ImmuPharma

The Life Sciences DIVISION

US licensing deal: Major Opportunity Within Lupuzor™ Unlocked

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ImmuPharma Plc	Public Company	1, 5
AstraZeneca Plc	Public company	None

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ImmuPharma announced a major US licensing deal on 28 November 2019 with Avion Pharmaceuticals ("Avion"), a US specialty business that has a focus on Rheumatology, Women's health (Lupus afflicts women more) Dermatology and other therapeutic areas. Avion have a strong marketing and commercialisation operation (with over 100 specialist sales reps). Avion has exclusively in-licensed Lupuzor™ for the US market for Lupus (SLE) and other indications and agreed to fund an international Phase III clinical trial for up to US$25m. In addition, Avion will pay up to US$70m in milestones and a royalty stream tiered to 17% has been agreed. We have always believed that ImmuPharma could deliver such a successful deal for the US market (given the track record of the previous deal executed with Cephalon). This deal with Avion was aided by the strength of the clinical data (and safety profile) from the Phase III trial announced last year. Our detailed analysis of the respective cohort data, driven by the performance of the peptide in the auto ds-DNA antibody positive patients validated our assumptions of the value of Lupuzor™. We now see Lupuzor™ as having the ability to generate blockbuster sales in the US (US$1bn+) alone (previously US and EU combined) – which when coupled with a royalty stream of up to 17% on revenues, could see an annual royalty to ImmuPharma's bottom line of US$170m per year. What is particularly impressive about this deal is not only ImmuPharma's ability to identify and execute a new licensing partner for Lupuzor™ but also the opportunity available for ImmuPharma to find new distribution and marketing partners outside the US for Lupuzor™, for e.g. in Europe, where a new trial would not even be required given Avion's funding commitment. This means that there is a distinct possibility that further licensing deals could follow bringing in an attractive additional royalty stream, and additional upfront and milestone payments. Outside of Lupuzor™, we believe that ImmuPharma has the potential to generate news-flow on its other pipeline assets including Nucant and UreKa. Based on the financial assumptions for this deal, and a lower risk profile (reduction in risk premium in our DCF model) we increase our target price (which is 50% discounted) from 76p to 100p / share. BUY.

Licensing deal - US: Avion will conduct a new optimised clinical trial (the second Phase III trial for Lupuzor™), with ImmuPharma sitting on a joint steering committee. We view this licensing deal as significant since it delivers on management's promise to fully fund Lupuzor™ through a partner in both US and Europe. In early 2020, we believe that both parties will map out the clinical path to market, before consulting the FDA, and beginning the study.

Lupus market set to open up significantly: With the full clinical data set now available for Anifrolumab (AstraZeneca, targeting IFN receptors) and the US licensing deal for Lupuzor™ executed, it now appears that Lupuzor™ could be the second or third (after Anifrolumab - if approved) new biologic to reach the US market for Lupus (SLE). Importantly, Lupuzor™ with a 71.1% response rate in the anti-ds DNA auto antibody - positive patients, could also eventually be the product with the best overall response rate and safety profile in the market.

Adjustment to Forecasts: We have updated our 2019E and 2020E forecasts (see page 4) and DCF model which has resulted in a new target price of 100p. We believe that our new model forecasts reflect accurately the true commercial potential of Lupuzor™ in the US market, as we can now also point to a full and independent level of due diligence validated by the specialist US Pharmaceutical company Avion Pharmaceuticals.

Recommendation: We reiterate our BUY rating and new target price of 100p.

Forecasts and ratios	2016A	2017A	2018A	2019E	2020E
Revenues	164,784	150,462	81,281	84,532	87,914
PBT	-6,314,437	-6,997,445	-7,955,155	-4,983,350	-4,388,392
Net income/loss	-5,324,016	-6,223,201	-7,206,549	-4,583,350	-4,038,392
EPS (GBP) FD	-4.54	-4.75	-5.19	-2.74	-2.41

Source: ImmuPharma (actuals), TLSD (**new estimates**: 2019E, 2020E)

Company Activities

ImmuPharma is developing autoimmune and cancer therapeutics in several indications using peptide biological drug therapy. The company has completed one Phase 3 trial determining the efficacy and safety of its lead compound Lupuzor™ and is primed to begin a second Phase III trial. Additionally, the company has a portfolio of earlier stage assets which it is developing concurrently.

London Stock Exchange: AIM

Ticker IMM.L (Reuters), IMM LN (Bloomberg:)
Stock rating BUY / Corporate
Stock Data
Market Cap: GBP35.3 million
Shares outstanding: 167,390,920
Share price close 4/11/19: GBP20.90

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Dr Fanny Valleix, PhD
Head of Clinical Research

Elisabeth Zimmer Pharm.D
Vice President French Affairs

Lisa Baderoon
Head of Investor Relations

Dr Tim Franklin PhD
Commercial Advisor

Contact

Dr. Navid Malik. PhD MBA MSc ACSI
+44 (0) 207 874 1890
navid@thelifesciencesdivision.com

Prof. Ashley George. PhD FRSC
+44 (0) 207 874 1890
ashley@thelifesciencesdivision.com

Alia Minhas. MBA ACSI
+44 (0) 207 874 1890
ali@thelifesciencesdivision.com

US Deal Impact on Financial Forecasts

As a result of the deal with Avion Pharmaceuticals, we have reviewed our forecasts for the next two calendar years (2019E and 2020E), post the licensing partner, Avion, committing to pay for clinical development of Lupuzor™ in the US and European markets.

In our revised forecasts (2019E, 2020E) in Table 2, we have reduced the overall R&D spend by GBP400k in 2019E and GBP3m in 2020E. In addition to the reduced R&D spend, the higher share price as measured by VWAP related to the Lanstead deal, has in our view, likely resulted in a higher monthly cash-based payment from Lanstead for the month of November (the Benchmark price is 13.33p).

We have also adjusted our forecasts for the 2019E interest charge (disclosed in the interims), to reduce significantly, the intertest charge we had factored into our forecasts for that year, which is an accounting charge (created as a result of the Lanstead deal, and subject to periodic review). This lower forecast interest charge has resulted in a significantly reduced interest charge to our forecasts, which has contributed to a further reduction in the PBT 2019E forecast.

Table 1: Previous forecasts as of interims

Forecasts and ratios	2016A	2017A	2018A	2019E	2020E
Revenues	164,784	150,462	81,281	84,532	87,914
PBT	-6,314,437	-6,997,445	-7,955,155	-6,225,643	-7,388,392
Net income/loss	-5,324,016	-6,223,201	-7,206,549	-5,825,643	-7,038,392
EPS (GBP) FD	-4.54	-4.75	-5.19	-3.48	-4.20

Source: ImmuPharma (actuals), TLSD (estimates)

Table 2: New forecasts, post Avion Pharmaceuticals deal

Forecasts and ratios	2016A	2017A	2018A	2019E	2020E
Revenues	164,784	150,462	81,281	84,532	87,914
PBT	-6,314,437	-6,997,445	-7,955,155	-4,983,350	-4,388,392
Net income/loss	-5,324,016	-6,223,201	-7,206,549	-4,583,350	-4,038,392
EPS (GBP) FD	-4.54	-4.75	-5.19	-2.74	-2.41

Source: ImmuPharma (actuals), TLSD (estimates)

Discounted Cash flow model changes

We have updated our key assumptions in our financial model. As we have stated previously, we have strong conviction in the potential of Lupuzor™ in the more severe forms of Lupus.

Our previous assumptions, as accounted for in our financial model were based on our own market-based assumptions, these were:

- Assume a base population of 1.5m patients (adjusted for incidence and deaths for the disease to give a total addressable population, less deaths
- A conservative 20% of (base population) patients diagnosed (this will improve over time as better diagnosis approaches are developed)
- Assume, 70% of this patient pool are diagnosed as having systemic disease
- Assume, 80% of this patient pool are treated with a therapeutic agent
- Assume, 70% of this pool are patients with positive anti-dsDNA auto antibodies – hence eligible to receive Lupuzor™ (based on the Phase III trial eligibility criteria)
- Assume, conservatively, only 20% of this net patient pool (ds DNA) are prescribed Lupuzor™ (peak penetration)
- Assume list price per patient per year of US$20,000 (adjusted for inflation and assuming a 3% price increase)
- Launch year 2022E
- Peak US market sales potential of at least US$764m, based on treating 29,266 patients [we have 50% probability weighted all royalty payments]
- Assumed tax rate of 30%
- No milestone assumptions were factored into a potential US market deal, until the Avion Pharmaceuticals deal was announced

Here are our original assumptions in our DCF model:

- Risk free rate of 3% and terminal value of 1%
- Risk premium of 40%
- Beta of 0.4
- Required rate of return (CAPM) 19%
- This resulted in our pre-deal target price (discounted by 50%) of 76p (as per our update note from the interims reflecting the higher number of shares in issue)

Our assumptions in our updated, post-deal financial model are now:

- Assume a base population of 1.5m patients (adjusted for incidence and deaths for the disease to give a total addressable population, less deaths
- A conservative 20% of (base population) patients diagnosed (this will improve over time as better diagnosis approaches are developed)
- Assume, 70% of this patient pool are diagnosed have systemic disease
- Assume, 80% of this patient pool are treated with a therapeutic

- Assume, 70% of this pool are patients with dsDNA auto antibody (positive) – hence eligible to receive Lupuzor™ (based on the Phase III trial)
- Assume, conservatively, only 35% of this net patient pool (ds DNA) are prescribed Lupuzor™ (peak penetration)
- Assume list price per patient per year of US$20,000 (adjusted for inflation and assuming a 3% price increase)
- Launch year 2023E (both US and Europe)
- Peak US market sales potential for Avion Pharmaceuticals of at least US$1.3bn, based on treating 51,216 patients, 3% of the total Lupus market, based on 2032E prevalence [we have 50% probability weighted all royalty payments]
- Assumed tax rate of 20%
- We have now factored into our US forecasts US$70m of milestones and a 17% royalty (which we further net off due to payments to CNRS)
- A licensing deal on any other territory is upside to our forecasts – for the EU/RoW market, we have assumed a similar deal structure to the US deal with Avion Pharmaceuticals; however, we believe future deals will hold higher potential value for shareholders

Here are revised assumptions in our updated DCF model:

- Risk free rate of 3% and terminal value of 1%
- Risk premium of 30%
- Beta of 0.4
- Required rate of return (CAPM) 15%

This results in a new target price (discounted by 50%) of 149p, which we further revise based on a 12-month target price of 100p (further risk adjusted) – to capture the progress towards opening the second trial.

Development and Commercialisation Pathway

ImmuPharma's structured and diligent approach to identifying and executing this licensing deal is a testament to the experienced management team, who have previously completed the Cephalon deal and outlines a pathway that can be potentially repeated in other regions outside of US.

In successfully negotiating terms with Avion, they have now delivered a partner for Lupuzor™ that is perfectly suited to its product and patient demographics (age, sex, location). Should Lupuzor™ successfully (after the steering committee navigate a clinical trial) gain an FDA marketing approval, the next steps of delivering sales will have been planned well in advance by this proactive specialty partner. Avion develops and markets a range of branded and prescription drugs including in Rheumatology, Dermatology and Women's health all specialty indications that are directly relevant to Lupus patients. Avion have taken time to complete thorough due diligence and have recognized and understood the Lupuzor™ platform. They have deep in-house expertise within both medical and regulatory affairs and late-stage clinical development, together with a strong marketing and commercialization operation.

Avion's sales team reaches throughout North America with more than 100 sales representatives with significant specialist therapeutic experience. Since 2012, Avion has launched more than 55 New Drug Candidates (NDCs) and 20+ generic product extensions.

Avion's launch earlier this year of a new gout product (Gloperba®) for adults is an excellent sales and marketing fit for the future commercialisation of Lupuzor™, as rheumatologists are the core prescribers and therapeutic influencers in both gout and Lupus.

The Avion deal specifies $5m towards each additional approval from the Lupuzor™ peptide, a fact which readers appreciate is a platform technology and thus could unlock further value within other auto immune indications outside of Lupus.

Further Clarity on AZN's Anifrolumab from American College of Rheumatology

Recent data published and presented[1] by AstraZeneca at the American College of Rheumatology (ACR) meeting in Atlanta (13 November 2019), disclosed results from both the TULIP II and TULIP I studies for Anifrolumab. Under adverse drug events we note that a patient death was disclosed (in the abstracts) in the active (anifrolumab) group from pneumonia. This complete dataset complemented data published in abstract form several weeks earlier.

AstraZeneca is targeting a filing with FDA for the US market in H2 2020. As a reminder Anifrolumab is a monoclonal antibody targeting Lupus patients through the IFN (interferon) alpha receptor pathway (note several drugs failed when targeting interferon alpha itself – e.g. Rontalizumab from Roche and Sifalimumab from AstraZeneca/MedImmune – both clinical trials failed at Phase II stage). It is assumed that between 60 and 80% of Lupus patients have

[1] Furie R, Morand E, Bruce I, Manzi S, Kalunian K, Vital E, Lawrence-Ford T, Gupta R, Hiepe F, Santiago M, Brohawn P, Berglind A, Tummala R. A Phase 3 Randomized Controlled Trial of Anifrolumab in Patients with Moderate to Severe Systemic Lupus Erythematosus [abstract]. Arthritis Rheumatol. 2019; 71 (suppl 10). https://acrabstracts.org/abstract/a-phase-3-randomized-controlled-trial-of-anifrolumab-in-patients-with-moderate-to-severe-systemic-lupus-erythematosus/. Accessed November 13, 2019.

IFN gene signatures. We have already explored Anifrolumab in detail in our (TLSD) note dated: 23 September 2019, comprising 7 pages.

Important points to consider following the disclosure of the complete Anifrolumab dataset. Firstly, the only successful clinical trial was the TULIP II study (362 patients) evaluating Anifrolumab in a Q4W (4 week dosing scheme) at a dose of 300mg. Secondly, the primary endpoint was BICLA response at 52 weeks – an endpoint that has not been used for approval of a Lupus product by the FDA. The BICLA score is driven by BILAG which captures only a partial improvement within an organ system and weighs organ systems equally. Thus, BICLA relies on improvements across all organ systems (of BILAG) when compared to baseline activity. SRI (SLE Responder Index) as a primary endpoint, on which both Benylsta and Lupuzor™ have been evaluated and which is accepted by the FDA as a recognised and approvable endpoint, relies on SLEDAI scores which are a binary measure in specific symptoms of Lupus and applies a greater weighting to key organs.

One interesting aspect of the side effect profile of Anifrolumab across all of its clinical studies was a significant imbalance in Herpes Zoster seen in the Anifrolumab group (7.2%) vs. placebo (1.1%), although the overall safety profile of Anifrolumab at the 300mg dose were lower than placebo, benefiting from lower steroid use.

We note that the TULIP I study failed on SRI-4. The SRI-4 response in the Anifrolumab group in TULIP II study was 55.5% and in TULIP I was 36.2%, as a reminder, the SRI-4 response in the ITT (intention to treat) population for Lupuzor™ (Phase III) was 52.5% whereas in the European cohort (and Mauritius), the SRI-4 response was 71.1%.

Based on this clinical data we view Lupuzor™ as being a potentially superior (in terms of efficacy and safety) new biologic in the Lupus field as a second or third potential new entrant in the field.

It should be noted that as with all clinical development programs, there is always a risk that a second Phase III clinical study for Lupuzor™ may not be successful. However, the excellent safety profile and the promising results on its ability to target the patients with the more severe form of the disease efficaciously, provides for a significant opportunity in, what is a deeply discounted UK biotechnology sector.

Ms Alia Minhas MBA ACSI
Chief Executive Officer

The Life Sciences Division.
10 Fitzroy Square, Fitzrovia,
London, W1T 5HP.

+44 207 874 1890 (Direct)
+44 7590 696 057 (Mobile)

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