Immune Pharmaceuticals, Inc.  

(IMNP - NASDAQ)

CURRENT RECOMMENDATION  
Buy

PRIOR RECOMMENDATION  
N/A

DATE OF LAST CHANGE  
02/28/2014

CURRENT PRICE (08/19/15)  
$1.53

TARGET PRICE  
$6.00

UPDATE

On August 14, 2015, Immune Pharmaceuticals announced financial results for the second quarter of 2015 and provided a business update. Recent highlights for the company include the raising of up to $21.5 million in gross proceeds from institutional investors, the initiation of Phase 2 clinical trials of bertilimumab in bullous pemphigoid and ulcerative colitis, and the expansion of the company's immuno-dermatology portfolio with nano-formulated Cyclosporine A.

For the second half of 2015, we anticipate top line results from the bullous pemphigoid trial, the potential for orphan drug designation for bertilimumab in bullous pemphigoid, and the out-licensing of Amiket.

SUMMARY DATA

| 52-Week High | $4.09 | Risk Level | Above Average |
| 52-Week Low | $1.51 | Type of Stock | Small-Growth |
| One-Year Return (%) | -61.75 | Industry | Med-Biomed/Gene |
| Beta | 2.75 | |
| Average Daily Volume (sh) | 144,661 | |

| Shares Outstanding (mil) | 27 | |
| Market Capitalization ($mil) | $41 | |
| Short Interest Ratio (days) | 2.32 | |
| Institutional Ownership (%) | 2 | |
| 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

ZACKS ESTIMATES

Revenue
(In millions of $)

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

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

| Q1 | Q2 | Q3 | Q4 | Year |
| (Mar) | (Jun) | (Sep) | (Dec) | (Dec) |
| 2014 | -$0.35 A | -$0.03 A | -$0.73 A | -$0.32 A | -$1.46 A |
| 2015 | -$0.15 A | -$0.12 A | $0.31 E | -$0.20 E | -$0.19 E |
| 2016 | | |
| 2017 | | | | | -$0.26 E |
| | | | | | -$0.30 E |
WHAT’S NEW

Financial Update

On August 17, 2015, Immune Pharmaceuticals, Inc. (IMNP) announced financial results for the second quarter of 2015 and provided a business update. As expected, the company did not report any revenue for the quarter. Net loss for the second quarter of 2015 was $2.9 million, and was comprised of $1.1 million in R&D and $1.7 million in G&A. Total cash burn for the quarter was $2.2 million, and the company exited the second quarter of 2015 with approximately $1.4 million in cash and cash equivalents.

Subsequent to the end of the second quarter, 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 $13.5 million in gross proceeds: $9 million from Discover and $4.5 million from Hercules. The company may borrow an additional $5 million from Hercules prior to June 15, 2016 and expects to receive an additional $3 million from Discover upon an effective registration statement for the securities and stockholders approval. Thus far, stockholders with close to 50% of the voting power have agreed to vote in favor of the proposal. We anticipate the registration statement to become effective by mid-September 2015.

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.

With the current financing, we predict this will extend Immune’s cash runway for the next 18 months. Perhaps more importantly, it frees the company to maximize the value of AmiKet, as Immune is now not relying solely on upfront payments from an AmiKet partnership to provide necessary working capital. This will strengthen the company’s negotiating power and should provide the framework to deliver a deal that accurately reflects the financial potential of Amiket.

Lastly, the financing will allow Immune to both broaden the number of clinical indications for bertilimumab as well as advance additional pipeline products into clinical testing. With the newly acquired funds, the company is likely to expand testing of bertilimumab into nonalcoholic steatohepatitis (NASH), bring the newly licensed nano-formulated Cyclosporine A into the clinic, and advance the first NanoMabs candidate into clinical testing.

Phase 2 Clinical Trials of Bertilimumab Enrolling Patients

On June 25, 2015, Immune announced that the Phase 2 clinical trial for ulcerative colitis (UC) has been initiated and that the Phase 2 bullous pemphigoid (BP) clinical trial will commence on July 1, 2015. This was welcome news as much of the second half of 2014 was spent working through quality control issues on the manufacturing of bertilimumab that delayed the start of the two planned Phase 2 trials. Immune initiated the development of an enhanced manufacturing process, which has demonstrated a higher comparable performance and improved productivity than the previous process. This includes a new cell line that should lower costs and improve margins on the finish goods as well.
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. We expect results from this trial near the end 2016.

Bullous Pemphigoid: The BP Phase 2a trial is an open-label trial expected to enroll 10 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 endpoints 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 initial data from the trial to be reported in late 2015 or early 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 trial to be reported in late 2015 or early 2016 before they grant the designation.

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.
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.

**Partnership of Amiket Should Occur By the End of 2015**

AmiKet™ is a topical formulation of the FDA approved compounds amitriptyline (4%) and ketamine (2%), which the company is developing for the treatment of post-herpetic neuralgia (PHN). PHN is thought to be the result of nerve damage caused by the varicella zoster virus, which causes both chickenpox and shingles. Of the 1,000,000 individuals who develop shingles every year in the U.S., approximately 20% of them will develop PHN. There is currently no way of knowing beforehand who will develop PHN and who will not, although the condition is mostly restricted to patients who suffer from shingles after the age of 60.

In late December 2014, Immune initiated a comprehensive process targeting the 20 most likely development and commercial partners with the objective of commercializing AmiKet™. Several companies are in advanced due diligence and term sheet discussions. The company continues to anticipate an agreement to develop and commercialize AmiKet™ during 2015.

In this regard, the company provided an important update in March 2015 when Immune entered into an agreement to develop a topical nanoparticle formulation of AmiKet™, which we expect will increase the market exclusivity through novel patents, allow clinical development in additional indications, and increase the overall value of AmiKet™ to potential commercialization partners. New IP on this formulation will push patent protection to 2036, allowing expansion of the clinical program beyond the planned Phase 3 in PHN, an indication for which AmiKet™ was granted Orphan Drug designation in 2010, to other forms of neuropathy, such as diabetic peripheral neuropathy (DPN) and chemotherapy induced peripheral neuropathy (CIPN), an indication for which Immune received Fast Track designation from the FDA in 2012.

We believe that a partnership deal for Amiket™ focused on PHN could bring in between $15 to $25 million in upfront money, with an additional $200 million in backend and milestone payments along with low-teens royalties on sales.
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,
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. Licensing and joint-development agreements between STC and Immune should be finalized during the second quarter 2015.

Conclusion and Recommendation

With financing in place for the next 18 months, focus can now shift away from when Immune will sign a partnership deal for Amiket and instead onto clinical development of bertilimumab, the true value driver for the company in the near term. This is not to say that a deal for Amiket won’t get done, in fact we anticipate a deal before the end of 2015, just that investor’s should focus their attention on the progress of the ongoing Phase 2 clinical trials for bertilimumab. Positive topline results in the BP trial (the company should release the topline data in the fourth quarter of 2015) could be a real inflection point for the company and cause a rapid revaluation of the shares.

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 later in 2015 and 2016 occur.
## PROJECTED FINANCIALS

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<th>Q1 A</th>
<th>Q2 A</th>
<th>Q3 E</th>
<th>Q4 E</th>
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<th>2016 E</th>
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<td><strong>Non-Operating Expenses (Net)</strong></td>
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<td>($0.2)</td>
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<td>($0.15)</td>
<td>($0.12)</td>
<td>$0.31</td>
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<td><strong>YOY Growth</strong></td>
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<td>30.0</td>
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<td>27.8</td>
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Source: Zacks Investment Research, Inc.  
David Bautz, PhD
HISTORICAL ZACKS RECOMMENDATIONS

IMMUNE PHARMACT (IMMU)

Price

↑↓ Zacks Rec

Price ($)

6.00
5.75
5.50
5.25
5.00
4.75
4.50
4.25
4.00
3.75
3.50
3.25
3.00
2.75
2.50
2.25
2.00
1.75
1.50


▲ Buy  △ Hold  ▼ Sell

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