



# ImmuPharma

BioPharma | Creation | Evolution

September 2023

# ImmuPharma Snapshot

- Listed on UK AIM (LSE:IMM)
- Pipeline of innovative peptide-based therapies
- 2 therapy areas - Autoimmunity/Inflammation and Anti-infection
- 4 core assets & 1 non-core asset for high medical need markets
  - **Lupuzor®** (P140) for Lupus (Ph 2/3)
  - **P140** for CIDP (Ph2/3)
  - **BioAMB**, a novel, improved amphotericin-B (Preclinical)
  - **BioCIN**, a novel, improved vancomycin (Preclinical)
  - **IPP-20410**, radiopharmaceutical for cancer (Pre-clinical, non-core)
- New board and management in August 2021
- Board strengthened and aligned with business progress in August 2023

# ImmuPharma Business Model

- Out-license assets at key value inflection points
- Minimize in-house development costs
- Partners support final development and distribution
- Milestone/royalty income streams to ImmuPharma
- Therapeutic focus - Autoimmunity/Inflammation and Anti-infection
  - High medical need
  - Highly differentiated product profiles



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Team



## NEW TEAM



# ImmuPharma



**Tim McCarthy FCCA, MBA**  
Chief Executive Officer



**Dr Tim Franklin, PhD, MBA**  
Chief Operating Officer



**Dr Sebastien Goudreau PhD**  
Chief Executive Officer of ImmuPharma  
Biotech



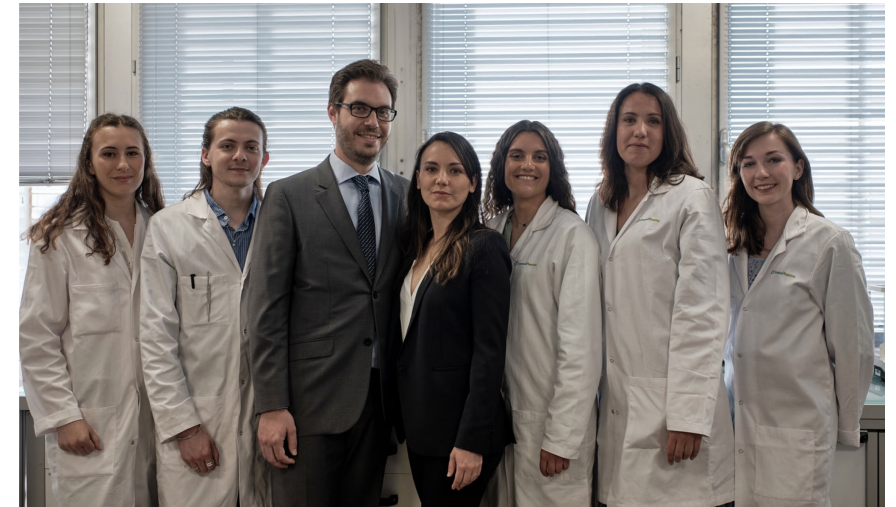
**Dr Laurence Reilly MBA**  
Senior Non-Executive Director



**Lisa Baderoon**  
Non-Executive Director  
and Head of Investor Relations

# ImmuPharma Biotech R&D Unit in Bordeaux

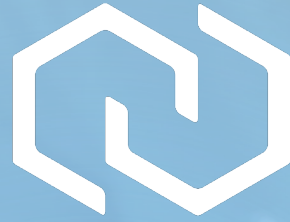
- A wholly-owned subsidiary of ImmuPharma PLC
- Dr Sebastien Goudreau – CEO
- Dr Laura Mauran – CSO
- Specialising in peptide science and technology
- Key focus on developing peptide-enhanced versions of P140, amphotericin-B and vancomycin



# Prof Sylviane Muller & CNRS

- Prof Muller is the discoverer of P140 and scientific advisor to ImmuPharma
- Research Director at CNRS (The French National Centre for Scientific Research) & Co-founder of ImmuPharma France
- CNRS Laboratory of Therapeutic Immunology and Chemistry at the Institute of Molecular and Cellular Biology in Strasbourg
- Expertise in peptide immunochemistry, molecular and cellular pathways behind autoimmune disease
- For her contributions to understanding immune-inflammatory diseases she was recently awarded the prestigious Legion D'Honneur
- Prof Muller continues to support and advise on all scientific aspects for P140 across all potential therapeutic applications





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## Portfolio & Pipeline



# Pipeline

Preclinical

Phase I

Phase II

Phase III

Partners

**\*P140 (Lupuzor™)  
Lupus**

**\*P140  
CIDP**

**P140 2.0  
Asthma, IBD,  
Periodontitis, gout**

**BioAMB  
Fungal infections**

**BioCIN  
Bacterial infections**

**\*\*IPP-204107  
Cancer**



\*Phase 2/3 adaptive study \*\*Radiopharmaceutical



Autoimmune/anti-inflammatory



Anti-infection



Non-Core

# Pipeline Objectives & News Flow 2023

## Autoimmunity & inflammation

- Lupus - Type-C FDA meeting for Phase 2/3 adaptive study on 7<sup>th</sup> June 2023 ✓
- CIDP - Pre-IND Type B FDA meeting for Phase 2/3 adaptive study on 16<sup>th</sup> May 2023 ✓
- Lupus - \*commencing Phase 2/3 adaptive study (H2 2023) ✓
- CIDP - IND approval for phase 2/3 adaptive study and Orphan Drug designation (H2 2023)
- P140 2.0 - Preclinical studies

## Anti-infection

- Complete Bio-AMB (novel amphotericin) efficacy/tox study versus voriconazole in Aspergillosis rodent model to realise immediate value inflection (2023)
- BioAMB Pre-clinical toxicology to commence in 2023
- BioCin (novel vancomycin) Pre-clinical PK/PD and toxicology to commence in 2023



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# Autoimmunity & Inflammation

## The P140 platform

# P140 MOA is relevant to several diseases

- P140 core action is in chaperone-mediated autophagy
- P140 binds to the constitutively-expressed HSPA8/HSC70 protein
  - P140 hampers its chaperone functions *in-vitro*
  - P140 reduces HSPA8/HSP90 interaction
  - Restricts stimulation of autoreactive T cells and consequently autoreactive B cells
  - Not immunosuppressive. Does not affect whole immune system
- Positive clinical insight already in Lupus patients
- New Phase 2/3 programs underway for lupus and CIDP
- Animal models published to support therapeutic potential in:
  - CIDP *Journal of Autoimmunity* 92 (2018) 114–125
  - IBD *Journal of Autoimmunity* 128 (2022) 10281
  - Asthma *Cells* 2021, 10, 2468
  - Gout *Cells* 2022, 11, 3709
  - Periodontitis *Cellular and Molecular Life Sciences* (2022) 79:518

# LUPUZOR™ for Lupus

Lupuzor™, (P140) is commencing a new phase 2/3 adaptive study in lupus patients in H2 2023

Lupuzor™, has the potential to be a novel first-line drug therapy for the treatment of lupus.

Lupuzor™, binds to heat shock protein, overexpressed on autoimmune cells. It has a novel action distinct from all other therapeutic strategies.

Lupuzor™, modulates the immune system. Unlike other therapies it is not an immunosuppressant. It “normalizes” what is otherwise a hyperactive immune response.

Clinical data provides an indication of efficacy, extreme safety and tolerability

Target profile is a convenient monthly injection.

## About Lupus



**Systemic lupus erythematosus (SLE)** is a chronic, life-threatening autoimmune, inflammatory disease with a pattern of flares and remission. It can affect multiple organs such as skin, joints, kidneys, blood cells, heart and lungs.

**About 50% of SLE patients** develop Lupus nephritis : an inflammation of the kidney that is caused by SLE.



**Treatment:** Unmet market need due to the lack of safe and effective treatments. Current monoclonal drugs Benlysta and Saphnelo have serious side-effects and limited effectiveness.



**Market:** 5 million people globally suffer from lupus (1.5 million lupus sufferers in Europe/US/Japan).

**\*Peak annual global sales potential > \$3.5bn**

## SLE Clinical Activity for P140 in 2023

- Agreed Phase 2/3 study design with US partner Avion in Jan 2023
- FDA Type-C meeting feedback received – ensured study design
- Final approach - higher subcutaneous dosing, once monthly
- \*Commenced phase 2/3 study activities





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# P140 for CIDP

# P140 for CIDP

P140 shows efficacy in \*pre-clinical model of Chronic Inflammatory Demyelinating Polyneuropathy (“CIDP”)

P140 MOA on the autoimmune mechanism is proven in CIDP, an inflammatory condition of the nerves

A phase 2/3 adaptive pivotal study protocol will be submitted for an IND. Regulatory approval and orphan drug designation is expected 2023

Orphan drug status provides market exclusivity for 7-yrs post-approval

P140 offers potential to:

- reduce the frequency of CIDP disease flares
- reduce the need for hospital IV IgG therapy
- Improve convenience through IV injection 1/month vs long infusion
- reduce costs for patient and healthcare system

## About CIDP



**CIDP** is neurological autoimmune disease targeting the nerves. Symptoms include: fatigue, areas of numbness, slow reflexes, weakness in arms and legs. It is characterized by a relapsing-remitting or progressive course. Demyelination of nerves. Similar to but not the same as MS



**Treatment:** Currently no effective approved drug on the market. IgG is the only successful treatment. Hospital visits every 4-6 weeks and long IV duration of several hours



**Market:** The prevalence of CIDP ranges from 0.7 to 10.3 cases per 100,000. There is a male predominance, with a gender rate ratio ranging from 1.5 to 4. CIDP primarily affects adults, and the incidence rises with advancing age. P140 could be granted ‘Orphan Drug Designation’ + fast approval.

**\*Peak annual global sales potential \$1.2 billion**



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**P140 2.0**

for autoimmune/inflammatory diseases

# P140 2.0 is the next generation P140

- Same active peptide, same MOA
- Proprietary peptide-based Bio-Drug engineering
- Enhanced PK/PD profile
- Easier to administer (dose/frequency), lower absolute amount of drug
- New IP and new product life cycle following 1<sup>st</sup> generation P140
- Allows expansion into other indications beyond Lupus and CIDP



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# BioAMB

for systemic fungal infections

# BioAMB for systemic fungal infections

BioAMB is a novel biomodified peptide-based drug that offers a potential improvement on Amphotericin-B (“Amp-B”).

Currently marketed AMB-B formulations may cause serious kidney toxicity and other severe reactions

BioAMB aims to:

- Significantly reduce toxicity and improve tolerance to amphotericin-B therapy
- Simple injection vs IV infusion
- Improve the frequency & duration of therapy
- Provide a more powerful alternative to existing 1<sup>st</sup> line azole antifungal therapy where there is increasing resistance

## About Anti-Infectives



**Anti-infectives** : Increased antibiotic and anti-fungal resistance is one of the biggest threats to global health, cost and mortality (WHO).

Despite the obvious threats, anti-infectives is a therapy area that attracts one of the lowest R&D spends in the biopharma industry: 80% of biopharma are focused on oncology and orphan drugs, while drug development for anti-infectives is shorter and less costly. -> big opportunity.

A significant problem in immunosuppressed patient are serious fungal infections. Significant resistance is emerging to another antifungal class, the azole class of antifungals (1<sup>st</sup> & /2<sup>nd</sup> line).



**Treatment** : Amp-B is one of the few effective treatments for serious and life-threatening fungal infections such as aspergillosis.



**\*Peak annual global sales potential \$800 million**





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# BioCIN

for severe bacterial infections

# BioCIN for severe bacterial infections

BioCIN is a novel biomodified peptide-based drug that offers a potential improvement on Vancomycin

Vancomycin, a generic drug, is a last resort therapy for the treatment of sepsis and lower respiratory tract, skin, and bone infections caused by Gram-positive bacteria and the killer bug methicillin-resistant *Staphylococcus aureus* (MRSA) and

Marketed since 1954 it is poorly absorbed from the gut and currently requires carefully controlled IV therapy over many hours

BioCIN aims to:

- Act on Gram-negative bacteria for the first time
- Significantly reduce toxicity and improve tolerance to vancomycin therapy
- Simple injection &/or oral admin vs IV infusion
- Improve the frequency & duration of therapy
- Improve efficacy through improved tolerance



## About Anti-Infectives

**Anti-infectives** : Increased antibiotic and anti-fungal resistance is one of the biggest threats to global health, cost and mortality (WHO).

Despite the obvious threats, anti-infectives is a therapy area that attracts one of the lowest R&D spends in the biopharma industry: 80% of biopharma companies are focused on oncology and orphan drugs. Drug development for anti-infectives is shorter and less costly.

There is an increasing risk of resistance to existing antibiotics. Better tolerance to last line therapies such as vancomycin, should help to treat more patients, without side effect problems.

**Treatment** : Vancomycin is last-line treatment for serious and life-threatening bacterial infections such as MRSA. There is nothing else. Vancomycin has a long list of side effects and rare but serious allergic reaction to infusion.

**\*Peak annual global sales potential \$400 million**



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**IPP-204107**

Radiopharmaceutical for cancer

## IPP-204107 a potential breakthrough in cancer

- IPP-207107 is a pseudopeptide that binds to a receptor on cancer cells
  - Transported to the cancer cell nucleus
  - Previously studied PC and to Phase I
- 12-month collaboration with OranoMed (from April 2023)
  - OranoMed - subsidiary of Orano (multinational nuclear fuel cycle company)
  - Orano funding the program
- IPP-207107 modifications to carry a radioisotope bullet
- Orano a leader in nuclear materials
  - Rare radioisotope provides power at short distance to destroy cancer cells and limit impact on healthy cell tissue
- Expect lead candidate within 12 months
- Global radiopharmaceutical market sales forecast is \*\$8.5bn by 2031



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# Company Value

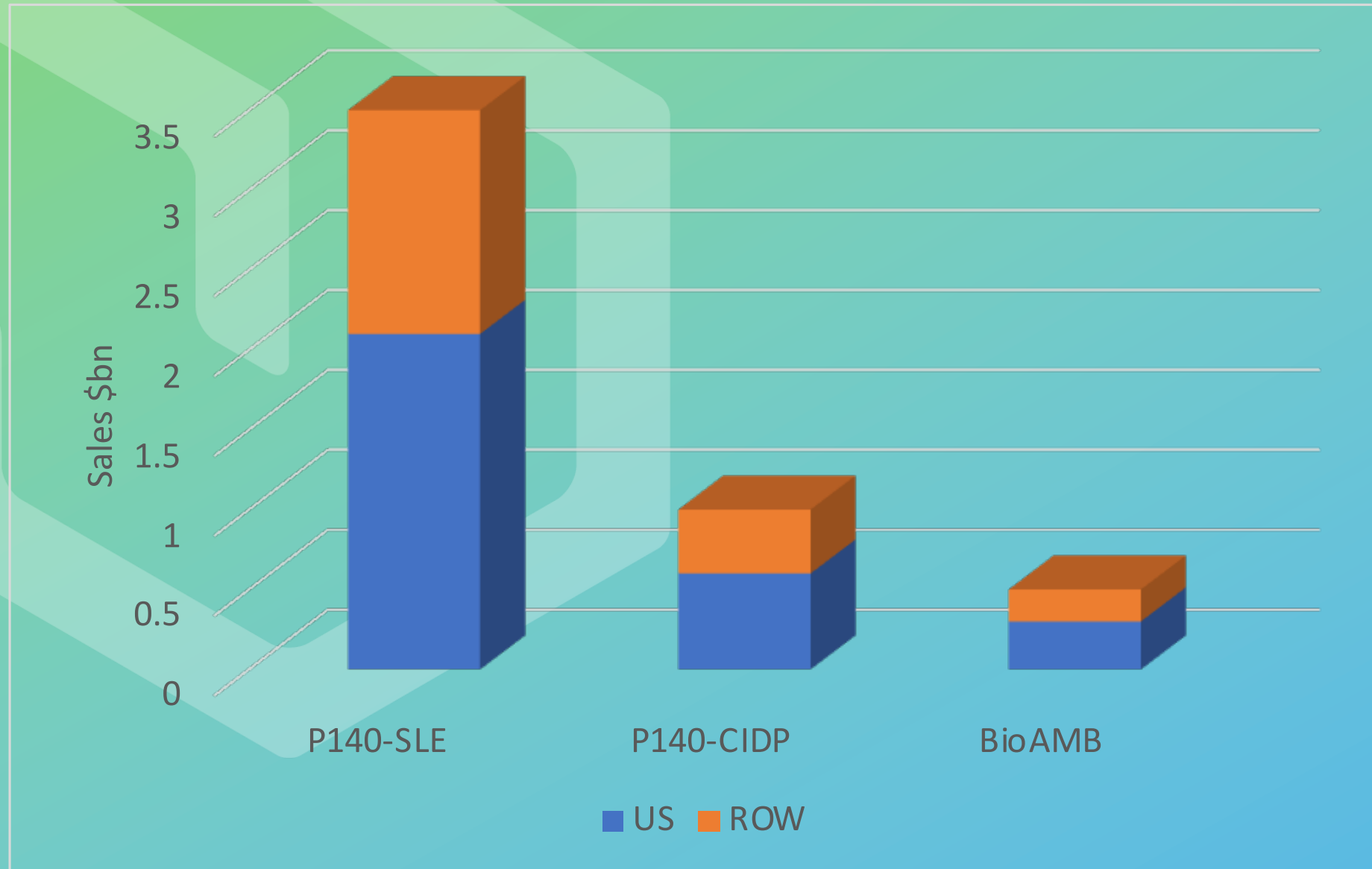
A significantly undervalued stock

## ImmuPharma embedded value ....

- Mid to late-stage clinical pipeline with significant product differentiation
- High medical need and commercially attractive markets
- Biotech company peers are valued at least 100x higher on average by the markets
  - Biotech's with similar stage products valued ~\$680-1750m
  - ImmuPharma ~\$10m
- Actively exploring new collaborations
- News flow quality will be a major catalyst to unlocking value in 2023



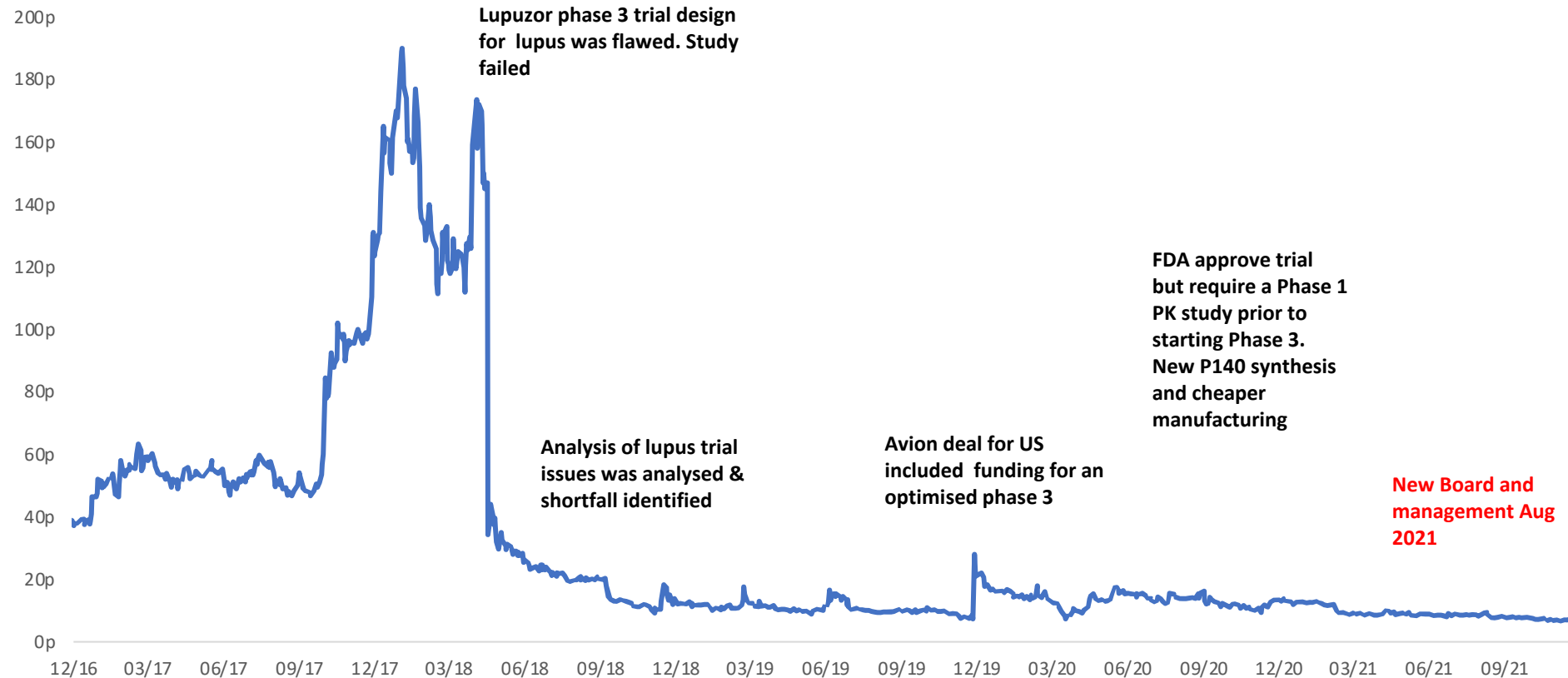
## PORTFOLIO FORECAST SALES POTENTIAL OF ~\$5.5bn



# Potential News Flow 2023/4

- Lupuzor adaptive 2/3 pivotal study activities in lupus \*commenced
  - Regular monthly updates on clinical trial set-up and progress
- Positive IND outcome for new CIDP study and orphan drug designation
- BioAMB efficacy, safety data and toxicity data versus voriconazole
- BioAMB preclinical toxicity commences
- BioCIN PK/PD data in animals & commence preclinical toxicity
- IPP-207107 potential for lead candidate in cancer
- Partnering activities across the portfolio

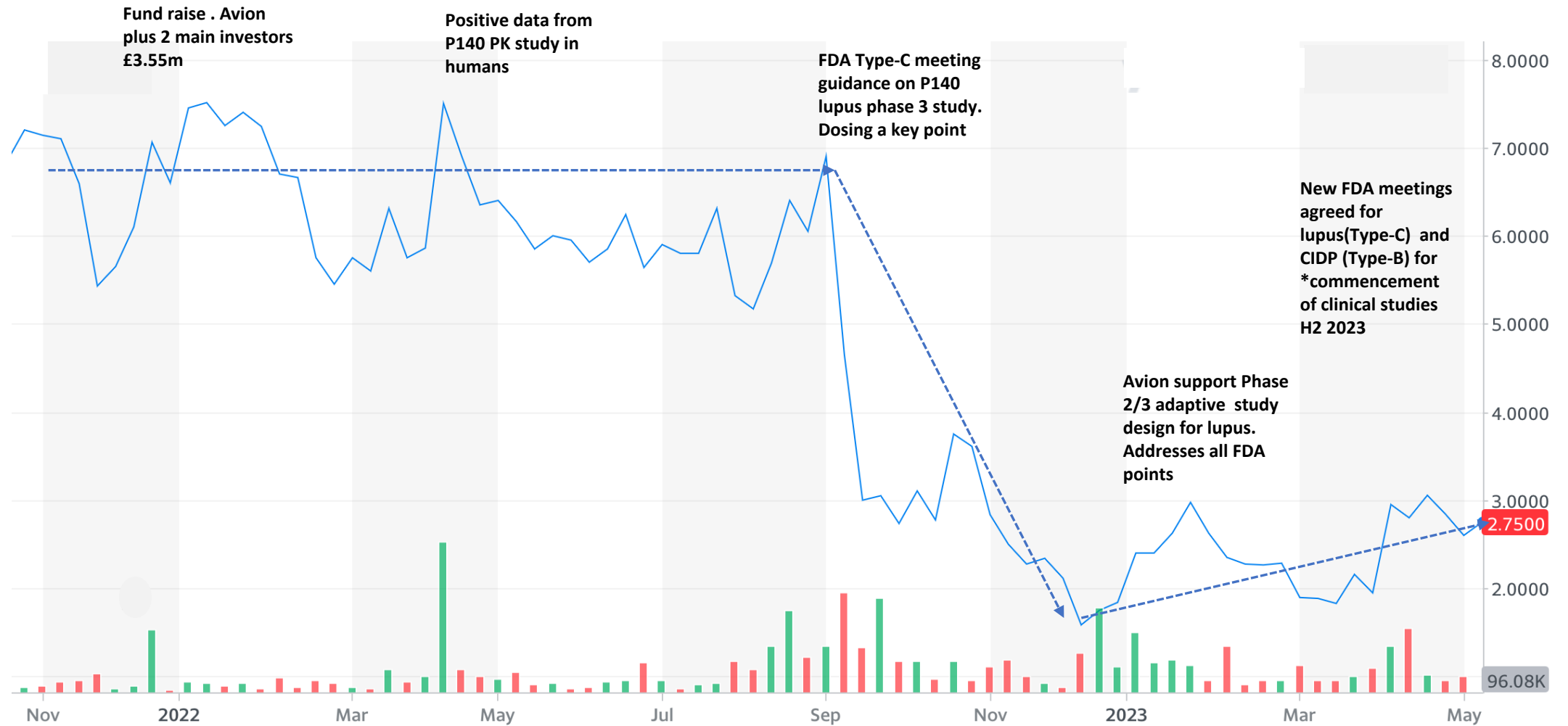
# ImmuPharma PLC share price is an opportunity



**1 product company**  
Lupuzor (P140) in lupus phase 3

**4 product company**  
Lupuzor (P140) in lupus phase 3  
P140 in CIDP phase 2/3  
BioAmb antifungal late preclinical  
BioCin antibacterial early preclinical

# The last 2 years.....getting it right with the FDA



# IMMUPHARMA UNDERVALUED ON GLOBAL PEER COMPARISON

