Zacks Small-Cap Research

November 12, 2013
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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Third Quarter Financial and Signs for Progress…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/05/2012
Current Price (11/12/13)	$3.69
Target Price	**$5.00**

UPDATE

We wouldn't call Aastrom a "pretty situation", but it looks like the majority of damage has been done and with several potential catalysts on the horizon: 1) Completing enrollment in ixCELL-DCM in the first quarter 2014, 2) reporting data from the 40 patients in REVIVE-CLI in the second quarter 2014, and 3) reporting data from ixCELL-DCM in the second quarter 2015. However, it is difficult to call a bottom in the shares given the need for potentially as much as $15 to $20 million in new capital to fund operations in 2014 and 2015.

That being said, the recent offering at $6.00 per share is a good sign, showing that investors are still willing to put cash into the Aastrom story. We think the shares are fairly-valued between $5.00 and $7.50 per share, but remain 'Neutral' with respect to owning the stock ahead of long-term financing.

SUMMARY DATA

52-Week High	**$29.80**
52-Week Low	**$3.66**
One-Year Return (%)	**-87.28**
Beta	**0.79**
Average Daily Volume (sh)	**188,564**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**0.72**
Institutional Ownership (%)	**N/A**
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)
2012	0 A	0 A	0 A	0 A	0 A
2013	0 A	0 A	0 A	0 E	0 E
2014					0 E
2015					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$5.03 A	-$4.41 A	-$3.33 A	-$3.61 A	-$14.31 A
2013	-$3.03 A	-$2.14 A	-$0.75 A	-$1.00 E	-$6.12 E
2014					-$2.63 E
2015					-$2.36 E

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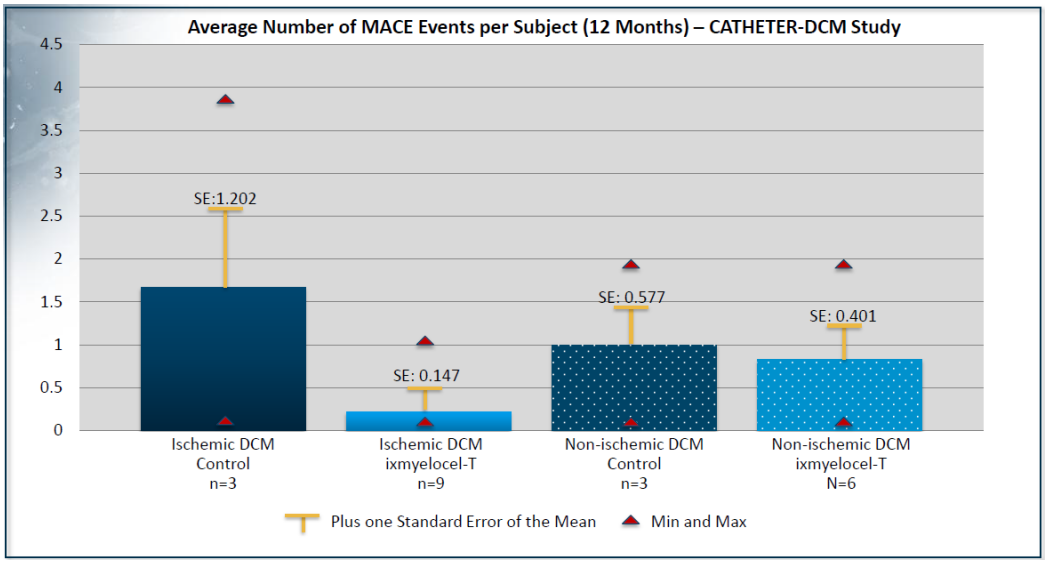
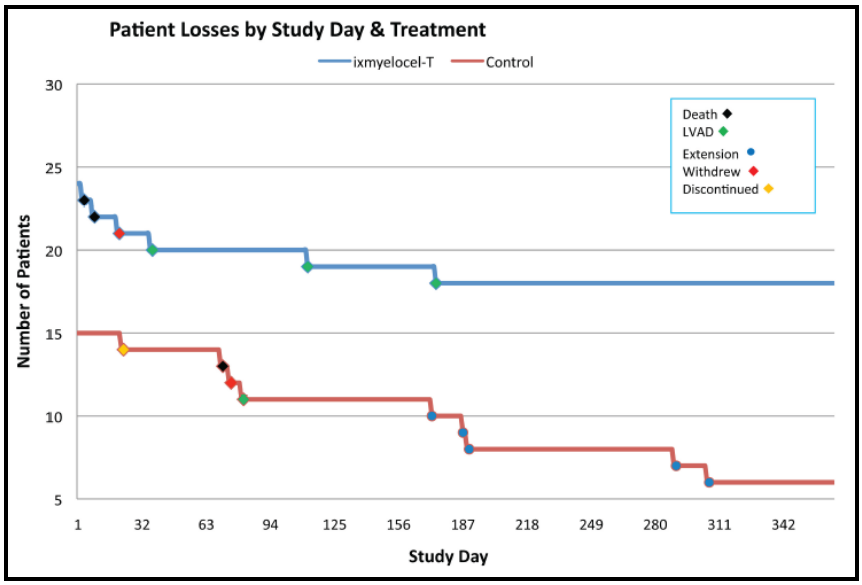
WHAT'S NEW

Focus Moves To DCM

Enrollment in the Phase 2 ixCELL-DCM study, initiated in April 2013, continues on plan. The company had previously generated strong proof-of-concept in 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. Slides from this presentation can be found via this link. This was a 22 patient study designed to evaluate the safety and efficacy of intra-myocardial delivery of ixmyelocel-T in ischemic and non-ischemic DCM patients with NYHA Class III/IV heart failure. A summary of the efficacy findings is presented below.

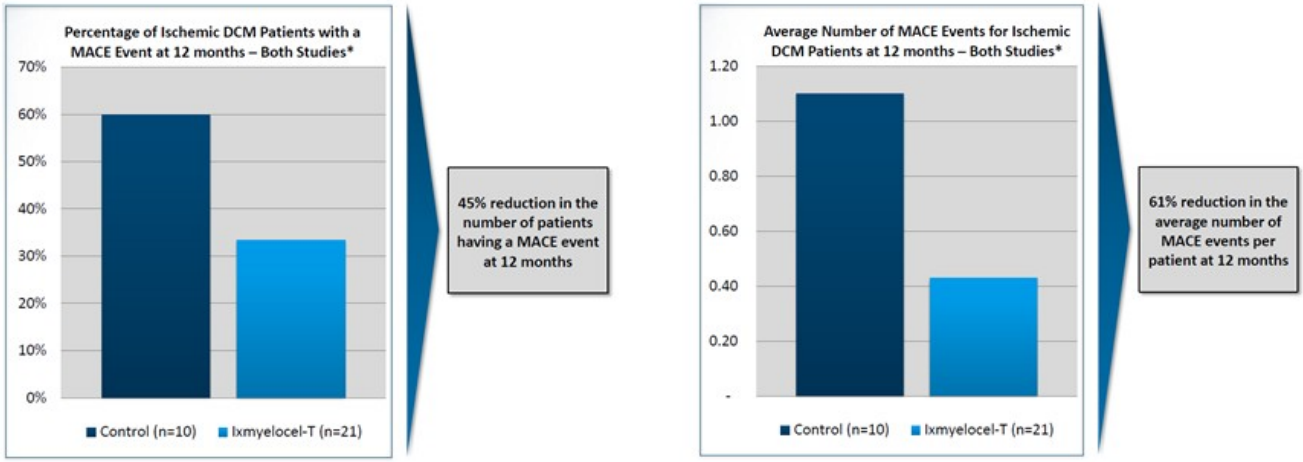


Proof-of-concept for ixmyelocel-T was also demonstrated in the IMPACT-DCM phase 2a trial (see poster presentation from the HFSA annual meeting in September 2011 or this interim analysis of the results presented at the IC3D meeting in January 2011. IMPACT-DCM was a 40 patient study in which patients received ixmyelocel-T via a mini-thoracotomy or thorascoscopy for injection into the left ventricle. Results of this study showed superior outcomes for ischemic DCM patients (on MACE, NYHA Class, and 6 minute walk) compared to the control. Study discontinuations were also significantly less for the ixmyelocel-T group vs. the control (as seen below):



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.

Combined Data From Phase 2a DCM Studies



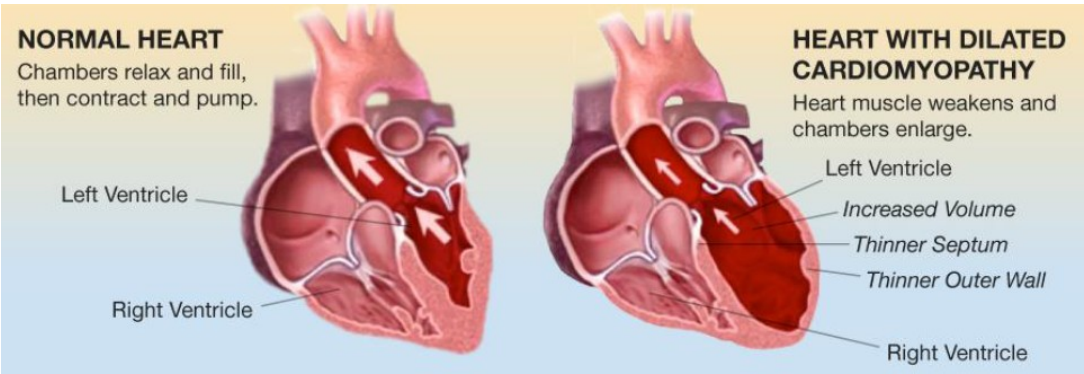
…The ixCELL-DCM Study…

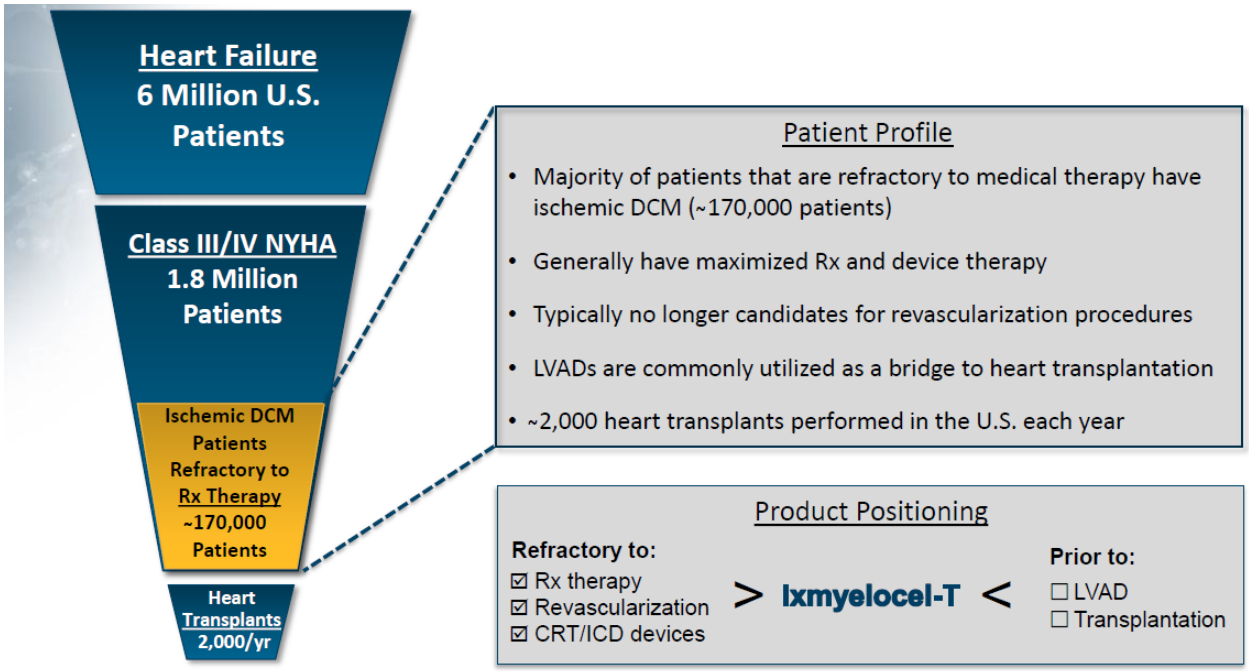
The company's ixCELL-DCM study is designed to evaluate the safety and efficacy of ixmyelocel-T compared to placebo in patients with advanced heart failure due to ischemic DCM. The ixCELL-DCM trial is a randomized, double-blind, placebo-controlled phase 2b study with a planned enrollment of 108 patients age 30-85 at approximately 30 sites in the U.S. and Canada. Subjects will be diagnosis of ischemic DCM according to WHO criteria and be classified as NYHA Class III or IV heart failure, with LVEF ≤ 35%. In the study, ixmyelocel-T will be administered via catheter-based injections using the NOGA® Myostar™ injection system.

The primary endpoint of the trial will be the number of events per patient, which include all-cause mortality, all-cause hospitalizations or unplanned hospital visits to treat worsening heart failure over 12 months (MACE). Secondary endpoints include additional clinical function, structural, symptomatic / quality of life, and biomarker measures at 3, 6, and 12 months. Guidance is to complete enrollment in the study by the end of the first quarter 2014, and then present top-line data in the second quarter 2015.

…A Little On DCM…

Ischemic DCM is a fairly large market opportunity for Aastrom. There are over 1.5 million Americans with NYHA Class III/IV heart failure. The New England Journal of Medicine estimates that in the U.S. alone 120,000 people currently suffer from ischemic DCM. Other sources report estimates of up to 150,000. These are patients that have maximized their benefit on pharmaceutical options, may be failing left ventricular assist devices (LVADs) and currently awaiting heart transplantation. Given a potential population of 125,000 (our estimate) patients seeking an alternative treatment option, we see Aastrom's ixmyelocel-T as a potential $500 million opportunity.





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

We remind investors that the FDA has granted Orphan Drug Designation to Aastrom for use of its ixmyelocel-T in patients with DCM. Aastrom also recently established a steering committee of internationally-renowned cardiovascular and cell therapy clinical investigators to support and help guide the ixCELL-DCM study. In addition to Dr. David Recker, the company's Chief Medical Officer, the committee is comprised of Dr. Amit Patel, Director of Clinical Regenerative Medicine and Tissue Engineering at the University of Utah; Dr. Timothy Henry, Director of Research at the Minneapolis Heart Institute Foundation; Dr. Anthony DeMaria, Chair in Cardiology and Founding Director of the Sulpizio Cardiovascular Center at UC San Diego; and Dr. Gary Schaer, Director of Cardiology Research at Russ Medical Center in Chicago.

Pipeline Not Lost

…PAD / CLI…

Despite the strategic change in R&D focus and discontinuation of enrollment in the phase 3 REVIVE-CLI study, Aastrom did manage to enroll 40 patients at 15 clinical sites. The company owes it to these patients, and investors, to continue to monitor these 40 patients and provide an update on the outcome from the truncated REVIVE-CLI when they can. As such, management anticipates reporting top-line data for safety and certain efficacy end points, including mortality, amputations and wound closure at 12 months, late in the second quarter 2014. 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.

…Craniofacial Reconstruction…

Finally, 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.

Financial Review

On November 12, 2013, Aastrom Biosciences reported financial results for the third quarter 2013. The company did not report any meaningful revenues in the quarter. Operating expenses in the quarter totaled $3.6 million, consisting of $2.6 million in R&D and $1.1 million in SG&A. Both R&D and SG&A were down significantly from the second quarter 2013 on a number of reasons. R&D declined due to reduction in clinical trial expenses due to stopping enrollment in the Phase 3 REVIVE-CLI clinical trial. Both R&D and SG&A declined due to corporate restructuring and the reversal of non-cash stock compensation expense related to the forfeiture of stock options.

Net loss for the quarter was $2.3 million, or $0.75 per share. The company exited the quarter with $10.8 million in cash and investments. On August 13, 2013, Aastrom announced the pricing of a public offering of 29.0 million units at $6.00 per unit (reverse-split adjusted). Each unit consists of one share of stock and one warrant to purchase one share of stock at $7.40 (reverse-split adjusted) per share. The warrants are exercisable immediately and have a term of five years. Aastrom granted underwriters (Aegis and Maxim) a 45-day option to purchase up to an additional 0.215 million units to cover over-allotments.

On August 16, 2013, the offering closed, grossing proceeds from the offering, along with 0.05 million shares of the allocated over-allotment, roughly $9.0 million. Based on a similar projected cash burn of $4.5 to $5.0 million in the next several quarters going forward, we believe Aastrom now has enough cash to fund operations until the end of March 2014. As such, we believe the company will require additional capital to keep the primary clinical stage program, ixCELL-DCM, ongoing to the data presentation in 2015.

Conclusion – Is There A Light At The End Of This Tunnel?

We wouldn't call Aastrom a "pretty situation", but it looks like the majority of damage has been done and with several potential catalysts on the horizon: 1) Completing enrollment in ixCELL-DCM in the first quarter 2014, 2) reporting data from the 40 patients in REVIVE-CLI in the second quarter 2014, and 3) reporting data from ixCELL-DCM in the second quarter 2015. However, it is difficult to call a bottom in the shares given the need for potentially as much as $15 to $20 million in new capital to fund operations in 2014 and 2015. That being said, the recent offering at $6.00 per share is a good sign, showing that investors are still willing to put cash into the Aastrom story.

For Aastrom, the focus needs to be on generating the clinical data with ixmyelocel-T in both DCM and CLI that the market so desperately needs to see before an uptrend in the shares becomes likely, but there does seem to be a light at the end of this somewhat long tunnel. We've made a number of changes to our DCF model and believe that $5.00 to $7.50 per share is a reasonable valuation given the potential for ixmyelocel-T in DCM and CLI.

PROJECTED FINANCIALS

Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-11	Dec-12	Mar-13	Jun-13	Sep-13	Dec-13	Dec-13	Dec-14	Dec-15
	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
R&D Agreements / Grants	**$0**	**$0.021**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*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	$21.3	$26.0	$5.5	$3.7	$2.6	$3.5	$15.3	$12.5	$15.0
% R&D	-	-	-	-	-	-	-	-	-
Selling, General, and Admin	$7.7	$7.8	$1.6	$1.6	$1.1	$1.3	$5.6	$4.5	$5.0
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($29.1)	($33.8)	($7.2)	($5.2)	($3.6)	($4.8)	($20.8)	($17.0)	($20.0)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Income (Expenses)	$9.4	$4.3	$0.4	$0.3	$1.4	$0.3	$2.4	$1.2	$1.1
Pre-Tax Income	($19.7)	($29.5)	($6.8)	($4.9)	($2.3)	($4.5)	($18.5)	($15.8)	($18.9)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($19.7)	($29.5)	($6.8)	($4.9)	($2.3)	($4.5)	($18.5)	($15.8)	($18.9)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($10.19)**	**($14.31)**	**($3.03)**	**($2.14)**	**($0.75)**	**($1.00)**	**($6.12)**	**($2.63)**	**($2.36)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	1.9	2.1	2.2	2.3	3.0	4.5	3.0	6.0	8.0

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

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