Zacks Small-Cap Research

March 14, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Four Reasons Why Aastrom Is Starting To Look Interesting…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/05/2012
Current Price (03/14/14)	$3.65
Target Price	**$5.00**

UPDATE

On March 13, 2014, Aastrom Biosciences, Inc. (ASTM) reported financial results for the fourth quarter and year ended December 31, 2013. The cash position has always been a focal point for investors in Aastrom stock. Aastrom exited 2013 with $8.1 million in cash, but reported having $10.8 million at the end of February 2014 thanks to a $5.4 million raise via the company's ATM financing facility in January and February 2014.

We believe Aastrom's stock is starting to look interesting for investors at today's price, mainly based on valuation, misconception, and committed access to cash. Below we outline four reasons why Aastrom is "on watch".

SUMMARY DATA

52-Week High	**$26.20**
52-Week Low	**$3.21**
One-Year Return (%)	**-84.88**
Beta	**0.85**
Average Daily Volume (sh)	**98,779**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**0.93**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**43**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 E	0 E	0 E	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$3.03 A	-$2.14 A	-$0.75 A	-$0.65 A	-$5.18 A
2014	-$0.48 E	-$0.45 E	-$0.40 E	-$0.40 E	-$1.73 E
2015					-$1.41 E
2016					-$1.35 E

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Results

On March 13, 2014, Aastrom Biosciences, Inc. (ASTM) reported financial results for the fourth quarter and year ended December 31, 2013. The company did not report meaningful revenues in either the quarter or during the full year. This was in-line with expectations. Net loss in the fourth quarter totaled $2.9 million, or $0.65 per share. Loss was driven by $3.3 million in R&D and $1.6 million in SG&A. For the full year ended December 31, 2013, net loss totaled $15.6 million, or $5.18 per share. Loss in 2013 was driven by $15.1 million in R&D and $5.9 million in SG&A. Over the past few quarters, management at Aastrom has done a very good job in reducing cash burn and lowering operating expenses. For example, operating loss in the first quarter totaled $6.8 million. The number was reduced to $4.9 million in the second quarter 2013.

Aastrom exited 2013 with $8.1 million in cash and investments. However, we remind investors that the company current has an At-The-Market (ATM) financing facility in place with MLV, LLC dating back to June 2011. It allows for the sale of registered securities up to $20.3 million. From inception of the agreement through December 31, 2013, the company has raised total gross proceeds of $5.2 million. Subsequent to December 31, 2013 through March 6, 2014, Aastrom raised another $5.4 million in gross proceeds utilizing the ATM. Cash as of the end of February 2014 stood at $10.8 million. We model cash at the end of the first quarter ended March 31, 2014 will be roughly $9 million. We expect the company to utilize the remaining $9.7 million via the ATM in the next one to two quarters. We believe the company's goal is to maintain cash at roughly two quarters runway – or at least $8 million – until the release of the top-lined from the truncated REVIVE-CLI Phase 3 study around the middle of the year. If the data is positive, this could give the company an opportunity to raise additional new capital.

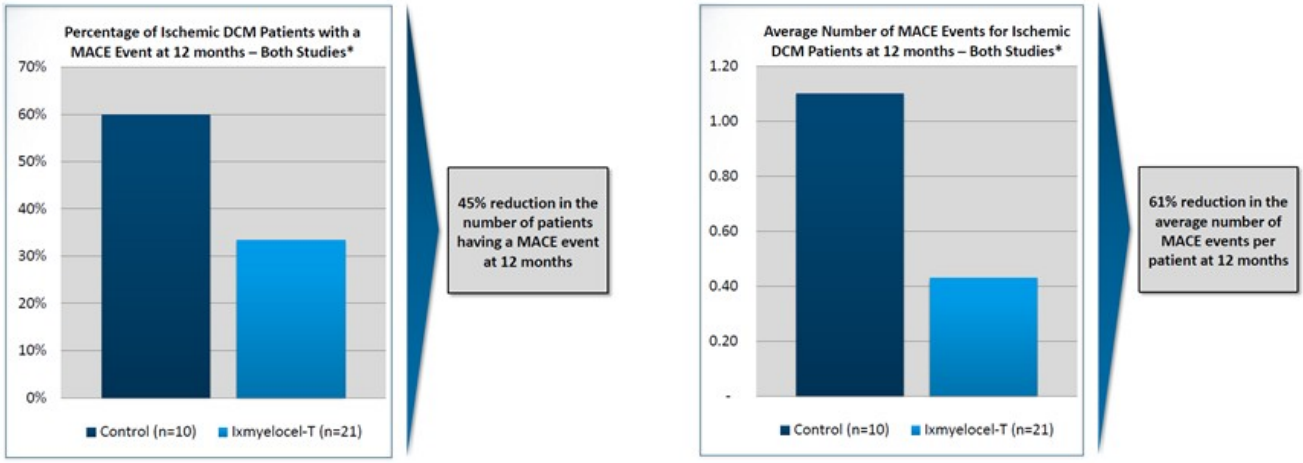
On January 21, 2014, the company entered into a common stock purchase agreement (CSPA) with Lincoln Park Capital Fund, LLC (Lincoln Park) to sell to Lincoln Park up to $15.0 million in shares of its common stock, subject to certain limitations, from time to time over the 30-month period. Terms allow for Aastrom to sell, at its sole discretion, up to 50,000 shares of common stock in regular purchases, increasing to amounts of up to 100,000 shares depending upon the closing sale price of the common stock. Lincoln Park buys the shares at the 10 business day trading average for Aastrom stock, and has a floor price of $2.50 per share.

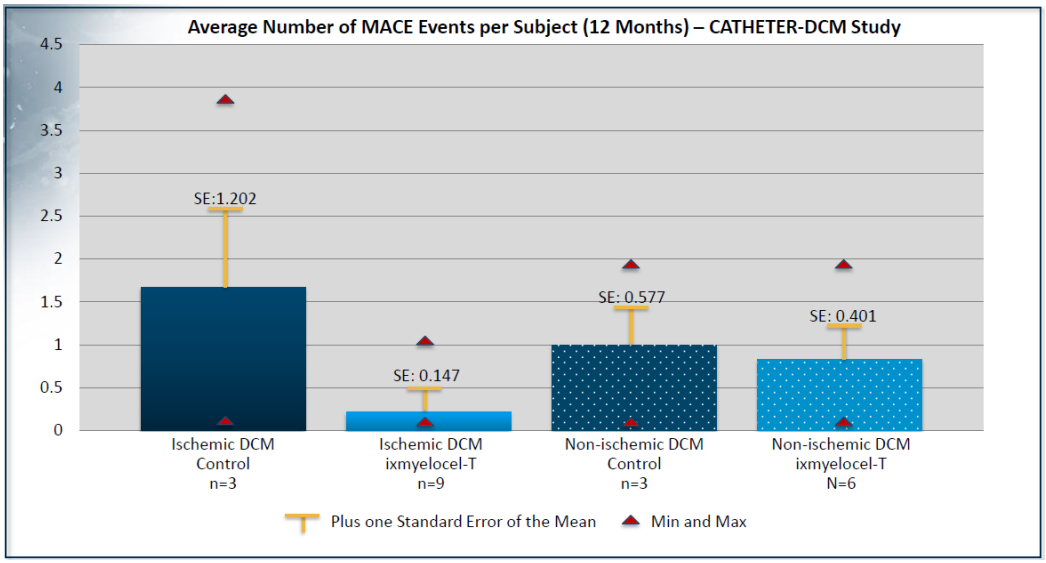
REASON # 1 → Between the ATM with MLV and the CSPA with Lincoln Park, we believe Aastrom has enough cash or access to cash to fund operations through the very important Phase 2 results of the ixCELL-DCM study around the middle of 2015.

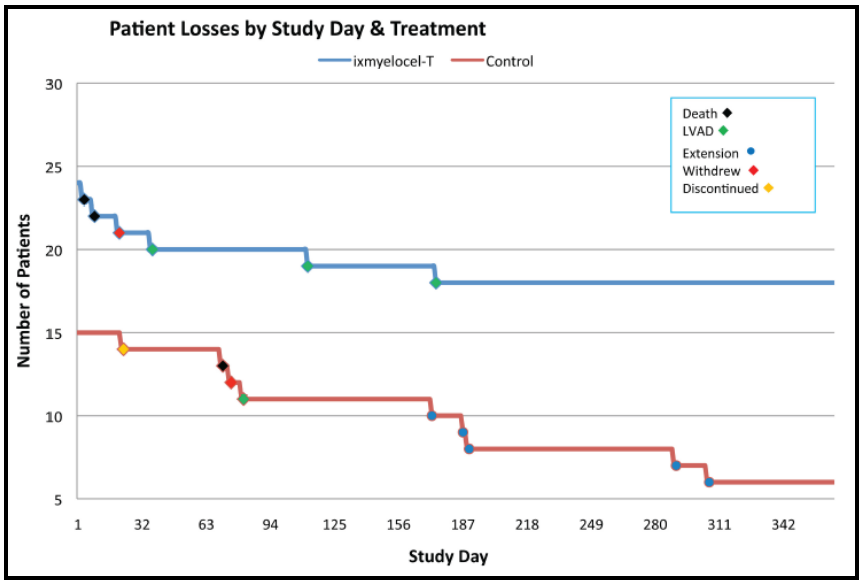
ixCELL-DCM On Track

According to management, the company's Phase 2b ixCELL-DCM study, initiated in April 2013, continues on plan. Enrollment has progressed at 38 centers so far, and we believe will be completed by the middle of 2014. Aastrom has previously generated strong proof-of-concept in ischemic DCM. A twelve month follow-up analysis from the company's phase 2a Catheter-DCM study was presented at the Society for Cardiovascular Angiography and Interventions (SCAI) in May 2012. We learned that management will publish the combined data from both Phase 2a DCM studies, Impact and Catheter, sometime during the second quarter 2014. We believe publishing this data in a respected, peer-reviewed journal will help drive interest and awareness to Aastrom and the potential for ixmyelocel-T in this indication. Below we highlight the key primary findings from these two studies.

Combined Data From Phase 2a DCM Studies

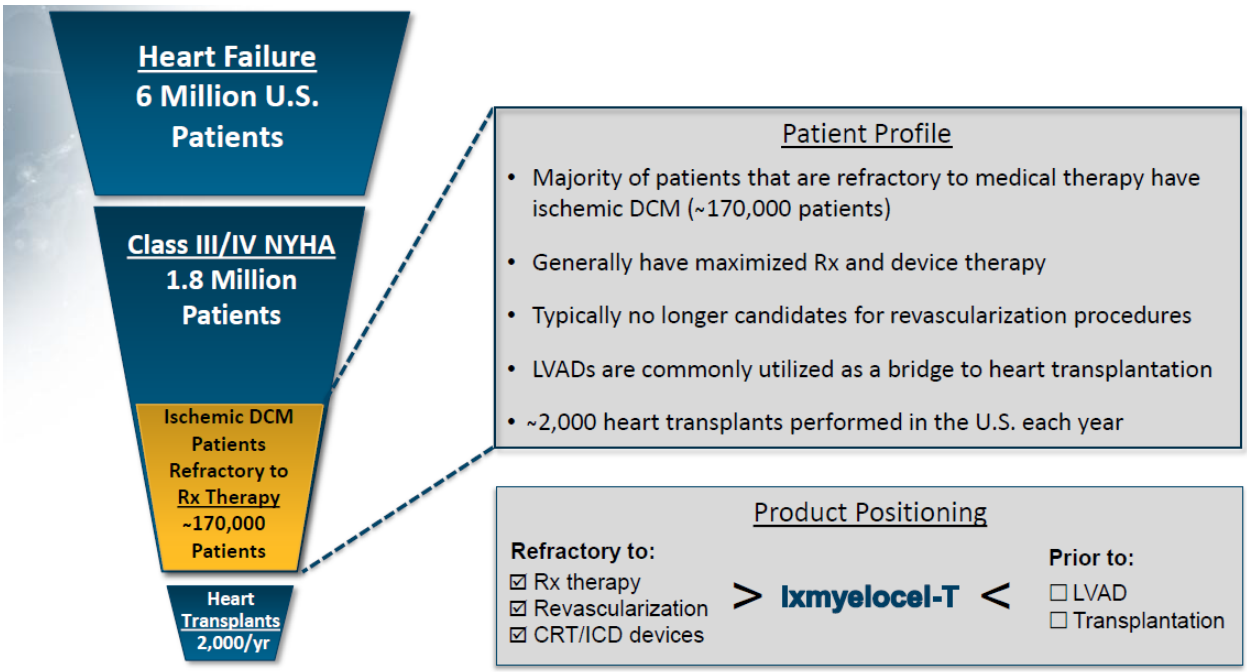






These were both small studies, so no statistically significant results can really be determined, but both trials pointed to a reduction in MACE and improvement in quality of life measures with Ixmyelocel-T vs. the control. Also, and similar for both studies, the data showed an improved outcome for the ischemic DCM patients far greater than for the idiopathic DCM patients. We believe that efficacy observations related to structural and functional end points including MACE, New York Heart Association (NYHA) functional classification, 6-minute walk distance were consistent with improved function of impaired myocardium.

It is clear to us based on the data Aastrom has generated to date that ixmyelocel-T has utility in ischemic DCM. Management was clearly excited about the potential for the drug given the large market opportunity, with an estimated 170,000 patients seeking treatment, and "sweet-spot" focus for ixmyelocel-T positioned as an alternative to LVAD or heart transplantation. We expect top-line data from ixCELL-DCM around the middle of 2015.



Sources: Heidenreich et al. Circulation 2011;123:933-944; Health Research International; America Heart Association

…What's It Worth…

We have done our best to try to value ixmyelocel-T in DCM. Above we noted top-line data from the ixCELL-DCM study around the middle of 2015. Assuming this data is positive, we believe Aastrom will be able to partner the drug for a Phase 3 trial to start in 2016. We believe the Phase 3 trial will take a similar two years to enroll and report data, putting the potential NDA in 2018 and approval in 2019. Approximately 0.6% of the U.S. adult population is classified NYHA Class III/IV. Approximately 15% of these patients have DCM and approximately 60% are considered ischemic in nature (source: American Heart Association). This equates to a target patient population of around 170,000, consistent with the graphic shown above.

We model 5% peak market penetration in 2024, with ixmyelocel-T priced at $75,000 per course of treatment, which sounds high but is less than half the cost of an LVAD or heart transplant. This equates to peak U.S. sales of $600 million. We believe sales outside the U.S. will total $400 million, bringing peak worldwide sales of ixmyelocel-T in DCM to $1.0 billion. We believe Aastrom can partner for this indication for $25 million upfront, $75 million regulatory, and $250 million in backend milestones plus 20% royalty on sales. We apply a 25% discount rate and 20% probability of success to arrive at a current NPV for the program of $30 million.

REASON # 2 → Our calculated fair-value for ixmyelocel-T in DCM of $30 million is higher than the current market capitalization of the entire company only $22 million.

Don't Ignore CLI

All hope is not lost in CLI however. REVIVE-CLI did enroll 41 patients, and management expects to report findings from the study around June 2014. The data from these 41 patients, which essentially amounts as another Phase 2 study, along with the previous Phase 2 work from RESTORE-CLI, will be packaged for review by the FDA and potential development partners. Ultimately, we believe Aastrom will look to re-position ixmyelocel-T in CLI as an adjunctive therapy alongside of last-hope revascularization. We sat down for a face-to-face meeting with management in January 2014. During our meeting management spoke about the potential use of the autologous cell therapy in wound healing, an area of significant interest by managed care providers when treating severe CLI patients. In the meantime, Aastrom is also working with potential independent investigators looking to conduct small studies evaluating ixmyelocel-T as adjunct therapy to an endovascular procedure in CLI patients. The company anticipates filing an IND for this indication prior to the end of the year. Assuming a study can begin in the first quarter 2014, we anticipate initial study results in the second quarter 2015.

…What's It Worth…

We have done our best to try to value ixmyelocel-T in CLI. Above we noted top-line data from the truncated REVIVE-CLI study around June 2014. Assuming this data is positive, we believe Aastrom will be able to partner the drug for a second Phase 3 trial to start in 2015. We believe the Phase 3 trial will take a similar two years to enroll and report data, putting the potential NDA in 2018 and approval in 2019. Approximately 5% of the U.S. adult population has peripheral artery disease (PAD). Approximately 20% of these patients have progressed to critical limb ischemic (CLI), and approximately 5% are considered "no option" for revascularization (source: American Heart Association). This equates to a target patient population of around 135,000. This is consistent with data we found noting approximately 75,000 lower limb amputations in the U.S. each year.

We model 6% peak market penetration in 2024, with ixmyelocel-T priced at $50,000 per course of treatment, which sounds high but is roughly the same cost as a lower-limb amputation procedure. This equates to peak U.S. sales of $500 million. We believe sales outside the U.S. will total $300 million, bringing peak worldwide sales of ixmyelocel-T in CLI to $800 million. We believe Aastrom can partner for this indication for $25 million upfront, $75 million regulatory, and $250 million in backend milestones plus 20% royalty on sales. We apply a 25% discount rate and 20% probability of success to arrive at a current NPV for the program of $25 million.

REASON # 3 → Our calculated fair-value for ixmyelocel-T in CLI of $25 million is higher than the current market capitalization of the entire company only $22 million.

Manufacturing & Platform Technology

Something that we think the market is missing about Aastrom is the manufacturing capabilities and scalability of the platform, as well as the economics of the platform. Most investors will tell you allogenic products, mistakenly characterized as "off-the-shelf" products, will carry significant gross margin advantages over an autologous product like ixmyelocel-T. However, management tells us the cost of goods on one treatment with ixmyelocel-T is around $2,500 to $3,000. Given the suspected commercialization price for DCM around $75,000 per treatment, a bargain compared to the $150,000+ for implantation of an LVAD, ixmyelocel-T will carry greater than 90% gross margin once commercialized. That's the beauty of having an orphan drug designation. Those impressive economics are sure to attract a pharmaceutical partner if the data is good.

Beyond DCM and CLI, Aastrom is working with the University of Michigan, the National Institutes of Health, the Burroughs Welcome Fund, and the Oral and Maxillofacial Surgery Foundation evaluating ixmyelocel-T treatment for patients with craniofacial defects undergoing reconstructive surgery. Results from the first of these studies, which were recently published in the Journal of Cell Transplantation, demonstrated that ixmyelocel-T accelerated bone regeneration in craniofacial bone defects. These findings further highlight the potential utility of ixmyelocel-T to repair damaged tissue. Enrollment in another study is expected to be completed by the end of this year. We anticipate data from this study in the second quarter of 2015.

REASON # 4 → We believe there is an inherent misunderstanding of Aastrom's platform technology, the scalability of the manufacturing, and the strong economics behind the business model. We do not believe this hard asset is reflected in the current valuation.

PROJECTED FINANCIALS

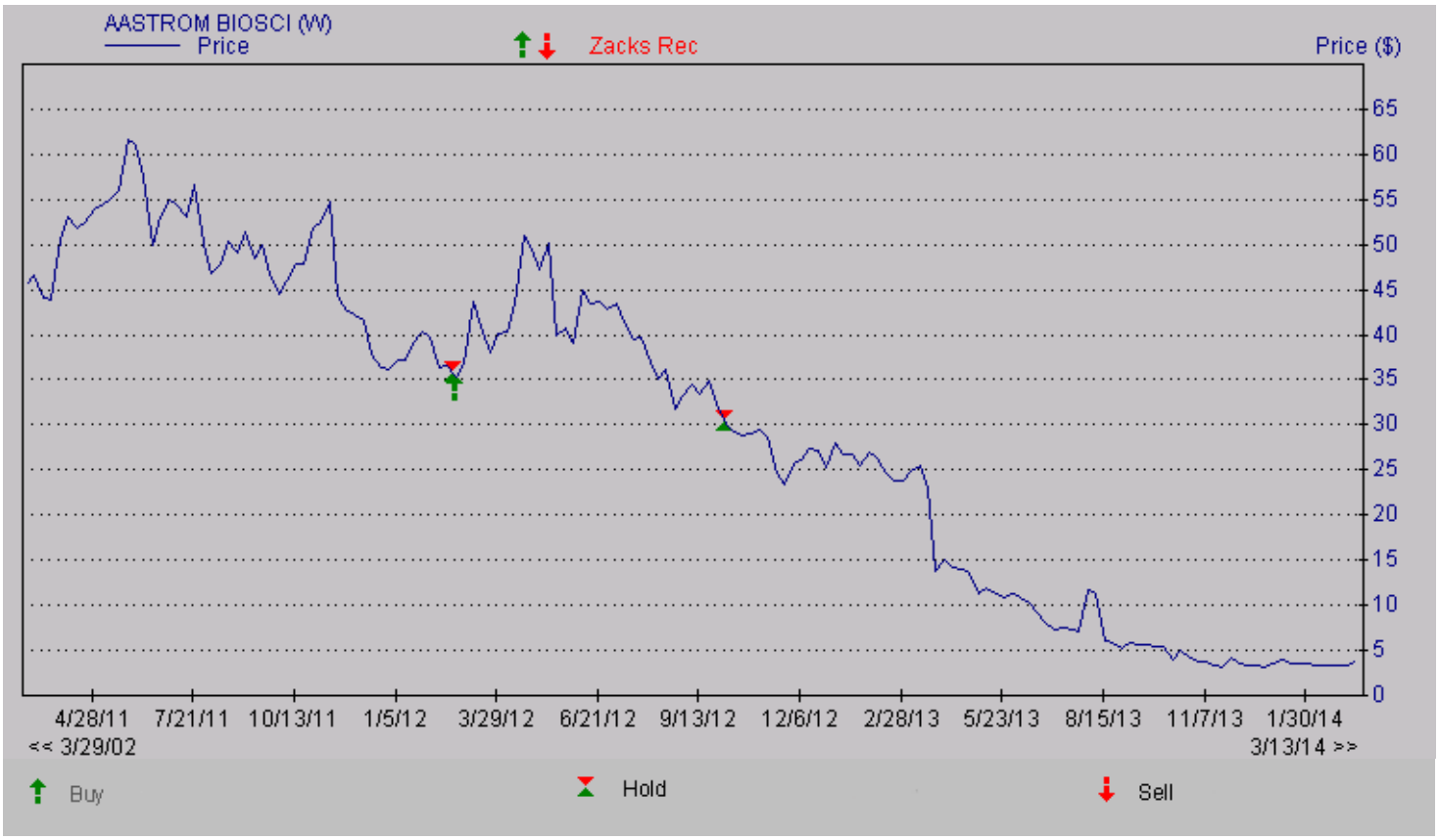
Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-12	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Dec-15	Dec-16
	2012 A	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
R&D Agreements / Grants	**$0.021**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0.0%*	*0%*	-	-	-	-	*0.0%*	*0%*	*0%*
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0.0%*	*0.0%*	-	-	-	-	*0.0%*	*0.0%*	*0.0%*
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Product Sales & Rentals	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-
Research & Development	$26.0	$15.1	$3.5	$3.8	$3.5	$3.6	$14.4	$15.0	$16.0
% R&D	-	-	-	-	-	-	-	-	-
Selling, General, and Admin	$7.8	$5.9	$1.5	$1.3	$1.4	$1.5	$5.7	$6.0	$6.5
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($33.8)	($21.0)	($5.0)	($5.1)	($4.9)	($5.1)	($20.1)	($21.0)	($22.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Income (Expenses)	$4.3	$5.3	$2.0	$2.1	$2.2	$2.3	$8.6	$9.0	$9.0
Pre-Tax Income	($29.5)	($15.6)	($3.0)	($3.0)	($2.7)	($2.8)	($11.5)	($12.0)	($13.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($29.5)	($15.6)	($3.0)	($3.0)	($2.7)	($2.8)	($11.5)	($12.0)	($13.5)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($14.31)**	**($5.18)**	**($0.48)**	**($0.45)**	**($0.40)**	**($0.40)**	**($1.73)**	**($1.41)**	**($1.35)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	2.1	3.0	6.2	6.6	6.8	7.0	6.7	8.5	10.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2014, Zacks Investment Research. All Rights Reserved.

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, Jason Napodano, 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, investment 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 per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities in the issuers which they cover. 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 1047 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- 16.5%, Hold/Neutral- 77.7%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.