

ImmuPharma

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Phase III trials for Lupuzor™ to begin soon

■ ImmuPharma has announced that the pivotal Phase III clinical trials for Lupuzor™ are to commence soon with a yet un-disclosed partner. The partner, that is believed to have strong credentials and expertise in late stage clinical development, will run the pivotal phase III clinical programme based on the strengthened study protocol agreed between ImmuPharma and the FDA. Further newsflow is expected when the development agreement is finalised. The company has already made significant progress in putting the building blocks in place for the trials, having established a world class Scientific Advisory Board and having manufactured the drug product. Lupuzor™ has been granted an updated Special Protocol Assessment (SPA) and Fast Track status by the FDA. The group has a strong cash position and the £50m equity finance facility with Darwin Strategic provides the group with the financial flexibility to enable it to assist in the funding of the Phase III trials.

■ Interim results reveal strong cash position

Aside from the positive update on Lupuzor™ the group has announced interim results. In common with other drug development companies the group remains pre-revenue importantly keeping cash burn controlled. The results in themselves were inline (pre-tax profit -£1.8m, eps -2.2p) and showed a strong cash position of £5.18m (2013: £7.67m).

■ Further progress being made with the pipeline

The Nucant cancer programme IPP-204106 has completed a Phase I/IIa clinical trial using the next generation 'polyplexed Nucant' drug formulation. Trial results and the next steps for the programme are expected to be released soon. In addition, ImmuPharma has been granted new patents surrounding an 'optically pure' version of its Nucant family which broadens its usage into other indications. ImmuPharma has also initiated the development of an innovative peptide technology platform in collaboration with the CNRS with access to pioneering research through the University of Bordeaux and IECB, an international and interdisciplinary research incubator. This has added a breakthrough technology called 'Urelix' to the group's portfolio, initially to be targeted at diabetes. These assets could offer exciting potential for the group.

■ Pivotal stage in Lupuzor™'s development could translate into attractive upside for investors

The 'gearing up' into pivotal Phase III trials for Lupuzor™ is exciting news for the group and will take the drug through the next stage towards commercialisation. Lupuzor™ has a multi-billion dollar sales potential in a market of unmet needs. ImmuPharma has been exploring every avenue to maximise shareholder value from the Lupuzor™ asset and this is a giant step forward.

■ This month is Lupus Awareness Month for further details see www.lupusuk.org.uk

	Sales (£m)	PBT (£m)	EPS (p)	Net Cash (£m)	P/E (x)	EV/EBITDA (x)	Yield (%)
FY13a	0.0	-4.4	-4.5	5.4	0.0	0.0	0.0
FY14e	0.0	-4.5	-4.8	1.4	0.0	0.0	0.0
FY15e	0.0	-4.5	-4.9	-2.6	0.0	0.0	0.0



TDIM	IMM
Market cap (£m)	37.8
Net Cash (£m)	5.2
Free Float (%)	63
Avg daily volume (3m)	65k
Broker	Panmure Gordon
Listing	AIM

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Lupuzor™ to commence Phase III trials

Building blocks already in place for the commencement of the trials

Lupuzor™ granted an amended Special Protocol Assessment and has 'Fast Track' designation

The group has a strong cash position and financial flexibility

Cancer programme has completed a Phase I/IIa trial with results expected in the coming months

Grants of €1.72m received from the French government organisations

Phase III trials for Lupuzor™ set to commence

ImmuPharma has been focussed on progressing Lupuzor™ through Phase III trials. The recent announcement has confirmed the exciting news that ImmuPharma has completed detailed due diligence with a partner, which has enabled ImmuPharma to commence the preparatory steps for the pivotal Phase III trials. A further agreement is expected when the development agreement is finalised, however, it is expected that the trial will be funded by ImmuPharma and the partner.

ImmuPharma has been putting the building blocks in place for the commencement of the trials and has made significant and tangible progress. The group has established a well-regarded Scientific Advisory Board, which consists of prominent advisors and physicians in the field of lupus and they will provide guidance and support for Lupuzor™'s clinical development, in itself a strong endorsement for the drug. ImmuPharma has also completed the manufacturing of the Phase III drug supplies.

In 2013 Lupuzor™ was granted an amended Special Protocol Assessment (SPA), which reduced the number of patients required to complete the Phase III trial to a number below any other lupus candidates in clinical trial, a strong endorsement for the efficacy and safety profile demonstrated by the drug. This will also reduce the total costs of the Phase III trial. Lupuzor™ has already been granted 'Fast Track' designation by the FDA, which significantly reduces approval time to less than 6 months.

The group has a strong cash position and in 2013 the group secured a £50 million, 5 year equity financing facility with Darwin Strategic Limited, a subsidiary of Henderson Global, which strengthens the group's financial capacity to assist with the funding of the Phase III trials.

Nucant cancer programme IPP-204106

ImmuPharma's second potential blockbuster, IPP-204106 has shown exciting promise in the treatment of cancer. The drug has now completed a Phase I/IIa clinical trial, utilising the next generation 'polyplexed Nucant' formulation to determine the optimal dose for treating patients. The trials took place in three European hospitals including the prestigious Institut Jules Bordet in Belgium. This drug has shown impressive efficacy in pre-clinical trials and offers a novel mechanism of action aimed at preventing the spread of the disease. The trial results and next actions for the drug are expected to be released in the near future.

The next steps might be multi-faceted; for example investigating the possibility that the compounds could have potential in combination therapies or on selected patients carrying certain biomarkers. If efficacy is demonstrated then this will bring the drug to an exciting juncture with the company seeking to potentially license out the drug at that stage.

Up to now the group has received grants totalling €1.72m from French government organisations in support of its development.

Patents granted for "optically pure" version of the Nucant family

The patents granted for the "optically pure" version of ImmuPharma's Nucant compounds broadens the usage to other indications including age-related macular degeneration, diabetic retinopathy and wound healing.

Peptide technology platform collaboration and patent filing
Development of innovative peptide technology through collaboration

Co-owned patent filing for 'Urelix' with diabetes targeted

Our forecasts remain conservative with limited revenue and no corporate deal assumed.

The company had a strong cash position of £5.18m at the interim stage

Peptide technology platform collaboration and patent filing

Through its collaboration with its longstanding research partner Centre Nationale de la Recherche Scientifique (CNRS), ImmuPharma has initiated the development of innovative peptide technology. Through the collaboration the group has access to pioneering research at the University of Bordeaux and the Institut Européen de Chimie et Biologie (IECB). IECB is an interdisciplinary research incubator, which is under the joint authority of CNRS, Institut National de la Santé et de la Recherche Médicale (INSERM) and the University of Bordeaux.

This collaboration has led to ImmuPharma recently filing for a new co-owned patent for the breakthrough peptide technology called 'Urelix'. The initial focus is targeted at diabetes, a multi-billion dollar market. This technology has significant and diverse potential and ImmuPharma has established its own research team who are working in collaboration with the team from the Centre Nationale de la Recherche Scientifique (CNRS).

Interim results

Financials

In common with other drug development companies, ImmuPharma continues to have limited revenue. The focus of the company continues to be the development of novel medicines in specialist markets with unmet need, which provide high sales potential. Currently the company is focussing on the development of Lupuzor™, the company's most advanced drug candidate which is a potential blockbuster drug for Lupus and commencing Phase III pivotal trials. The company's second potential blockbuster compound IPP-204106, for cancer, has just completed a Phase I/II a clinical trial, with results expected to be released shortly.

Our forecasts remain conservative with no financial benefits from corporate deals being assumed. Obviously depending upon the detail of the deal with the Lupuzor™'s corporate partner this could provide significant upside to forecasts, either in the near term with an upfront payment followed by further milestone and royalty payments as development progresses, or through a greater share of the long term royalties. Either way the group is looking to maximise shareholder value from the Lupuzor™ asset.

The group's main costs are associated with general administration and research and development costs.

In the half year to 30 June 2014 the company reported a loss before tax of £1.83m (2013 H1: loss before tax £1.83m). The loss per share was 2.23p (2012 H1: 2.17p).

Cash balances

At the December 2013 year end the company had cash and cash equivalents of £5.39m (2012: £8.9m) and this has reduced to £5.18m at the interim stage, ahead of our forecasts. Cash burn remains at below £4.5m per annum. Current funds along with the Equity Financing Facility should enable the company the flexibility to continue to pursue the Phase III trials for Lupuzor™ whilst continuing the development path of IPP-204106.

Prospects

Lupuzor™ has multi-billion dollar sales potential

The leading drug candidate Lupuzor™ has a multi-billion dollar sales potential in a market with unmet needs. Lupuzor has a unique mechanism that modulates the immune system to correct abnormalities in Lupus. Current treatments for Lupus remain defective and either have serious side effects or limited effectiveness. Lupuzor™ has received a number of prestigious endorsements relating to its superiority/mode of action compared to conventional treatment.

Having completed detailed due diligence with an, as yet un-disclosed partner, ImmuPharma has taken the pivotal move in starting the preparatory steps for Lupuzor™'s Phase III clinical trials. Further newsflow is expected once the development agreement is finalised. However, it is expected that the partner and ImmuPharma will fund the Phase III trials for Lupuzor™. ImmuPharma has previously arranged a £50m, 5 year, equity financing facility with Darwin Strategic Limited, which provides them with financial flexibility to assist in the funding of the trial.

Tangible progress already made in progressing towards Phase III trials for Lupuzor™

The group has already made significant tangible steps in progressing towards the Phase III trials. The group has gained an updated SPA for Lupuzor™ granted by the FDA, which reduces the number of patients required for dosing in the Phase III trials and thereby reduces the cost of the trials. The group has also appointed a very well regarded Scientific Advisory Board for the trials and has manufactured the drugs required for the trial.

Cancer drug IPP-204106 also showing promise

ImmuPharma's second drug candidate, IPP-204106, has shown exciting promise in the treatment of cancer. The group has recently completed a Phase I/IIa clinical trial, with results and the next steps to be announced in due course. Ultimately this could provide a further opportunity for a licensing deal for the company.

The group has had patents granted surrounding an "optically pure" version of the Nucant family which will significantly broaden its use into further indications.

Collaboration on the development of innovative peptide technology platform could prove significant

In collaboration with CNRS the group have initiated the development of an innovative peptide technology platform. This collaboration has enabled the group to gain access to pioneering research on novel peptide drugs at the University of Bordeaux and the IECB. ImmuPharma and its partners have filed for a co-owned patent over the breakthrough peptide technology 'Urelix' which is initially being targeted at the multi-billion dollar diabetes market. The potential for the technology is significant and diverse and this could be another significant asset for ImmuPharma.

ImmuPharma retains a unique and ongoing relationship with the Centre National de Recherche Scientifique giving access to scientists and enabling low cost research

The group also boasts a unique and ongoing relationship with its research partner Centre National de la Recherche Scientifique, the largest fundamental research institute in Europe. This gives the company access to many scientists and physicians enabling low cost research. This relationship also provides the group with exclusive rights to commercially exploit certain discoveries on a worldwide basis.

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