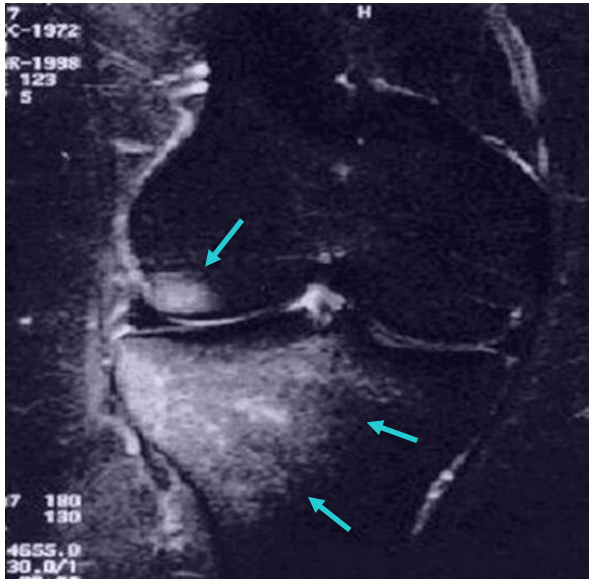
	2015			2016				2017				2018	
Clinical development timeline	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Bridging nasal toxicology study													
Nasal formulation development													
Nasal spray product development (Aptar device)													
Phase 2 safety study (n=20) - COMPLETED													
Ethics approval for Phase 2 trial													
Phase 2 placebo-controlled allergen challenge study - COMPLETED													
Phase 2 - Results Readout													
Partnering Discussions and preparation for a Pivotal Phase 3 Trial (assuming successful results)													

Bone Marrow Edema (BME)

Currently no approved treatments for bone marrow edema, growing market opportunity

What is bone marrow edema (BME or bone bruising)?

- Bone marrow edema or bone bruising is the accumulation of interstitial fluid or inflammation within the bone marrow, typically a consequence of a direct impact to bone



Addressable market based on acute traumatic injuries:

1.4 MILLION

knee & ankle injuries associated with bone bruising[1,2,3]

US$1,750

potential price per ZILOSUL® treatment

US$2.5+ BILLION

ZILOSUL® market in USA

(Market size could significantly increase with shoulder, elbow and hip injuries as well as chronic injuries)

Source:

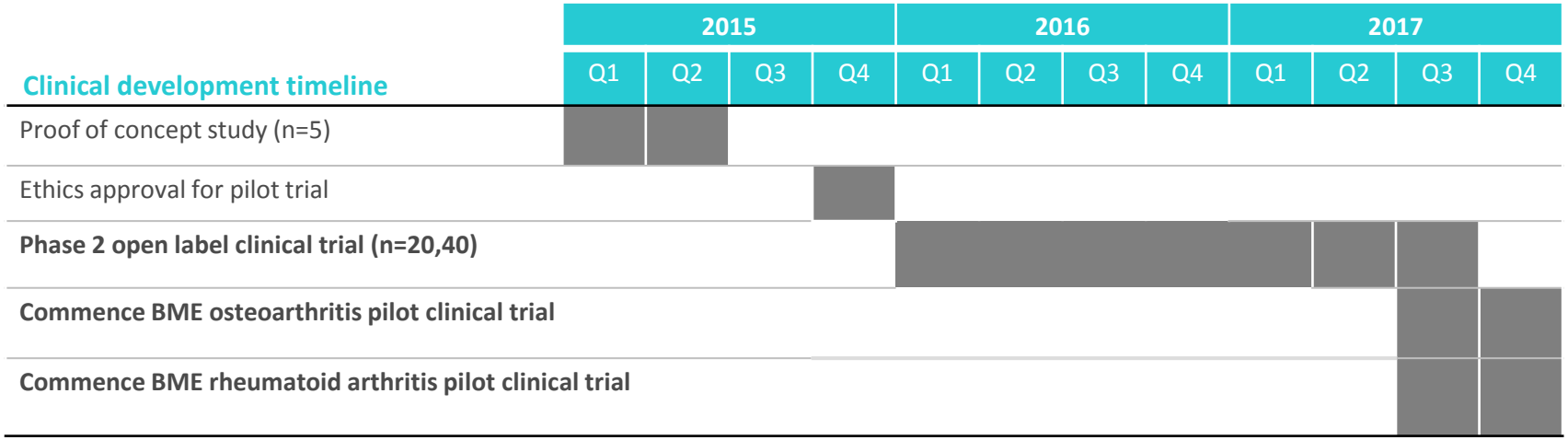
1. Based on 200k ACL injuries per annum, with 80% being associated with BME – Niall D, et al. (2004) and Friedberg R, et al. (2016)
2. Based on 1m meniscal injuries per annum, with 80% assumed as being associated with BME – Jones C, et al. (2012)
3. Based on 600k ankle injuries per annum, with 80% assumed as being associated with BME – Waterman B, et al. (2010)

BME: Clinical Timeline

Status update

Currently conducting an open label clinical trial investigating the safety, tolerability and efficacy of ZILOSUL® in patients with a bone marrow edema from a recent ACL injury;

- **10 participants already treated under the Phase 2 open label clinical trial;**
- **Close-out study expected June 2017;**
- **20 additional patients treated under the TGA SAS scheme. Very positive clinical signals from BME patients with osteoarthritis (OA) and rheumatoid arthritis (RA);**
- **Plan to undertake two pilot studies in BME patients with OA and RA.**



Note:
1. Closed label, randomised, double blind, placebo controlled trial expected to commence in Q3 2017, expected to be completed in 12-24 months after commencement

Preclinical study published in peer-reviewed journal (Journal of Virology)

JVI
Journals.ASM.org

Pentosan Polysulfate: a Novel Glycosaminoglycan-Like Molecule for Effective Treatment of Alphavirus-Induced Cartilage Destruction and Inflammatory Disease

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ABSTRACT

Arthritogenic alphaviruses such as Ross River virus (RRV) and chikungunya virus (CHIKV) cause large-scale epidemics of severe musculoskeletal disease and have been progressively expanding their global distribution. Since its introduction in July 2014, CHIKV now circulates in the United States. The hallmark of alphavirus disease is crippling pain and inflammation of the joints, a similar immunopathology to rheumatoid arthritis. The use of glycans as novel therapeutics is an area of research that has increased in recent years. Here, we describe the promising therapeutic potential of the glycosaminoglycan (GAG)-like molecule pentosan polysulfate (PPS) to alleviate virus-induced arthritis. Mouse models of RRV and CHIKV disease were used to characterize the extent of cartilage damage in infection and investigate the potential of PPS to treat disease. This was assessed using histological analysis, real-time PCR, and fluorescence-activated cell sorting (FACS). Alphaviral infection resulted in cartilage destruction, the severity of which was alleviated by PPS therapy during RRV and CHIKV clinical disease. The reduction in cartilage damage corresponded with a significant reduction in immune infiltrates. Using multiplex bead arrays, PPS treatment was found to have significantly increased the anti-inflammatory cytokine interleukin-10 and reduced proinflammatory cytokines, typically correlated with disease severity. Furthermore, we reveal that the severe RRV-induced joint pathology, including thinning of articular cartilage and loss of proteoglycans in the cartilage matrix, was diminished with treatment. PPS is a promising new therapy for alphavirus-induced arthritis, acting to preserve the cartilage matrix, which is damaged during alphavirus infection. Overall, the data demonstrate the potential of glycotherapeutics as a new class of treatment for infectious arthritis.

IMPORTANCE

The hallmark of alphavirus disease is crippling pain and joint arthritis, which often has an extended duration. In the past year, CHIKV has expanded into the Americas, with approximately 1 million cases reported to date, whereas RRV continues to circulate in the South Pacific. Currently, there is no licensed specific treatment for alphavirus disease, and the increasing spread of infection highlights an urgent need for therapeutic intervention strategies. Pentosan polysulfate (PPS) is a glycan derivative that is orally bioavailable, has few toxic side effects, and is currently licensed under the name Elmiron for the treatment of cystitis in the United States. Our findings show that RRV infection damages the articular cartilage, including a loss of proteoglycans within the joint. Furthermore, treatment with PPS reduced the severity of both RRV- and CHIKV-induced musculoskeletal disease, including a reduction in inflammation and joint swelling, suggesting that PPS is a promising candidate for drug repurposing for the treatment of alphavirus-induced arthritis.

Arthropod-borne arthritogenic alphaviruses such as Ross River virus (RRV) and chikungunya virus (CHIKV) cause large epidemics of severe musculoskeletal disease. They have been progressively expanding their global distribution, regularly emerging in new regions of the world (1, 2). The hallmark of alphavirus disease is crippling joint pain and arthritis, which often has an extended duration, leaving patients bedridden and incapacitated. In the past year, CHIKV further expanded its global distribution by entering the Americas, and it is circulating in several Caribbean islands. As of 24 October 2014, the Pan American Health Organization (PAHO) reported an estimated 964,341 cases, and local autochthonous CHIKV transmission in the mainland United States was first reported in July 2014 (3, 4). Due to the expanding range of alphaviral infections, understanding the mechanisms by which alphaviruses cause debilitating arthritic disease has become increasingly important, especially as there are no specific treatments available (5).

The severe arthralgia/arthritis in the joints caused by alphaviruses can be both acute and chronic. Ultrasonography of CHIKV patients with joint pain reveals striking tenosynovitis, bone erosion, and synovial thickening (6). RRV antigen has been detected by immunofluorescence in synovial monocytes and macrophages during the early phase of illness (7) and in basal epidermal and

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Accepted manuscript posted online 27 May 2015
Citation Herrero LJ, Foo S-S, Sheng K-C, Chen W, Forwood MR, Bucala R, Mahalingam S. 2015. Pentosan polysulfate a novel glycosaminoglycan-like molecule for effective treatment of alphavirus-induced cartilage destruction and inflammatory disease. J Virol 89:8063–8076. doi:10.1128/JVI.00224-15.
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doi:10.1128/JVI.00224-15

Viral Arthritis – Alphavirus

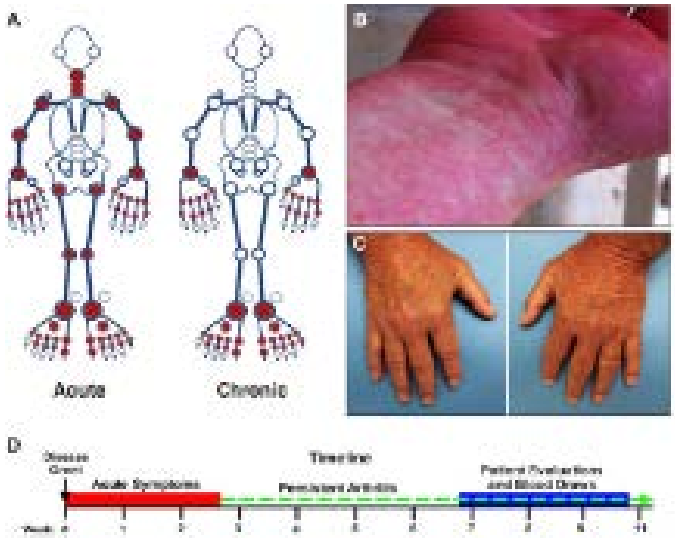
No approved treatment for severely debilitating virus infection

What is Viral Arthritis?

- Alphavirus infections result in the clinical symptoms of joint and muscle pain, fever and joint inflammation. Ross River Virus (RRV) and Chikungunya (CHIKV) are mosquito-transmitted arthritogenic alpha viruses that cause epidemics of severe musculoskeletal disease in many countries.
- No effective treatment, with sufferers left incapacitated
- Symptoms can persist for a number of years

Ross River Virus & Chikungunya Virus

- Paradigm acquired the patent from the Institute for Glycomics research at Griffith University. The patent claims the use of PPS to treat alphaviruses, including Ross River Virus (RRV) and Chikungunya Virus (CHIKV).



Viral Arthritis – Alphavirus

Ross River Virus

The Ross River virus could become a global epidemic on the same scale as the Zika virus, Australian researchers warn.

APP *February 22, 2017*

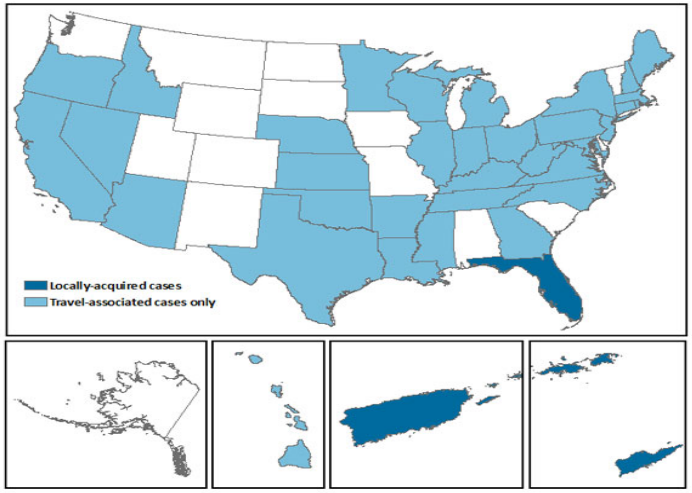
Chikungunya: The Agony Virus

A mosquito-borne virus has made the jump from Africa to the Americas, and it combines rapid transmission with searing pain. So swat that skeeter—or you may live to regret it

Laura Beil *September 11, 2014*

Chikungunya virus surrounds Australia: Outbreak 'a matter of time'

Jamie SeidelNews Corp Australia Network

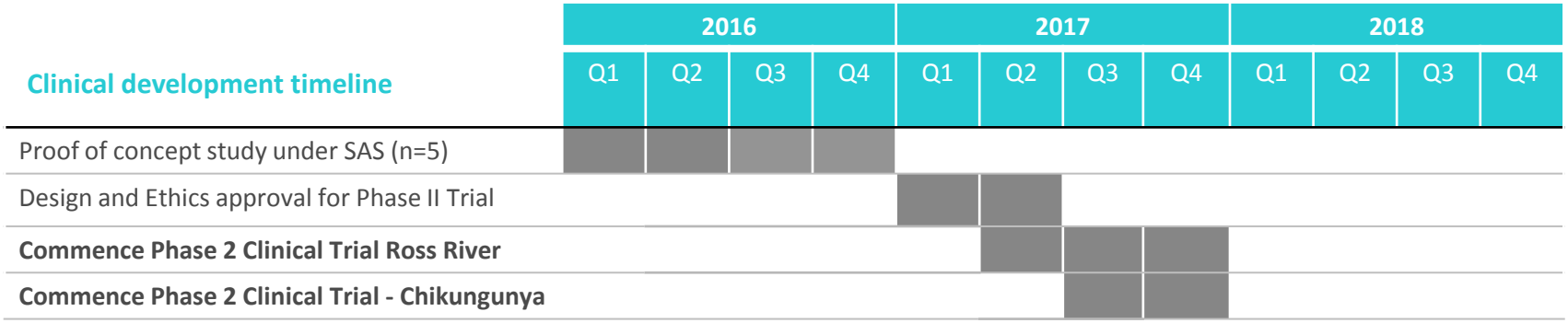



Recent floods, warmer weather and heavy rainfall are contributing to the unseasonably high number of mosquitoes. *Photo: Getty*

Viral Arthritis: Clinical Timeline

Potential to gain Orphan status, resulting in fast-tracked clinical development

- **Preclinical studies have been conducted by the Institute of Glycomics at Griffith University. The results suggested that:**
  - PPS significantly alleviated the severity of disease and reduced both the inflammatory response and the loss of articular cartilage;
  - PPS has the potential to treat both acute and chronic symptoms associated with mosquito transmitted alphavirus infections (Ross River virus (RRV) and chikungunya virus (CHIKV);
  - There currently is no effective disease modifying treatment for RRV or CHIKV
- 30 patients with RRV-arthralgia (joint pain) already treated with PPS under the TGA Special Access Scheme demonstrating tolerability and potential clinical effects
- **Upcoming Phase 2 – PPS to treat RRV and CHIKV**
  - Queensland Government have provided a A$300,000 grant for Ross River research
  - Paradigm to embark on two Phase 2 clinical trial to develop PPS for the treatment of RRV-and CHIKV-induced arthritis and arthralgia – **Potential for Fast-Track /Breakthrough/Accelerated Approval**



IP Protection

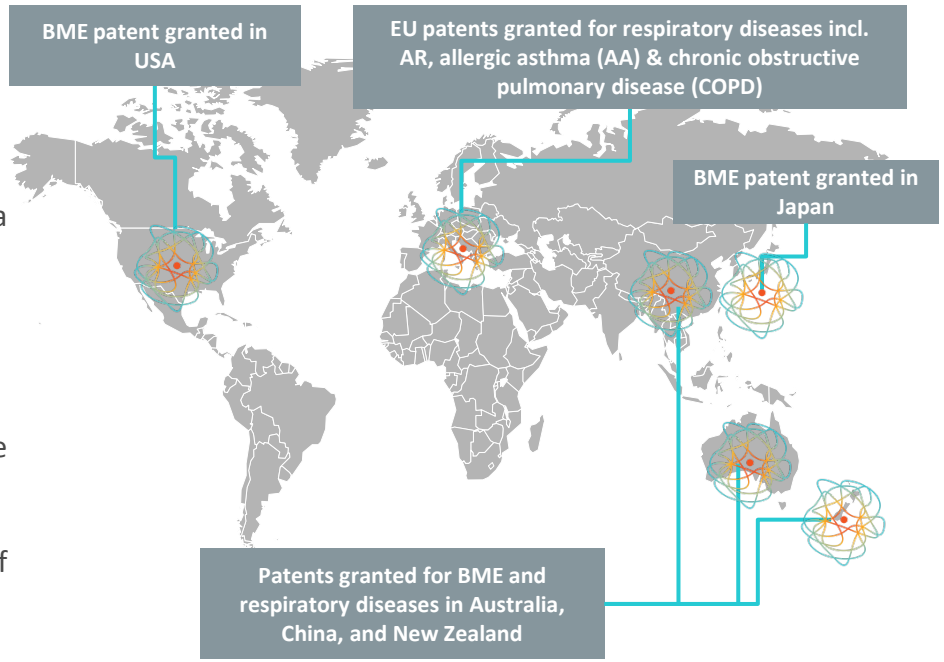
Multi-faceted IP protection increases barriers to entry for potential competitors

Valuable patent portfolio

- Paradigm has patent protection because it is using PPS for new indications
- Patents granted for specific indications
- Established regulatory exclusivity and trademarks
- Patent applications for Ross River virus and Chikungunya virus
- Assessing additional patent applications

Secure manufacturing and supply

- Exclusive 20 year supply agreement with bene PharmaChem[1]
- bene pharmaChem makes the only FDA-approved form of PPS
- Manufacturing methods are a well kept trade secret
- Reduces risks associated with manufacturing and supply



Note:
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

Undervalued Compared to Peers

Attractive investment given low risk development and large market opportunity

- Paradigm appears undervalued compared to similar stage, drug repurposing peers given its platform for successful development, secure industrial scale manufacturing and the size of its addressable markets

Peer	Ticker and exchange	Market cap (A$m)	Rationale	Clinical stage of key product	Addressable market size
Medical Developments International	MVP.ASX	283	Developing new markets and applications for Penthrox, recent focus on respiratory diseases, significant manufacturing IP	Commercialisation	US$1.5bn+
starpharma	SPL.ASX	267	Commercialising an old technology of synthetic branching polymers (dendrimers), with lead product VivaGel in Phase III trials	Phase III & commercialisation	US$3bn+
AXSOME THERAPEUTICS	AXSM.NASDAQ	129	Developing novel therapies for the management of central nervous system disorders, focusing on treatment of BME	Phase III	US$2.5bn+[2]
verona pharma	VRP.LN	228	Focused on commercialising an old compound for respiratory diseases, with dual inhibition of key enzymes	Phase I/II(a)	US$12bn+[3]
paradigm BIOPHARMA	PAR.ASX	59	Focused on the clinical development of PPS as a multi-target treatment for complex conditions, such as BME and AR and Ap	Multiple Phase II(a)	US$14bn+[4]

Source: Bloomberg, company filings

Note:

1. Market data as at 15 May 2017, exchange rates of AUDGBP 0.57 and AUDUSD 0.74
2. Based on BME addressable market size, excludes CRPS addressable market due to lack of available information and thus likely understates true market size
3. Only includes the market size for COPD which is US$12b+, excludes market sizes for other respiratory disease indications
4. Includes AR market US$11bn+ and BME market US$2.5bn+ & $0.5bn for viral arthritis ,excludes COPD addressable market size of US$12bn+ and Asthma addressable market size of US$15bn+

Global Interest in Respiratory and BME

Recent transactions highlight big pharma interest in respiratory and BME spaces

- Merck & Co (MSD) acquisition of Afferent for US$1.25B (inc milestones)
- Mylan's takeover offer of Meda in 2016 was at a 92% premium to last close and Dymista® is RHINOSUL®'s closest comparative product
- Merck's and AstraZeneca's transactions highlight big pharma's interest in respiratory businesses units

Date ↓	Target	Acquirer	Deal value (US$)	Relevance
Jun-16	Afferent PHARMACEUTICALS	MERCK	**$1.25Bn (inc $750m milestones)**	▪ Afferent develops novel drugs for the treatment of a range of neurogenic conditions - chronic respiratory and urologic sensory pathologies. ▪ E.g. idiopathic pulmonary fibrosis (IPF)
Feb-16	MEDA	Mylan	**$7.2Bn**	▪ Meda's third biggest product is Dymista®, which is a dual acting AR product
Dec-15	Takeda	AstraZeneca	**$575m**	▪ Acquired Takeda's respiratory business only ▪ Acquisition includes expanded rights to roflumilast, used to treat COPD
Jul-14	Almirall	AstraZeneca	**$2.1Bn**	▪ Acquired Almirall's respiratory products only ▪ Products focused on asthma and COPD
May-13	Knee Creations	ZIMMER BIOMET	**Undisclosed**	▪ Zimmer Biomet acquired Knee Creations for its Subchondroplasty procedure, designed to treat BME

Source: Bloomberg, company filings

Share Price Catalysts

Upcoming milestones should drive strong shareholder returns

HAY FEVER *Initiating human trials*	▪ **Publication of comparator study in "Allergy" expected in Q2 CY17** ▪ **Phase 2 'allergen challenge' results in late June 2017** ▪ Potential interest from Big Pharma post release of Phase 2 results
BME TRIAL *Phase 2 trial*	▪ Open label trial anticipated to confirm efficacy together with optimal dosing of ZILOSUL® and clinical endpoints ▪ SAS results Peer Review Publication ▪ Potential to expand to OA and RA
ALPHAVIRUSES AND OTHER MULTIPLE USES *Multiple indications available*	▪ Initiation of Ross River Virus/CHIKV Phase 2 clinical trials ▪ BME for PPS to treat other joints (hips, ankles, shoulders and elbows) & RA ▪ Further potential indications in other respiratory diseases
CORPORATE OPPORTUNITIES *Potential partners*	▪ Demonstrated interest from major pharmaceuticals companies in treatments for BME, Hay fever and Alpha Virus' ▪ Partnership with world-class manufacturers
EXPANSION *Market share*	▪ Expansion of BME market beyond acute injury therapy ▪ Respiratory expansion of PPS for allergic asthma (AA) and chronic obstructive pulmonary disease (COPD) ▪ Develop new IP (Alphavirus) and corporate opportunities in new indications

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