

7 FEBRUARY 2023

LUPUZOR TRIAL UPDATE

Productive discussions with Avion

ImmuPharma is developing a Lupuzor™ for the treatment of systemic lupus erythematosus (SLE, or lupus) with Avion Pharmaceuticals (Avion), its development and US commercial partner. Lupuzor represents a significant commercial opportunity. In September 2022, Avion received a written response from the FDA following a “Type C” meeting with the US regulator about its proposed trial protocol, which contained some proactive and helpful suggestions. Following discussions with its US partner, the decision has been made to proceed with an adaptive Phase II/III trial as the most efficient way of incorporating the constructive recommendations of the FDA and moving Lupuzor towards regulatory approval and commercialisation. The new study is expected to commence in 2H 2023.

Ticker IMM.L
Share price 2.5p
Market cap £8.7m
Net cash/(debt) £1.3m

Next event Final results

Share price performance 1 yr



Source: London Stock Exchange

Company Description

ImmuPharma is a UK-based biopharma company focused on the development of innovative drugs to treat serious medical conditions with high unmet medical need. The company has a US development and commercial deal with Avion Pharma for its most advanced product, Lupuzor, for the treatment of lupus.

Board & Management

CEO - Tim McCarthy
COO - Dr Tim Franklin
NED & Head of IR: - Lisa Baderoon
NED - Dr Sanjeev Pandya

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- Lupuzor strategy:** In conjunction with its partner, Avion, ImmuPharma has confirmed that the pivotal study for regulatory approval in the US will adopt an adaptive design, which seamlessly progresses from the dosing ranging Phase II element into the Phase III part of the study. This will avoid the need for stopping and starting two individual trials and eliminate duplication of regulatory checks, ethics approvals and site set-ups, thereby improving the overall timelines to complete the development programme.
- Study design:** The new protocol is designed to incorporate the constructive guidance from the FDA to investigate higher doses of Lupuzor, in order to optimise the potential for observing clinical benefits, and revised clinical measurements, both of which are aimed at maximising efficacy. The new design will be submitted to the FDA for review, with the aim of starting this study in 2H 2023.
- Support from Avion:** This news has eliminated any concerns about the continued support of Avion for Lupuzor. The seamless adaptive Phase II/III single protocol improves overall timelines and avoids duplication of some regulatory checks and ethics approvals. This chosen route is the more cost efficient, with costs being borne by Avion up to \$25m under the terms of the agreement signed in November 2019.
- Investment summary:** This news has removed uncertainty about which route the companies would take for the pivotal development of Lupuzor in the US and Avion’s continued support for the programme. The new clinical protocol will still need to be submitted to the FDA for acknowledgement that it encompasses the regulator’s previous suggestions. On the basis of acceptance under the usual FDA regulatory process, the target timeline for starting this new study remains on-track for 2H 2023. Meanwhile, we understand that Avion and ImmuPharma are continuing discussions to consolidate their relationship through a non-US commercial deal for certain Avion drugs.

Summary earnings outlook

Yr to December 31 (£m)	2019	2020	2021	2022E	2023E
Sales	0.08	0.13	0.12	-	-
R&D spend	(2.66)	(2.37)	(3.65)	(1.80)	(1.20)
EBITDA (adj)	(6.19)	(5.42)	(5.05)	(2.51)	(1.93)
EBIT (adj)	(6.28)	(5.59)	(5.16)	(2.62)	(2.04)
Pre-Tax Profit (adj)	(6.74)	(7.25)	(5.28)	(2.61)	(2.04)
Pre-Tax Profit (reported)	(6.74)	(7.25)	(8.94)	(3.49)	(2.04)
EPS (basic adj, p)	(3.99)	(3.43)	(1.80)	(0.75)	(0.54)
Net cash/(debt)	2.79	6.24	2.16	1.43	0.25

Source: Company data, Stanford Capital Partners estimates.

COMPANY INFORMATION

Country of Incorporation: England and Wales

Company Registration Number: 3929567

Main Country of Operation: France

Registered Office: One Bartholomew Close, London, EC1A 7BL, UK

Website: www.ImmuPharma.co.uk

BOARD OF DIRECTORS & SENIOR MANAGEMENT

BOARD OF DIRECTORS

Chief Executive Officer	Tim McCarthy
Chief Operating Officer	Dr Tim Franklin
Head of IR and NED	Lisa Baderon
Senior independent NED	Dr Sanjeev Pandya

Source: Company data, Stanford Capital Partners estimates.

ImmuPharma obtains its scientific expertise through its close relationship with senior scientists based at CNRS in Strasbourg, Bordeaux and Paris.

SCIENTIFIC TEAM

Professor Sylviane Muller*	Research Director at CNRS
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*Co-founder of ImmuPharma France

Source: Company data, Stanford Capital Partners estimates.

COMPANY ADVISORS

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NOMAD	SPARK Advisory Partners Limited
Joint Broker	Stanford Capital Partners Limited
Joint Broker	Si Capital Limited
Public and Investor Relations	investors@ImmuPharma.com
Solicitors	BDB Pitmans
Auditors	Evelyn Partners LLP (formerly Nexia Smith & Williamson)
Registrar	Computershare Investor Services PLC

Source: Company data, Stanford Capital Partners estimates.

SHARE CAPITAL

On 3 February 2023, there were 333,403,115 Ordinary shares of 10p nominal value in issue. In addition, there were 11.1m options (6.4m exercisable) and 146.32m warrants in issue.

MAJOR SHAREHOLDERS

Directors	2,722,425	0.82%
Lanstead Capital Investors LP	36,307,599	10.9%
Luca & Associates AG	22,000,000	6.6%
Alora Pharmaceuticals LLP (parent of Avion)	10,909,091	3.3%

Source: Company reports.

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