Zacks Small-Cap Research

November 11, 2015
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Enumeral Biomedical Holdings, Inc. (ENUM-OTC)

ENUM: Phase I study planned in 2016 for PD-1 program, Great progress has been made in pipeline advancement----Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/29/2014
Current Price (11/11/15)	$0.24
Target Price	**$2.00**

OUTLOOK

Enumeral has identified multiple PD-1 antibodies that that appear to bind to the PD-1 inhibitory checkpoint protein in a manner different from that of currently marketed anti-PD-1 antibodies. The company plans to initiate Phase I study with its PD-1 program.

Enumeral recently signed an agreement with Merck. The collaboration includes use of Enumeral's human approach to interrogating the tumor microenvironment in colorectal cancer tissues obtained directly from patients in order to identify functional cellular responses to immuno-oncology therapies being developed by Merck.

We believe the shares are attractively valued.

SUMMARY DATA

52-Week High	**$1.25**
52-Week Low	**$0.27**
One-Year Return (%)	**-73.00**
Beta	**-0.29**
Average Daily Volume (sh)	**41,320**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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	**High**
Type of Stock	**Small-Cap Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$0.05 A	$0.00 A	$0.07 A	$0.04 A	$0.16 A
2015	$0.27 A	$0.38 A	$0.48 A	$0.49 E	$1.63 E
2016					$1.50 E
2017					$5.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.27 A	-$0.27 A	-$0.22 A	$0.06 A	-$0.26 A
2015	-$0.05 A	-$0.06 A	-$0.05 A	-$0.05 E	-$0.21 E
2016					-$0.15 E
2017					-$0.12 E

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Update on Third Quarter Financials Ended September 30, 2015

Total revenue for 3Q15 was $483,825, an increase of $413,417 as compared to $70,408 for 3Q14. This increase is attributable to the Company's collaboration agreement with Merck and its grant from the National Cancer Institute.

R&D expenses for 3Q15 were $1.8 million, as compared to $1.1 million for the three months ended September 30, 2014. This increase is primarily attributable to increases in payroll and personnel expenses related to the hiring of additional R&D employees, increases in outsourced services, increased laboratory costs, and an increase in depreciation expense.

G&A expenses for 3Q15 were $1.4 million, as compared to $1.2 million for the three months ended September 30, 2014. This increase is primarily attributable to increases in payroll and personnel expenses and increased professional services fees.

GAAP net income was $618,284 for 3Q15, as compared to a GAAP net loss of $8.8 million for 3Q14. This increase was primarily due to an increase in the change in fair value of derivative liabilities of $8.1 million, and an increase in revenues of $413,417, offset by an increase of $930,376 in research and development and general and administrative expenses.

Non-GAAP net loss was $2.7 million ($0.05 per share) for 3Q15, as compared to non-GAAP net loss of $2.2 million ($0.05 per share) for 3Q14.

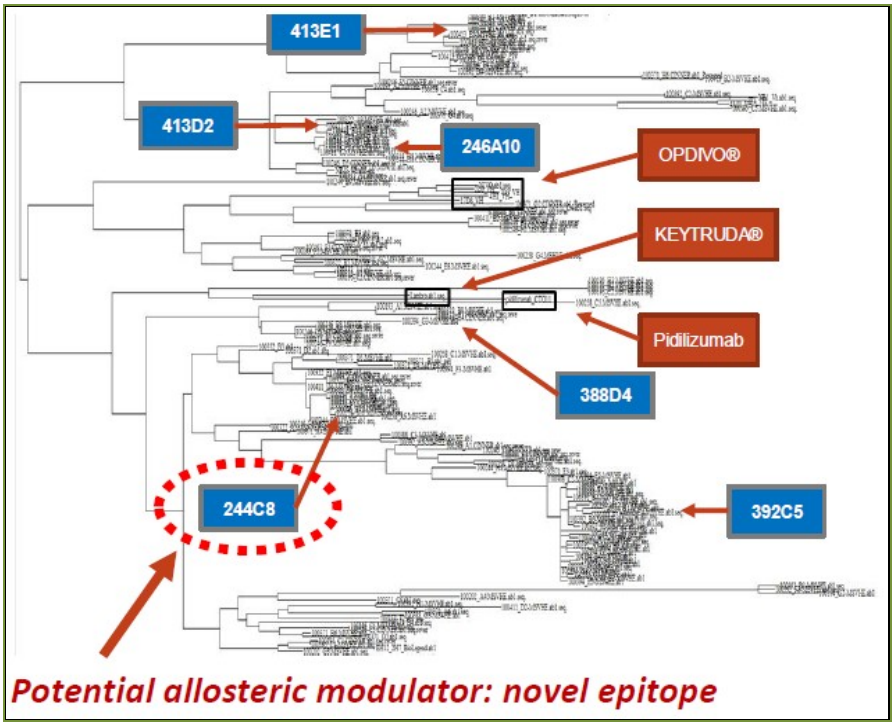
As of September 30, 2015, the company held $5.9 million in cash, cash equivalents and marketable securities. According to our model, current cash balance, combined with anticipated cash flow from collaborations, will be sufficient to support its operations into the second quarter of 2016.

We believe the earnings report is a non-event for Enumeral. As an early stage development biotech company, investors should focus on the achievements the company has made in advancing its pipeline and business development. In this regard, we think Enumeral has made great progress in the last few quarters.

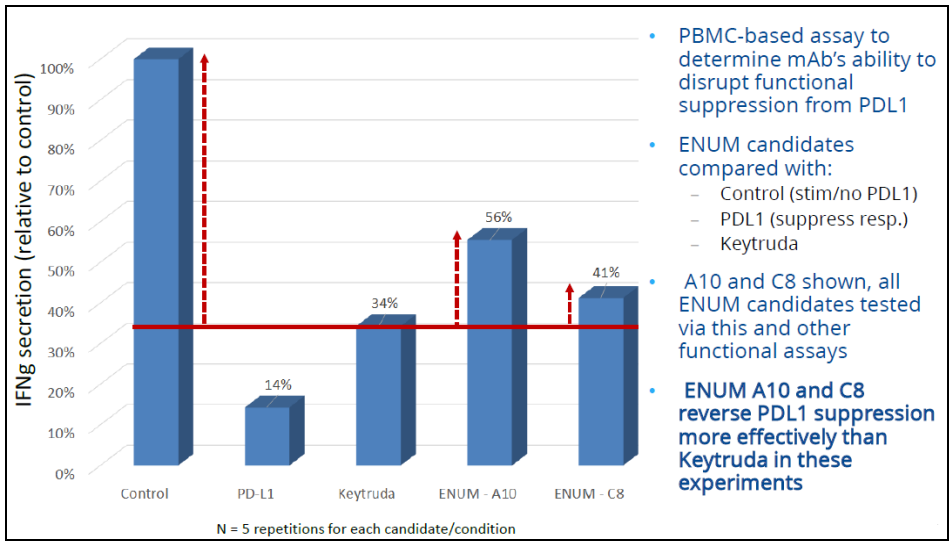
ENUM's Anti-PD-1 Antibodies Have Differentiated Mechanism of Action

Enumeral has identified antibodies that appear to bind to the PD-1 inhibitory checkpoint protein in a manner different from that of currently marketed anti-PD-1 antibodies, while retaining activity in cell-based assays. Enumeral reported that these novel antibodies do not appear to compete with currently marketed antibodies for binding to PD-1, nor do they appear to compete with PD-L1, providing further evidence of a differentiated mechanism of action. Enumeral presented these and related findings during the recent CRI-CIMT-EATI-AACR Inaugural International Cancer Immunotherapy Conference and the Biopharm America Conference.

Enumeral has advanced **six lead clones** into pre-clinical characterization, **four of which** are undergoing humanization. The humanization of 388D4 and 244C8 has been completed. The Company anticipates that the humanization process will be completed before the end of 2015, which will enable initiation of cell line development for IND-enabling studies.



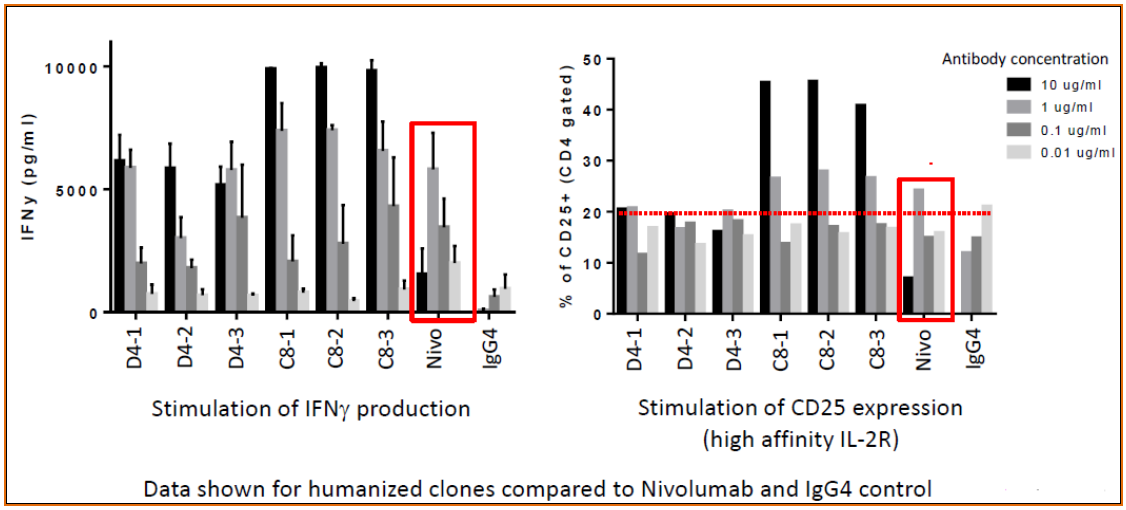
Enumeral's PD-1 antibodies have superior function than Keytruda. In the PBMC-based assays, ENUM A10 and C8 reverse PDL1 suppression more effectively than Merck's Keytruda.



Enumeral has humanized two lead antibodies (C8 and D4) and tested them in cell-based assays. As reported at the recent immunotherapy meeting, C8 and D4 showed enhanced activation of T cells in mixed lymphocyte reaction (MLR) and other assays than associated with currently-marketed antibodies, including:

- Increased dose-dependent stimulation of IFN□ production;
- Dose-dependent increases in T cell CD25 expression.

The stimulation of CD25 expression by Enumeral antibodies may be partially responsible for the elevated production of interferon gamma, perhaps through an autocrine IL-2 signaling mechanism, in contrast to other types of antibodies, which do not appear to have an effect on CD25 expression.



The above results were further confirmed in Ex Vivo **human assays**. Enumeral's researchers measured the ability of its anti-PD-1 antibodies to restore interferon gamma production by tumor infiltrating lymphocytes (TILs) derived from tumor biopsy specimens obtained from patients diagnosed with lung cancer. Compared to the use of currently marketed anti-PD-1 antibodies, experiments with Enumeral's anti-PD-1 antibody resulted in approximately 50% to 100% higher interferon gamma production by the TILs.

The Implications

From these initial results, we believe Enumeral's PD-1 antibodies are differentiated, which might elicit desirable cellular immune responses among subsets of tumor infiltrating lymphocytes (TILs) that differ from those observed with competitor antibodies against the same target.

We already knew that Anti-PD-1/PD-L1 non-responders constitute the majority of patients even in "immune therapy" tractable tumors like melanoma and RCC. Recent melanoma studies have reported response rates in the range of 20-40% using anti-PD-1 or anti-PDL-1.

Tumor Type	Anti-PD-1/PD-L1 mAb Non-Response
Melanoma	~ 60 - 80%
Triple Negative Breast (TNBC)	~ 70 - 82%[1]
Renal Cell Carcinoma (RCC)	~ 71%
Lung Carcinoma (NSCLC)	~ 79 - 83%
Head & Neck (H&N)	~ 80%[2]
Bladder	~ 84%[3]
Gastric	~ 69%[2]

Since Enumeral antibodies do not compete with PD-L1, yet still display activity in relieving the immunosuppressive effects of PD-L1, they may prove useful in treating patients who have failed prior PD-1 therapy. Further, this potentially distinct class might be synergistic when combined with other PD-1 pathway-directed therapies, including anti-PD-L1 therapy.

Enumeral is further investigating the mechanism of action of these differentiated antibodies, and has initiated testing in immuno-humanized mouse models of cancer, which enable testing of PD-1 modulatory therapies. The Company expects data from these studies to be available in December 2015.

We look forward to the completion of humanization process of these antibodies and the initiation of the IND-enabling studies by the end of this year. Positive data from the combination study may further strengthen the company's negotiation power with potential partners.

Update on TIM-3 Program and LAG-3 Program

The T-cell inhibitory receptor **Tim-3** (T-cell immunoglobulin and mucin-domain containing-3) is one of the check point proteins, which exhibits several unique features that make it an intriguing candidate for the next wave of therapies that target immune checkpoints in cancer. Tim-3 is currently receiving much attention due to its demonstrated success in multiple preclinical cancer models.

In Enumeral's TIM-3 program, the Company has isolated 124 TIM-3 binding antibodies to date. The screening efforts are ongoing. Enumeral's bioinformatics analysis indicates desirable diversity, with the antibodies falling into 42 distinct clades that bind to TIM-3. Enumeral plans to apply its unique approach to cellular immune response profiling to further understand the utility of these different antibodies for modulation of different tumor infiltrating lymphocytes.

We believe Enumeral's TIM-3 antibodies may have the potential to promote anti-cancer immune responses, either as a monotherapy or in combination with other therapies, including other immune checkpoint-targeted drugs. The company currently anticipates nominating lead clones in 4Q15, and beginning the humanization process by the end of this year.

In Enumeral's **LAG-3 program**, the Company has isolated 102 LAG-3 binding antibodies that fall into 40 distinct clades that bind to LAG-3. The Company is currently in the process of selecting antibody clones for further characterization.

Update on Collaboration with Merck

In December, 2014, Enumeral signed an oncology-focused collaborative study agreement with **Merck**. The collaboration includes use Enumeral's human approach to interrogating the tumor microenvironment in colorectal cancer tissues obtained directly from patients in order to identify functional cellular responses to immuno-oncology therapies being developed by Merck. Enumeral's human-driven immune profiling platform may increase the probability of finding rare immune cells associated with disease or drug response through improved efficiency and sensitivity. Studying rare cells obtained directly from human patients for their functional responses can potentially lead to identification of those patients responsive to a therapy, while elucidating the underlying cellular basis for such a response.

We think this is a huge validation of Enumeral's platform. Although terms of the agreement were not disclosed, Merck will provide R&D funding to Enumeral. Additionally, Enumeral is eligible to receive undisclosed future milestone payments if certain goals are achieved. Merck has exclusive rights to data related to its proprietary compounds that are generated from the studies.

On September 8, 2015, Enumeral announced that it has achieved the first milestone in its collaboration with Merck. Though no details were disclosed about the achievement, we believe Enumeral will receive a milestone payment from Merck.

Enumeral and UMass Medical School Enter into Research Study Agreement

On August 26, 2015, Enumeral announced that it has entered into a research study agreement with University of Massachusetts Medical School **(UMMS),** which includes its clinical partner, UMass Memorial Health Care, Inc.

Pursuant to the study agreement, UMass Medical School will provide Enumeral with tissue samples and blood samples from subjects with melanoma who are being treated with Ipilimumab (Yervoy). Enumeral will fund the tissue collection activities, and Enumeral will have access to the samples for research-only use in in-vitro studies.

Enumeral will apply the company's proprietary platform technology to analyze single immune cells within the patient samples. The study will be conducted under the direction of William Walsh, M.D., Clinical Associate Professor of Medicine at UMMS and principal investigator.

We believe this collaboration will allow Enumeral to study the effects of checkpoint blockade on the immune system at single cell resolution, by analyzing blood and tumor-tissue directly from individual patients using Enumeral's unique immunoprofiling platform. Information generated from the study could enable Enumeral to get insights into which immunotherapeutic strategies may be successful in patients that are not well-treated by currently marketed drugs and could lead to the development of new immunotherapies from Enumeral's Human Approach.

Valuation & Recommendation

We maintain our Buy rating on Enumeral shares and reiterate our 12-month price target of $2.00 per share.

We continue to be optimistic about the prospect of the company, especially about its internal anti-check point antibody programs and the potential for licensing opportunities.

Enumeral is an early development stage biotech company with a focus on immunotherapy for cancer and inflammatory disease. The Company has developed a proprietary platform technology with the ability to screen antibodies at a single cell level, which holds multiple advantages over existing technologies.

Based on this platform technology, Enumeral is currently focused on therapeutic discovery and immune profiling with the goal to build a robust pipeline rapidly and in a cost effective way. Currently, the discovery is focused on antibodies targeting immune checkpoints of PD-1, TIM-3, OX40 and Lag-3. The Company plans to file IND and initiate Phase I clinical trial for PD-1 in 2016 in collaboration with a co-development partner.

In addition to its internal programs, Enumeral also plans to monetize its technology by establishing partnerships with big pharma or biotech companies, the most recent agreement with Merck was signed in December 2014. Prior to the Merck collaboration, the company already had multiple proof-of-concept partnerships with a few big pharma companies. We anticipate more deals coming in 2016. We believe such large-scale collaborations will not only provide non-dilutive financing to the company, but also further validate Enumeral's technology and programs.

In terms of valuation, we think Enumeral is undervalued at the current market price. Currently, Enumeral shares are trading at about $0.25 per share, which values the company at about $12.5 million in market cap based on 52 million outstanding shares. We acknowledge that Enumeral is still in the early development stage with a Phase I trial starting in 2016. But when we look at the company in detail and the industry in which it operates, we realize that this company has the potential to grow dramatically in

the next few years. The unique platform technology not only provides the basis for rapidly building a robust pipeline, but also forms the basis for corporate partnerships that will generate near term revenue for the company.

Our price target of $2.00 per share corresponds to a market cap of $104 million, which we think is appropriate at this point of time if the company executes on its objectives and is able to see its lead programs progress into Phase I clinical testing by the end of 2016. Risks associated with our price target include the failure of the internal program development and failure to find appropriate corporate partners. But generally speaking, we think Enumeral is a company with great potential and a name with favorable risk/reward profile for investors with a relatively long investment horizon.

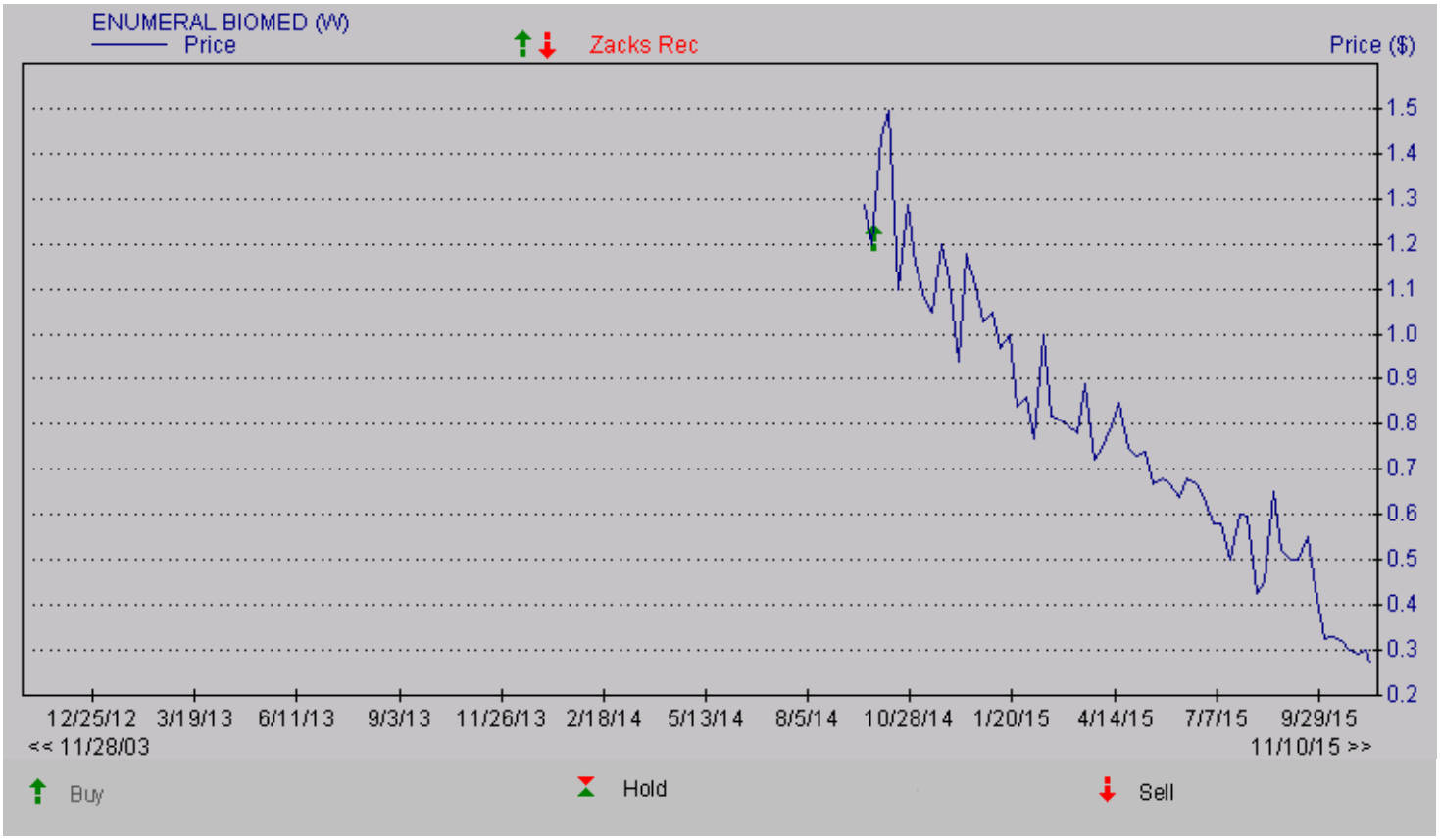
INCOME STATEMENT

	2013	2014					2015					2016	2017	2018	2019
$ in millions except per share data	FY	Q1	Q2	Q3	Q4	FYE	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Collaboration/license Revenue	$0.27	$0.05	$0.00	$0.07	$0.00	$0.12	$0.21	$0.29	$0.40	$0.40	$1.29	$1.50	$5.00	$7.50	$10.00
Grant Revenue	$0.18	$0.00	$0.00	$0.01	$0.04	$0.05	$0.07	$0.09	$0.09	$0.09	$0.34	$0.00	$0.00	$0.00	$0.00
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*
Total Revenues	**$0.45**	**$0.05**	**$0.00**	**$0.07**	**$0.04**	**$0.16**	**$0.27**	**$0.38**	**$0.48**	**$0.49**	**$1.63**	**$1.50**	**$5.00**	**$7.50**	**$10.00**
YOY Growth	-	-	-	-	-	-	*441.7%*	-	*587.2%*	*1042.1%*	*893.7%*	*-8.0%*	*233.3%*	*50.0%*	*33.3%*
CoGS	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Gross Income	**$0.45**	**$0.05**	**$0.00**	**$0.07**	**$0.04**	**$0.16**	**$0.27**	**$0.38**	**$0.48**	**$0.49**	**$1.63**	**$1.50**	**$5.00**	**$7.50**	**$10.00**
Gross Margin	*100.0%*	*100.0%*	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$2.37	$0.69	$0.79	$1.06	$1.04	$3.58	$1.23	$1.81	$1.80	$1.95	$6.78	$5.50	$7.50	$9.00	$12.00
% R&D	*527.7%*	*1351.5%*	*#DIV/0!*	*1503.7%*	*2425.1%*	*2180.0%*	*447.9%*	*473.4%*	*371.7%*	*398.0%*	*416.2%*	*366.7%*	*150.0%*	*120.0%*	*120.0%*
SG&A	$1.83	$0.50	$0.34	$1.16	$1.01	$3.02	$1.42	$1.49	$1.35	$1.45	$5.72	$4.00	$4.50	$5.00	$5.50
% SG&A	*408.0%*	*994.0%*	*#DIV/0!*	*1652.1%*	*2352.2%*	*1840.6%*	*518.7%*	*391.3%*	*279.9%*	*295.9%*	*351.0%*	*266.7%*	*90.0%*	*66.7%*	*55.0%*
Others	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($3.8)**	**($1.1)**	**($1.1)**	**($2.2)**	**($2.0)**	**($6.4)**	**($2.4)**	**($2.9)**	**($2.7)**	**($2.9)**	**($10.9)**	**($8.0)**	**($7.0)**	**($6.5)**	**($7.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	($0.1)	($0.1)	($0.1)	($6.7)	$5.0	($1.7)	$4.7	$2.9	$3.3	$0.0	$10.8	($0.8)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	**($3.9)**	**($1.2)**	**($1.2)**	**($8.8)**	**$3.0**	**($8.2)**	**$2.3**	**($0.0)**	**$0.6**	**($2.9)**	**($0.0)**	**($8.8)**	**($7.8)**	**($7.3)**	**($8.3)**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-60.2%*
Reported Net Income	**($3.9)**	**($1.2)**	**($1.2)**	**($8.8)**	**$3.0**	**($8.2)**	**$2.3**	**($0.0)**	**$0.6**	**($2.9)**	**($0.0)**	**($8.8)**	**($7.8)**	**($7.3)**	**($13.3)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*4.5*	*16.7*	*18.7*	*40.7*	*52.1*	*32.0*	*52.8*	*51.6*	*53.0*	*53.0*	*52.6*	*60.0*	*65.00*	*70.00*	*75.00*
Reported EPS	**($0.86)**	**($0.07)**	**($0.06)**	**($0.22)**	**$0.06**	**($0.26)**	**$0.04**	**($0.00)**	**$0.01**	**($0.05)**	**($0.00)**	**($0.15)**	**($0.12)**	**($0.10)**	**($0.18)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One-time charge	$0.00	$0.00	$0.00	$6.67	($5.05)	$1.62	($4.67)	($2.89)	($3.29)	$0.00	($10.85)	$0.00	$0.00	$0.00	$1.00
Non GAAP Net Income	**($3.9)**	**($1.2)**	**($1.2)**	**($2.2)**	**($2.0)**	**($6.6)**	**($2.4)**	**($2.9)**	**($2.7)**	**($2.9)**	**($10.9)**	**($8.8)**	**($7.8)**	**($7.3)**	**($12.3)**
Non GAAP EPS	**($0.86)**	**($0.07)**	**($0.06)**	**($0.05)**	**($0.04)**	**($0.20)**	**($0.05)**	**($0.06)**	**($0.05)**	**($0.05)**	**($0.21)**	**($0.15)**	**($0.12)**	**($0.10)**	**($0.16)**

Source: company filings and Zacks estimates

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Grant Zeng, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1165 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
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- 23.4%, Hold/Neutral- 60.1%, Sell/Underperform – 13.5%. Data is as of midnight on the business day immediately prior to this publication.