Zacks Small-Cap Research

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Immune Pharmaceuticals, Inc. (IMNP - NASDAQ)

IMNP: Clinical Sites to Open for BP Trial in the U.S.…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	02/28/2014
Current Price (11/17/15)	$1.03
Target Price	**$6.00**

UPDATE

On November 11, 2015, Immune Pharmaceuticals announced financial results for the third quarter of 2015 and provided a business update. Recent highlights for the company include the acceptance of an Investigational New Drug (IND) application for bullous pemphigoid (BP) by the U.S. FDA, which will allow for the opening of clinical sites in the U.S., and the initiation of a 10b5-1 stock purchase plan by the company's CEO, Dr. Daniel Teper.

The company is continuing patient enrollment in the Phase 2 studies of bertilimumab in BP and ulcerative colitis (UC), which should increase once the clinical sites in the U.S. open for patient enrollment. Results for the BP study are likely in 2016 while results from the UC study should be available at the end or 2016 or the first half of 2017.

SUMMARY DATA

52-Week High	**$2.91**
52-Week Low	**$1.01**
One-Year Return (%)	**-64.11**
Beta	**2.46**
Average Daily Volume (sh)	**206,211**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**2.46**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 E	0 E
2015	0 A	0 A	0 A	0 E	0 E
2016					15.0 E
2017					15.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.35 A	-$0.03 A	-$0.73 A	-$0.32 A	-$1.46 A
2015	-$0.15 A	-$0.12 A	-$0.35 A	-$0.21 E	-$0.63 E
2016					-$0.60 E
2017					-$0.55 E

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WHAT'S NEW

Financial Update

On November 11, 2015, Immune Pharmaceuticals, Inc. (IMNP) announced financial results for the third quarter of 2015 and provided a business update. The company did not report any revenue for the quarter. Net loss for the third quarter of 2015 was $9.5 million, and was comprised of $1.1 million in R&D and $2.1 million in G&A. In addition, the company recorded a non-cash charge of $5.4 million in connection with the company's Series C Preferred Stock. Total cash burn for the quarter was $5.4 million, and the company exited the third quarter of 2015 with approximately $9.0 million in cash and cash equivalents. We believe the company's current cash position together with the $5 million available under the revolving line of credit (see below), is sufficient to fund operations for the next 12 months.

In July 2015, Immune announced two financing agreements that could bring in up to $21.5 million to the company. The first agreement, with Hercules Technology Growth Capital, Inc., is for a term loan of up to $9.5 million. The second agreement, with Discover Growth Fund, is for the sale to Discover of newly created Series D Preferred Stock for up to $12 million in gross proceeds. Thus far, Immune has received $16.5 million in gross proceeds: $12 million from Discover and $4.5 million from Hercules. The company may borrow an additional $5 million from Hercules prior to June 15, 2016

The newly created Series D Preferred Stock have a purchase price of $10,000 and are convertible to common stock at a fixed price of $2.50 per share with a six and a half year maturity term, after which the shares will automatically convert to common stock at $2.50 per share. The shares carry an accrued annual dividend rate of 8%, which can range from 0-15% based on certain adjustments and conditions. The dividend is payable in cash or common stock according to Immune.

In connection with the financing, Immune issued to Hercules a warrant to purchase 214,853 shares of common stock at an exercise price of $1.70. TriPoint Global Equities, LLC was the sole placement agent for the deal with Hercules and received warrants to purchase an aggregate of 350,000 shares of common stock at an exercise price of $1.78 per share. Chardan Capital Markets, LLC and Roth Capital Partners, LLC acted as co-placement agents for the Preferred Shares and received warrants to purchase an aggregate of 275,000 shares of common stock at an exercise price of $2.50 per share.

Business Update

FDA Accepts Investigational New Drug Application for Bertilimumab

On November 9, 2015, Immune announced that the U.S. Food and Drug Administration (FDA) accepted the company's Investigational New Drug (IND) application for bertilimumab for the treatment of bullous pemphigoid. This acceptance will enable the company to expand recruitment for the ongoing Phase 2 clinical trial to three planned clinical trial sites in the U.S., including Mount Sinai School of Medicine in New York City. The company is planning to follow the same regulatory pathway for the Phase 2 trial of betilimumab in ulcerative colitis (UC) such that patient enrollment can commence in the U.S.

Bullous Pemphigoid: The BP Phase 2a trial is an open-label trial expected to enroll 10-15 moderately to severely affected patients who have been newly diagnosed with BP, which means they have not received prior treatment for the disease (NCT02226146). All patients will be initiated on low dose oral prednisone (30 mg daily), which is approximately half of what a typical starting dose would be for a BP patient. The patients will also receive two infusions of bertilimumab, at a dose of 10 mg/kg, on days 0 and 14. The dosage of prednisone will be tapered down rapidly beginning as early as week one based on patient response.

All patients will be followed for eight weeks with primary efficacy end points focused on disease control as measured by the Bullous Pemphigoid Disease Area Index (BPDAI; Murrell *et al*., 2012), a quantitative measure of disease activity that takes into account the number and size of lesions as well as their location (skin vs. mucosa), as well as the percentage of patients who achieve a steroid dose of less than 10 mg per day. We anticipate data from the trial could be reported in the second half of 2016.

Prior studies of bertilimumab have shown a 100% reduction in eotaxin-1 levels within 24 hours of administering the drug with more than 50% of the inhibition lasting for greater than 50 days. Thus, while only dosing patients two times with bertilimumab may not seem like a thorough examination of the antibody's capabilities, theoretically there could be a rapid and sustained response to treatment if the prior pharmacokinetic (PK) data holds up in a population of BP patients. With the low dose of steroids given to each patient, there is unlikely to be more than one or two patients who respond to steroid therapy. Thus, a successful outcome for the Phase 2a trial could be if four or five patients respond to therapy with bertilimumab, as this would most likely be proof that the drug is working and can be advanced to the next clinical stage.

Development of bertilimumab for treatment of BP is somewhat complicated by the fact that BP is an orphan disease and that no drugs that have gone through the regulatory pathway for approval in this indication. We remind investors that Immune filed for Orphan Drug designation for bertilimumab in BP in October 2014. The FDA responded saying they would like to see some (we are not sure how much) patient data from the planned Phase 2 open-label study noted above before they grant the designation.

Ulcerative colitis: The Phase 2 trial of bertilimumab in UC is a randomized, double blind, placebo-controlled, parallel group, multi-center study that will evaluate the clinical efficacy and pharmacokinetic profile of bertilimumab in approximately 42 adult patients with active moderate to severe UC (NCT01671956). Eligible patients will be randomly assigned in a 2:1 ratio to one of two treatment groups, either bertilimumab at 10 mg/kg or matching placebo. Importantly, key inclusion criteria include high eosinophilia, as confirmed by eotaxin-1 levels (≥ 100 pg/mg protein) from a colon biopsy. The study will consist of three periods: a screening period of up to two weeks, a 4-week double-blind treatment period (three IV infusions at 2-week intervals), and a safety and efficacy follow-up period of approximately 9 weeks.

The primary endpoint is clinical response using the UC Mayo Clinic Index two weeks after final dosing. The Mayo Clinic Index was developed in 1987 and is a scoring mechanism that takes into account stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment (Schroeder *et al*., 1987). The score ranges from 0-12, with the higher score indicating more severe disease. For Immune's Phase 2 trial, the primary outcome of the study is the decrease in Mayo score from baseline of at least three points and at least 30%. Secondary endpoints include mucosal injury, eotaxin-1 and eosinophil levels in the mucosa, and clinical remission (Mayo score ≤ 2). As this is a proof-of-concept trial, statistical significance is not necessarily required to proceed to a Phase 2b trial, however some efficacy signal along with a clean safety profile will need to be exhibited. On November 17, 2015, Immune announced that the first patient has been enrolled into the trial. We expect results from this trial at the end 2016 or the first half of 2017.

Celgene Acquisition of Receptos Shows Potential for Mid-Stage UC Drugs

On July 19, 2015, Celgene Corp. (CELG) announced it would acquire Receptos (RCPT) for $7.2 billion in cash. Through the acquisition, Celgene gained the rights to ozanimod (RPC1063), an oral, once-daily, sphingosine-1-phosphate 1 receptor (S1P) modulator. In October 2014, Receptos reported positive results for RPC1063 in a Phase 2 clinical trial in patients with UC. The results showed that 16.4% of patients on the 1 mg does of RPC1063 achieved remission (Mayo score ≤ 2) compared to 6.2% of patients on placebo. A Phase 3 study of RPC1063 in patients with moderate to severe UC (Mayo score 6-12) is currently underway (NCT02435992), with results expected in 2018. RPC1063 is also being tested as a treatment for relapsing multiple sclerosis (RMS) in two Phase 3 clinical trials that should report data in the first half of 2017.

Analysts predict that upon being approved for both RMS and UC, ozanimod could have peak sales of $4-6 billion, thus justifying the $7.2 billion that Celgene paid to acquire the asset. Bertilimumab sales will likely not be quite that high, we currently forecast peak sales of approximately $1.5 billion in UC, thus we don't believe that Immune should immediately be valued on par with Receptos. Instead, it's important to understand that effective mid- to late-stage UC assets are proving to be valuable commodities, and with Immune's current valuation at approximately $50 million, the potential value of bertilimumab is not accurately reflected in the company's current stock price.

Immune Enhances Immuno-Dermatology Pipeline with Nano-Formulated Cyclosporin A

On June 10, 2015, Immune announced the signing of a license agreement for the development of a topical, biodegradable, nano-capsule formulation of cyclosporine A. Systemically administered cyclosporine A (Sandimmune®, Neoral®) is currently utilized to treat a wide range of dermatologic conditions including psoriasis, atopic dermatitis, pemphigus vulgaris, and other inflammatory skin conditions.

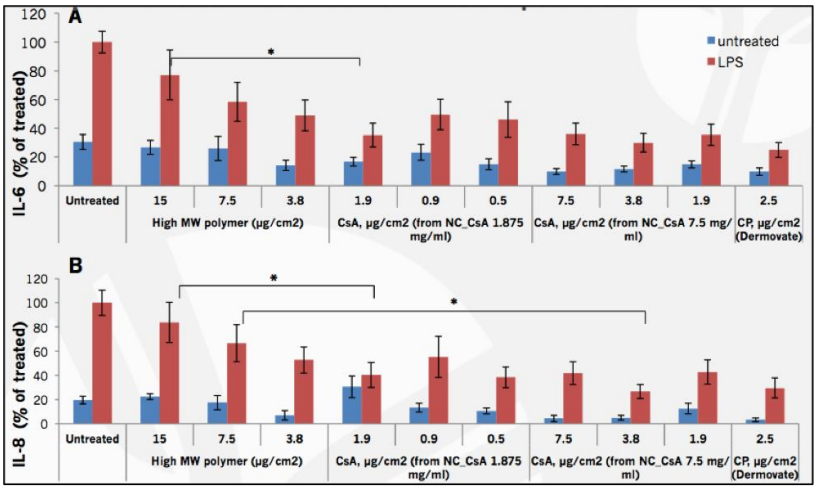
Cyclosporin A is a powerful immunosuppressive agent. It is known to decrease the production of cytokines, particularly interleukin-2, which are involved in T-cell activation (Russell *et al*., 1992). It was originally approved in the 1980's to prevent organ rejection after transplantation (Starzl *et al*., 1981). In 1997 it was approved for the treatment of psoriasis. Due to its poor water solubility, a number of suspension and emulsion formulations of the compound have been developed. Sandoz, now Novartis, first sold cyclosporine A under the name Sandimmune® in the form of soft-gel capsules, an oral solution, and a formulation for intravenous administration. Both the soft-gel and oral solution result in erratic absorption and decreased bioavailability compared to Neoral®, which is a microemulsion formulation of cyclosporine A that is administered as an oral solution or soft-gel capsules. A topical emulsion formulation exists for treating inflammation associated with chronic dry eye and is sold under the name Restasis®. Problems with systemically administered cyclosporine A include variability in bioavailability and metabolism, as well as the potential for hepatic and nephrotoxicity.

No topical formulation of cyclosporine A currently exists for the treatment of skin conditions. Immune plans to develop the topical nano-formulation of cyclosporine A as a treatment for psoriasis and atopic dermatitis.

Atopic Dermatitis: Otherwise known as eczema, atopic dermatitis (AD) is a chronic, inflammatory skin condition that typically begins during the first year of life. It affects between 10-12% of children and approximately 1% of adults in the U.S. The only symptom of the disease is excessive itching with children often scratching themselves uncontrollably. Typically the disease goes through cycles of flares and spontaneous remissions. Treatment involves a step-wise approach depending upon the severity of the disease. Those with dry skin only are typically treated with moisturizers and the avoidance of triggers, those with mild to moderate disease are typically treated with topical corticosteroids or topical calcineurin inhibitors, and those with severe disease are given systemic or photo-therapy (Akdis *et al*., 2006).

Psoriasis: Psoriasis is a common, chronic, noncontagious, multisystem inflammatory condition that most commonly presents on the skin of the elbows, knees, scalp, back, and thighs. There are multiple types of psoriasis, with plaque psoriasis, being the most common and affecting 80-90% of all individuals with psoriasis. Plaque psoriasis involves the hyperproliferation of epidermal keratinocytes that results in red or white, scaly, and typically itchy skin lesions. There is no known cure for the disease, thus depending upon the severity of the condition and how responsive it is to treatment, some patients are on therapy for life. The treatment of mild psoriasis typically involves the use of topical treatments, including corticosteroids, vitamin D, and moisturizers such as mineral oil or petroleum jelly. These treatments may be combined with phototherapy, typically psoralen-ultraviolet A (PUVA) therapy, which causes skin cells to grow less rapidly. Psoralen is a photosensitizer that is orally ingested prior to PUVA and makes the skin more sensitive to phototherapy.

Preclinical data using a human skin organ culture inflammatory model created to mimic a psoriatic condition showed that administration of the topical nano-formulation of cyclosporine A diffused through the epidermis within two hours and through the dermis over the next 24 hours (Frušić-Zlotkin *et al*., 2012). In addition, nano-formulated cyclosporine A also reduced the secretion of the inflammatory cytokines IL-1β, IL-6, IL-8, IL-20 and IL-23 with efficacy on-par with the most potent topical corticosteroid clobetasol propionate (CP). The following figure shows how the addition of lipopolysaccharides (LPS) to the human skin organ model results in the secretion of inflammatory cytokines. However, in the presence of nano-formulated cyclosporine A (CsA) or CP the amount of IL-6 and IL-8 is decreased compared to untreated samples.



Source: Frušić-Zlotkin *et al*., 2012; CsA = cyclosporine A, CP = clobetasol propionate

The company is planning to file an investigational new drug (IND) application with the FDA in 2016 such that clinical trials can be initiated in both AD and moderate psoriasis. The topical formulation of cyclosporine A could have therapeutic benefit in a market that could approach 170 million people worldwide (100 million with AD and 70 million with psoriasis) and provide efficacy on par with topical corticosteroids but without the side effects associated with systemic cyclosporine A usage.

NanomAbs Platform Offers Additional Upside

The NanomAbs platform is an antibody-drug conjugate (ADC) technology that was licensed from The Hebrew University of Jerusalem. It is a four-component technology consisting of: 1) a PEGylated PLGA nanoparticle (PPN) that transports the toxic compounds, 2) a proprietary linker that connects the monoclonal antibody to the PPN, 3) a mAb, that serves to target a cancer-specific antigen, and 4) a drug loaded within the PPN.

NanomAbs are considered a second-generation ADC and hold a number of advantages over traditional ADCs including:

- ✓ High payload – traditional ADCs are only able to carry an average of 4 toxic agents per antibody compared to up to 20,000 molecules per nanoparticle.
- ✓ Increased half-life – attaching PEG molecules to the outside of the nanoparticle extends circulation time and prevents clearance by immune cells.
- ✓ Diversity of delivered compounds – traditional ADCs can only carry chemotherapeutic agents while NanomAbs could theoretically deliver antisense drugs, peptides, and multiple chemotherapeutics at once.

On May 5, 2015, Immune announced that it entered into a strategic partnership with STC Biologics to accelerate the development of NanomAbs. Development will initially focus on HER2-targeting paclitaxel nanoparticles using an anti-HER2 monoclonal antibody developed by STC, and H-Ferritin targeted paclitaxel nanoparticles using an anti-H-Ferritin monoclonal antibody developed by Immune.

Significant Insider Purchases and Addition to Management Team

On September 15, 2015, Immune announced that CEO Dr. Daniel Teper had established a 10b5-1 stock trading plan for the purpose of purchasing $250,000 of common stock. Through November 9, 2015, Dr. Teper has purchases $125,000 worth of stock through the plan. In addition, two members of the Board of Directors each purchases 50,000 shares of common stock at $1.47 and $1.48 per share, respectively.

On September 8, 2015, Immune announced the appointment of Boris Shor, Ph.D. as Executive Director, R&D and Scientific Partnerships. Dr. Shor will be establishing and directing a new immunology research laboratory at the the company's headquarters in New York City. He will lead translational research efforts to support the development of the company's lead clinical stage candidate, bertilimumab, as well as the discovery and development of pipeline drugs utilizing NanomAbs®. Dr. Shor joins Immune from the Pfizer Oncology Research Unit where he led internal and external collaboration project teams to develop novel antibody-drug conjugates (ADCs) for the treatment of cancer. Most recently, Dr. Shor was also responsible for authoring regulatory documents including the non-clinical pharmacology section for the Biological License Application (BLA) of a late stage ADC. Dr. Shor received a Ph.D. in Molecular and Cell Biology at the State University of New York and performed a postdoctoral fellowship in the Inflammation Research team at Johnson & Johnson Pharmaceutical R&D prior to joining Pfizer.

Conclusion and Recommendation

We believe that bertilimumab has blockbuster potential. We forecast peak sales of approximately $1.5 billion for UC, which we view as reasonable given the large patient population (approximately 750,000 individuals in the U.S. have UC) and differentiated mechanism of action compared to currently available biologic therapeutics. BP is an orphan indication and thus we forecast peak sales for bertilimumab in BP of approximately $100 million. We model for Immune to receive approximately $20 million in upfront cash for licensing Amiket™ and to receive 15% royalties on forecasted peak sales of $400 million. Not factored into our current model are potential sales of bertilimumab for Crohn's disease, NASH, or asthma, or for nano-formulated cyclosporine A, thus offering additional upside to our current valuation. We think Immune shares are currently worth $6, and with the stock trading at a significant discount to our target price it represents a great opportunity to take a position before possible inflection points in 2016 with the release of data from the ongoing Phase 2 clinical trials.

PROJECTED FINANCIALS

Immune Pharma	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E
Bertilimumab	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
AmiKet	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
NanoMAbs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
Licensing and other Revenue	**$0**	**$0**	**$0**	**$0.0**	**$0**	**$0.0**	**$0**
YOY Growth							
Total Revenues	**$0**	**$0**	**$0**	**$0.0**	**$0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
General & Administration	$10.7	$2.3	$1.7	$2.2	$2.6	$8.8	$11.0
Research & Development	$5.6	$1.2	$1.1	$1.1	$3.5	$6.9	$12.5
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($16.4)	($3.5)	($2.8)	($3.4)	($6.1)	($15.7)	($23.5)
Operating Margin	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($7.2)	($0.1)	($0.1)	($0.8)	($0.2)	($1.2)	($0.5)
Pre-Tax Income	($23.6)	($3.6)	($2.9)	($4.2)	($6.3)	($16.9)	($24.0)
Income Taxes Paid	$0.0	$0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$0.9	$0	$0	$5.4	$0	$0	$0
Net Income	($24.4)	($3.6)	($2.9)	($9.5)	($6.3)	($16.9)	($24.0)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($1.46)**	**($0.15)**	**($0.12)**	**($0.35)**	**($0.21)**	**($0.63)**	**($0.60)**
YOY Growth	*$0.55*	-	-	-	-	*$0.79*	*($0.59)*
Basic Shares Outstanding	16.7	24.3	24.7	27.4	30.0	26.6	40.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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