Zacks Small-Cap Research

April 18, 2016
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Immune Pharmaceuticals, Inc.

(IMNP - NASDAQ)

IMNP: Phase 2 Clinical Trials of Bertilimumab Ongoing; Subsidiary to Develop Immunooncology Products….

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	02/28/2014
Current Price (04/18/16)	$0.49
Target Price	**$2.50**

UPDATE

On March 30, 2016, Immune Pharmaceuticals announced financial results for the fourth quarter and full year of 2015 and provided a business update. The company announced the formation of a subsidiary, Immune Oncology Pharmaceuticals Inc., that will focus on the develop of the company's immunooncology assets.

The company is continuing patient enrollment in the Phase 2 studies of bertilimumab in BP and ulcerative colitis (UC). 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. In addition, the company should file an IND for the nano-formulation of cyclosporine-A, a potential $1 billion market opportunity.

SUMMARY DATA

52-Week High	**$2.17**
52-Week Low	**$0.39**
One-Year Return (%)	**-80.25**
Beta	**1.50**
Average Daily Volume (sh)	**174,527**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**18**
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)
2015	0 A	0 A	0 A	0 E	0 E
2016	0 E	0 E	0 E	0 E	0 E
2017					0 E
2018					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.15 A	-$0.12 A	-$0.35 A	-$0.26 A	-$0.90 A
2016	-$0.18 E	-$0.17 E	-$0.15 E	-$0.15 E	-$0.64 E
2017					-$0.60 E
2018					-$0.55 E

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WHAT'S NEW

Financial Update

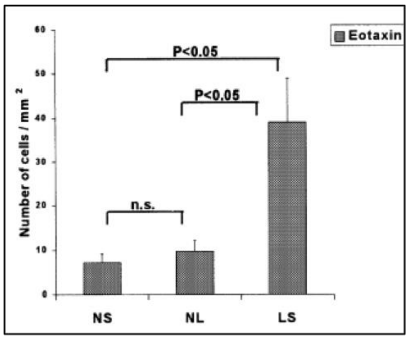
On March 30, 2016, Immune Pharmaceuticals, Inc. (IMNP) announced financial results for the fourth quarter and full year 2015 and provided a business update. As expected, the company did not report any revenues for the either the fourth quarter or full year. Net loss in the fourth quarter of 2015 was $8.2 million, or $0.27 per share, and included $2.5 million in R&D expenses and $3.6 million in G&A expenses. Total cash burn during the fourth quarter of 2015 was $4.1 million. For the full year 2015, the company reported a net loss of $24.1 million, or $0.90 per share, which included $5.9 million in R&D expenses and $9.8 million in G&A expenses. In addition, the company recorded a non-cash charge of $7.0 million in connection with the company's Series C and Series D Preferred Stock. Total cash burn for 2015 was $14.1 million and the company exited the year with $4.5 million in cash and cash equivalents. The company has an open $5 million revolving line of credit with Melini Capital Corp. that is available until Nov. 30, 2016, thus we estimate the company has sufficient funds to get to the third quarter of 2016. In addition, on March 30, 2016 the company entered into a binding term sheet with Regatta Select Healthcare LLC whereby Immune can sell to Regatta up to 3.5 million shares of common stock over a twelve-month period at the discretion of Immune.

In July 2015, Immune announced two financing agreements with Hercules Technology Growth Capital, Inc. and Discover Growth Fund. The agreement with Hercules is for a term loan of up to $9.5 million that was available to Immune in two tranches. Immune has borrowed $4.5 million from Hercules thus far. The agreement with Discover called for the sale of Series D Preferred Stock for $12 million in gross proceeds. The 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. Discover purchased a total of 1,200 shares of Series D Preferred Stock. Prior to Dec. 31, 2015, Discover converted 300 shares of Series D to 1,200,000 shares of common stock and Immune issued an additional 3,311,730 shares as payment of dividends and conversion premium. Subsequent to the end of 2015, Discover converted an additional 100 shares of Series D to 400,000 shares of common stock and Immune issued an additional 2,604,434 shares of common stock as payment of dividends and conversion premium.

Business Update

Immune to initiate Phase 2 Clinical Trial in 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. While the exact mechanism for how AD develops is unclear, one theory stipulates that it is caused by an imbalance of T-cell subtypes (e.g., Th1, Th2, Th17, Th22), which results in an overproduction of Th2 cells. This leads to an excess of Th2-derived cytokines such as interleukin (IL)-4, IL-13, and IL-5. These chemokines stimulate the development and chemotaxis of inflammatory cells such as eosinophils through induction of eotaxin-1. A study of eotaxin-1 expression in skin cells of AD patients showed that there was an increase in eotaxin-1 expressing cells in lesional skin (LS) from AD patients compared to non-lesional (NL) skin from those patients and normal skin (NS) from healthy controls (Yawalkar *et al.*, 1999).



Source: Yawalkar *et al.*, 1999

Recently, Regeneron and Sanofi reported Phase 3 results from two clinical trials of dupilumab, an anti-IL4Ra monoclonal antibody, in patients with atopic dermatitis. A total of 1,379 patients with moderate-to-severe AD were enrolled in the two trials. Results showed that approximately 37% of patients that received dupilumab achieved clearing or near-clearing of skin lesions, compared to approximately 9% with placebo. In addition, the overall rate of adverse events was comparable between dupilumab- and placebo-treated groups. Most importantly for Immune, these results show that targeting the IL-4/IL-13/eotaxin-1 signaling axis can lead to significant improvements in AD patients.

Immune is planning to initiate a small Phase 2a clinical trial of bertilimumab in AD patients before the end of 2016. The trial will be a randomized, placebo controlled study that will take place in multiple centers in North America. Results would be likely in 2017.

Phase 2 Clinical Trials for Bertilimumab in Ulcerative Colitis and Bullous Pemphigoid Underway

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

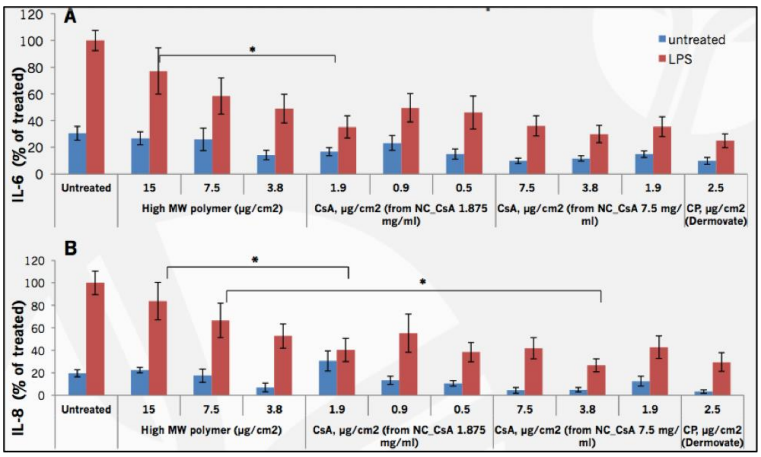
0-12, with the higher score indicating more severe disease. For Immune's Phase 2 trial, the primary outcome of the study is the decrease in Mayo score from baseline of at least three points and at least 30%. Secondary endpoints include mucosal injury, eotaxin-1 and eosinophil levels in the mucosa, and 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.

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

Earlier in 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.

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

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. Anacor Pharmaceuticals (ANAC) is developing crisaborole topical ointment, 2% for the treatment of mild-to-moderate AD. Crisaborole is a boron-containing small molecule inhibitor of PDE-4 that leads to the reduction of pro-inflammatory cytokine production. In July 2015, the company announced positive top-line results from two Phase 3 clinical trials of crisaborole in patients with mild-to-moderate AD, showing that a topical formulation product can be effective in

treating AD. Anacor recently submitted a new drug application (NDA) to the FDA seeking approval of crisaborole and the FDA has assigned a PDUFA data of Jan. 7, 2017.

Immune 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 with nano-cyclosporine A. 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.

Immune to Form Subsidiary to Develop Immunooncology Pipeline

Immune has initiated the establishment of a subsidiary to focus on the development of the company's immunooncology assets and technologies. The subsidiary, Immune Oncology Pharmaceuticals Inc., will be run under the leadership of Dr. Miri Ben-Arni and will seek independent funding to advance the development of the following assets.

Ceplene®

Ceplene® (histamine dihydrochloride) is used in combination with interleukin (IL)-2 for the maintenance of first remission in patients with Acute Myeloid Leukemia (AML). Following induction chemotherapy, most patients with AML will achieve complete remission (CR), however less than one-third (1/3rd) of adults patients with AML, as there is a high rate of relapse (Lowenberg *et al*., 1999). A 2006 publication reported results of a Phase 3 clinical trial that showed AML patients who were treated with the combination of Ceplene and IL-2 had an improvement in leukemia-free survival compared to patients with no treatment following attaining CR from induction chemotherapy (Brune *et al*., 2006). Ceplene® is currently approved in Israel and Europe.

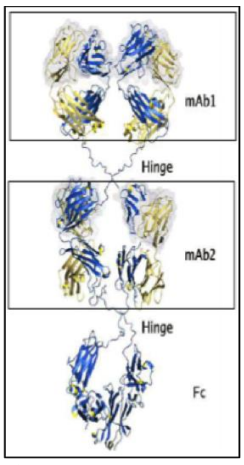
Immune recently announced that the results from a post-marketing clinical study showed that treatment with Ceplene® and IL-2 caused a re-distribution of cytotoxic T-cell subsets toward a cancer-killing phenotype and that the use of T-cell biomarkers could help to predict which patients are likely to benefit from Ceplene®/IL-2 therapy. The results will be presented during a poster session at the upcoming 2016 AACR Annual Meeting.

Crolibulin™ and Azixa®

Crolibulin™ and Azixa® are vascular disrupting agents (VDAs) that work by destroying tumor vasculature and blocking the flow of nutrients to cancer cells, thereby leading to their death. Crolibulin™ exhibited preliminary positive clinical efficacy in a Phase 1 trial for the treatment of solid tumors with a focus on anaplastic thyroid cancer (ATC) (Gramza *et al*., 2013). Results from two Phase 2a trials of Azixa® in patients with glioblastoma multiforme (GMB) showed durable responses when used both in combination with standard of care chemotherapy and as a monotherapy. The FDA has granted orphan drug designation to Azixa® for the treatment of GBM. Immune is planning to study both VDAs in combination with checkpoint inhibitors in upcoming clinical trials.

Bispecific Antibodies

On December 28, 2015, Immune announced it entered into an exclusive license with Atlante Biotech SAS for a new format of bispecific antibodies. The platform allows for the production of tetravalent IgG1-like bispecific antibodies that essentially combine two monoclonal antibodies into one, as shown in the figure on the right.



Source: Immune Pharmaceuticals

A publication in the Journal of Immunology described the production of the novel antibody platform as well as characterization of an anti-CD5/anti-HLA-DR bi-specific antibody that served as a proof-of-concept molecule (Golay *et al*., 2016). Importantly, it was shown that the bispecific antibody retained good binding specificity and affinity to both CD5 and HLA-DR. In addition, the bispecific antibody format is very stable both in neutral buffer and in serum. Lastly, treatment of mice inoculated with a leukemia xenograft showed the CD5/HLA-DR bispecific increased median survival by 15 days and was more effective than rituximab at the same dose.

Immune has initiated a number of bispecific antibody discovery programs. The first program is targeting two immune checkpoint proteins, PD-1 and OX40. The second program is targeting one immune checkpoint protein, PD-L1, and a tumor associated antigen, BCMA, that is a specific marker of multiple myeloma. A third program is targeting undisclosed targets.

NanomAbs

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.

Immune has begun development of NanomAbs targeting immunoinhibitor pathways, otherwise referred to as immune checkpoints (Mahoney *et al*, 2015). These pathways function to down regulate an immune response, and cancer cells typically express immune checkpoint proteins in order to evade detection by the immune system. First generation immune checkpoint inhibitors target cytotoxic T lymphocyte antigen 4 (CTLA-4), while second generation immune checkpoint inhibitors target the programmed cell death protein 1 (PD-1) and its ligand PD-L1. These inhibitors disrupt the interaction between immune checkpoint proteins and their ligands, resulting in a heightened immune response to a tumor. Immune is developing NanomAb products that target these immune checkpoint proteins on tumor cells such that 1) the NanomAb can be taken up by the tumor cell to deliver a toxic payload while 2) blocking the interaction between an immune checkpoint protein and its ligand, thereby disrupting the immunoinhibitory signal. The company is currently conducting preclinical work with NanomAbs that target various checkpoint pathways, along with dual-labeled NanomAbs that target both an immune checkpoint protein and a tumor associated antigen. We are hoping to see initial preclinical data from these programs later in 2016.

Conclusion and Recommendation

We believe that bertilimumab has blockbuster potential and we are looking forward to seeing data from the ongoing Phase 2 trials in both UC and BP later in 2016 and 2017. The company's decision to move into the immunooncology space is a smart one, and the novel bispecific antibody platform will help to differentiate Immune's products from others in the field. In addition, combination therapies are going to be key in developing immunooncology products that deliver effective and long-lasting treatment responses, thus having the ability to combine various targets into one compound could lead to partnership and licensing opportunities as more companies recognize the advantages of the bi-specific platform.

The negative sentiment surrounding the biotechnology sector has resulted in a steep decline in the Immune's share price over the past year. We have lowered our price target to $2.50 due to the decline in the company's share price leading to the potential for significant shareholder dilution from conversion of the Series D Preferred Stock. But we are maintaining a 'Buy' rating, as the potential for bertilimumab and the company's immunooncology pipeline is significant. Positive data from either of the company's ongoing Phase 2 studies or preclinical work with the bi-specific antibody platform or NanomAbs could move the shares significantly higher later in the year, and potential partnerships represent additional upside.

PROJECTED FINANCIALS

Immune Pharma	2015 A	Q1 E	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Bertilimumab	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
AmiKet	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
NanoMAbs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Licensing and other Revenue	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
General & Administration	$9.8	$2.3	$2.7	$3.0	$3.3	$11.3	$12.0	$13.0
Research & Development	$5.9	$2.0	$2.1	$2.2	$2.2	$8.5	$10.0	$11.0
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.7)	($4.3)	($4.8)	($5.2)	($5.5)	($19.8)	($22.0)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.4)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.5)
Pre-Tax Income	($17.2)	($4.4)	($4.9)	($5.3)	($5.6)	($20.2)	($22.5)	($24.5)
Income Taxes Paid	$0.0	$0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$7.0	$1.5	$1.5	$1.5	$1.5	$6.0	$5.0	$4.0
Net Income	($24.1)	($5.9)	($6.4)	($6.8)	($7.1)	($26.2)	($27.5)	($28.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.90)**	**($0.18)**	**($0.17)**	**($0.15)**	**($0.15)**	**($0.64)**	**($0.55)**	**($0.48)**
YOY Growth	*155%*	-	-	-	-	*-56%*	*270%*	*301%*
Basic Shares Outstanding	26.7	33.0	37.0	45.0	48.0	40.8	50.0	60.0

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

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 27.4%, Hold/Neutral- 50.3%, Sell/Underperform – 15.4%. Data is as of midnight on the business day immediately prior to this publication.