IMMUPHARMA PLC

24 NOVEMBER 2022

AVION STILL VERY SUPPORTIVE

Potential to generate ex-US sales of Avion drugs

ImmuPharma is a UK-based clinical-stage biopharma company with its main research operation in Bordeaux, France. It has a long-standing collaboration in France with Centre National de la Recherche Scientifique (CNRS), through which it obtained its P140 platform. Considerable clinical knowledge has been gained during the development of Lupuzor™, its lead product for lupus, a significant commercial opportunity with unmet medical need. In September, its development and US commercial partner, Avion Pharmaceuticals (Avion), received a written response from the FDA to its proposed Phase III trial protocol. The FDA made constructive recommendations, which are being incorporated into a revised protocol. Avion remains fully committed to Lupuzor and the two companies are also looking to expand their relationship to include non-US commercial arrangements for Avion drugs.

- **Strategy:** ImmuPharma is focused on the development of pioneering and novel peptide-based drugs in specialist therapeutic areas where there is a distinct lack of existing treatments. Through its well-established research collaboration with CNRS, it has exclusive rights to exploit the IP for certain medical assets. ImmuPharma's commercial strategy is to license out its assets at an appropriate valuation point to leading international corporations that are well-placed to further develop and/or commercialise its drugs.
- **Lupuzor update:** The FDA recommended that Avion/ImmuPharma uses higher doses of Lupuzor to maximise efficacy in lupus patients with different clinical measurements to improve the probability of success and, ultimately, approval. The companies and regulatory advisors are currently assessing whether to move forward with separate Phase II and Phase III trials, or to adopt an adaptive Phase II/III approach, before going back to the FDA.
- **Potential commercial deal:** Avion is a US-centric company with absolutely no infrastructure outside the US. The two companies are exploring the opportunity for ImmuPharma to act as a distribution partner for certain Avion products in the UK and Europe, initially on a "named patient" basis as a prelude to obtaining full regulatory approval. This is a win-win situation, with potential for first sales in 2023.
- **Risks:** As with all biopharma companies, clinical trials carry a significant risk. However, Avion remains committed to progressing Lupuzor through the remaining clinical trial programme to registration. Part of ImmuPharma's monthly working capital requirement is through an unusual "Sharing Agreement" with long-standing shareholder, Lanstead Capital Investors (Lanstead), whereby the quantum to be received by ImmuPharma over the next 24 months is dependent on share price performance.
- **Investment summary:** Although an unusual outcome, the FDA provided helpful guidance to Avion and ImmuPharma. The two companies have used this to consolidate their relationship and, indeed, to potentially expand it through a non-US commercial deal for certain Avion drugs. ImmuPharma's current cash runway is at least to the end of 2023.

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.

Ticker	IMM.L
Share price	2.3p
Market cap	£7.7m
Net cash/(debt)	£1.5m
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

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

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LUPUZOR UPDATE

BACKGROUND

In November 2019, ImmuPharma signed an exclusive Trademark, License and Development agreement with Avion for the Phase III development of Lupuzor (P140) for Systemic Lupus Erythematosus (SLE, frequently known as lupus) and its commercialisation in the US. As part of this programme, the US regulator required Avion/ImmuPharma to conduct a PK study to demonstrate a clear time- and dose-related profile following subcutaneous (SC) injection of P140 (200 and 800 micrograms (mcg)) compared with the absolute bioavailability seen following intravenous (IV) injection of P140 (800mcg), which acted as a control. Positive outcomes from this study were reported in April 2022, which allowed Avion and ImmuPharma to submit the data to the FDA for confirmation of a protocol for a Phase III trial due to start in 2H'22, but subject to it being reviewed with the US regulator following a "Type C" meeting. However, in September 2022, the written response from the FDA was not what the market had been expecting. Instead of rubber-stamping the protocol, the FDA made some proactive and helpful suggestions, but these will delay the start of the Phase III trial. It also raised fears that Avion might withdraw from the Lupuzor deal. However, a recent announcement suggests that Avion remains fully committed and supportive of both Lupuzor and ImmuPharma.

FDA WRITTEN RESPONSE

After considering data from the PK study submitted by Avion, the FDA made two important recommendations to improve the probability of Lupuzor being approved in the US.

- **Efficacy:** The FDA recommended the use of higher doses of Lupuzor – compared with the 200mcg dose originally planned– to optimise the potential for observing clinical benefits in lupus patients and maximise efficacy. ImmuPharma has safety data up to 2000mcg.
- **Endpoints:** The FDA also made suggestions regarding the clinical measurements, which would again support Lupuzor through the regulatory process to approval.

Whilst this was not the outcome that Avion/ImmuPharma had hoped for, following careful consideration and discussion, this written response could prove very helpful in the approval process.

However, the market response with respect to ImmuPharma's share price was very negative, as this created uncertainty, particularly in relation to the continued support from Avion.

REVISED PLANS

Avion remains committed to Lupuzor. Although a definitive decision has not been made, Avion/ImmuPharma and their regulatory advisors will adopt one of two approaches:

- undertake an adaptive Phase II/III trial that would encompass, initially, a dose-ranging element (Phase II) to define the optimum dose and then migrate into Phase III, all as a continuous single trial; or
- undertake a separate Phase II dose-ranging study to define the optimum dose that would then be used in a subsequent Phase III trial.

Whichever route is chosen, it will be agreed with the FDA.

TIMETABLE

From a market perspective, the written response delayed the start of the Phase III trial and has added to the overall timetable. In our opinion, the adaptive trial approach would take less time, as it eliminates the need for the Phase II dose-ranging trial to be completed and written up in a report from the CRO prior to commencing the Phase III trial. Whichever route is chosen, it is likely that:

- six months will be needed to obtain revised protocol acceptance from the FDA; and
- patient recruitment should commence in 2H'2023.

EX-US COMMERCIAL ARRANGEMENT

BACKGROUND

Avion is a US-focused specialty pharmaceutical company, whose mission is to improve the quality of patient lives. Its relationship with ImmuPharma originated from its strategy of identifying opportunities to develop, acquire and enhance the market potential of innovative, late-stage development or commercially available drugs to fulfil unmet medical needs. Lupuzor fitted well with this strategy. However, Avion's approach is US-centric, with absolutely no infrastructure for the distribution and commercialisation of its products outside the US. While discussing the way forward with Lupuzor in face-to-face meetings, ImmuPharma raised the idea that it could help Avion with the logistics of commercialising its products outside the US, particularly in the UK and EU. Given that this would all be incremental to Avion, the two companies have agreed to explore the potential of this opportunity further.

AVION PORTFOLIO

Avion's current product portfolio is focused on a number of specialist areas where there is clinical need, including:

- Female healthcare:
    - Prescription (Rx) pre-natal supplements – advanced nutritional support for pre-conception through post-partum.
    - Low-dose birth control – effective, low-dose, balanced birth control to enhance a woman's health.
    - Menopause support – transdermal symptom treatment in a cool, discreet gel.
- Neurology – support for patients with Parkinson's Disease.
- Endocrinology – support for patients with hypothyroidism.
- Haematology – Rx iron supplements designed for optimised absorption, with advanced ingredients that enhance tolerability.
- Dermatology – advanced therapies to support and sustain healthy skin.

Not all of these products would be suitable for the UK and EU markets and none are currently approved by the respective regulators. In our opinion, drugs in the endocrinology category would appear to have profiles best suited for commercialisation in Europe.

INITIAL TARGETS

At this stage, it is difficult to identify which products would be suitable for introduction into Europe. In order to generate sales as fast as possible, while drugs are going through the regulatory process, ImmuPharma intends to make suitable products available on a "named patient" basis. To that end, it is in discussions with potential partners that specialise in this space for distribution and commercialisation arrangements. These companies operate through specialist websites, which are accessed by healthcare professionals.

NEXT STEPS

Although discussions are still at an early stage, both parties agree that it is a win-win situation and are keen to progress the opportunity. Using previously announced deals as a precedent, the following steps, to be achieved over the next 8-12 months, seem rational:

- To conclude a signed agreement with Avion.
- To obtain regulatory approval for use on a named patient basis.

Consequently, there is an expectation that first sales could be generated by ImmuPharma towards the end of 2023, which would represent an important milestone.

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 Baderoon
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
Dr Gilles Guichard*	Research Director at CNRS, Université de Bordeaux

*Co-founder of ImmuPharma France
Source: Company data, Stanford Capital Partners estimates.

COMPANY ADVISORS

COMPANY ADVISORS	
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Joint Broker	Si Capital Limited
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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 23 November 2022, there were 333,403,115 Ordinary shares of 10p nominal value is issue. In addition, there were 11.1m options (6.4m exercisable) and 93.68m warrants in issue.

MAJOR SHAREHOLDERS		
Directors	2,722,425	0.82%
Lanstead Capital Investors LP	48,114,425	14.4%
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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