Zacks Small-Cap Research

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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Insight From Recent Meeting With Management

UPDATE

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/05/2012
Current Price (01/22/14)	$3.92
Target Price	**$5.00**

On Sunday, January 12, 2014, we arrived in San Francisco, CA for the annual JP Morgan Healthcare Conference, as well as the parallel Biotech showcase and OneMedForum Conferences. This was the eighth year in a row that we made the trip to San Francisco for these events, which are a must-attend for serious healthcare investors.

During my three days in San Francisco, I conducted 25 one-on-one meetings with various managements of small and mid-cap biotechnology and specialty pharmaceutical companies. Below are some "notes" from our meeting with Aastrom Bio.

SUMMARY DATA

52-Week High	**$27.80**
52-Week Low	**$3.21**
One-Year Return (%)	**-84.96**
Beta	**0.82**
Average Daily Volume (sh)	**215,382**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**2.06**
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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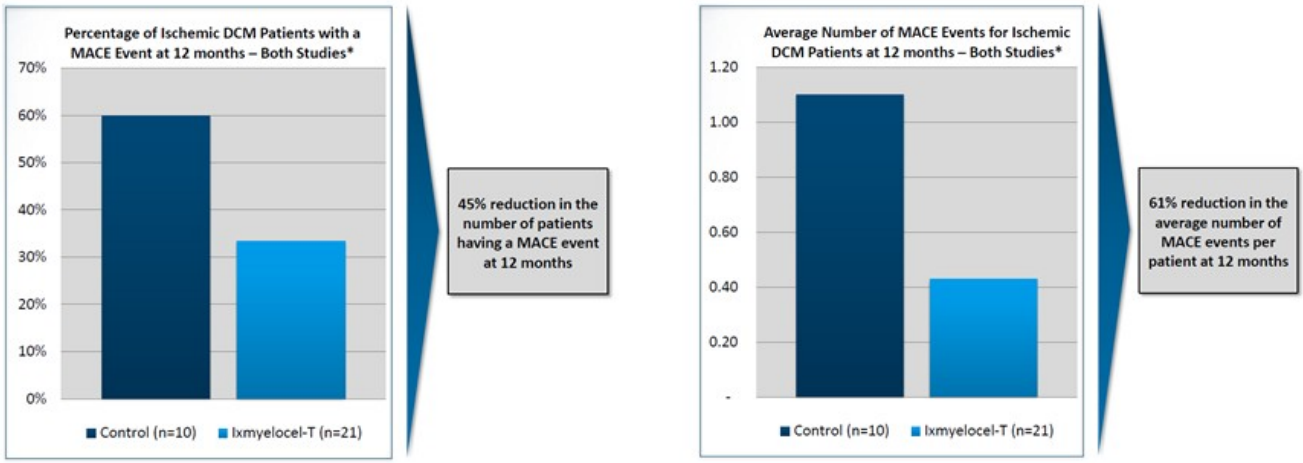
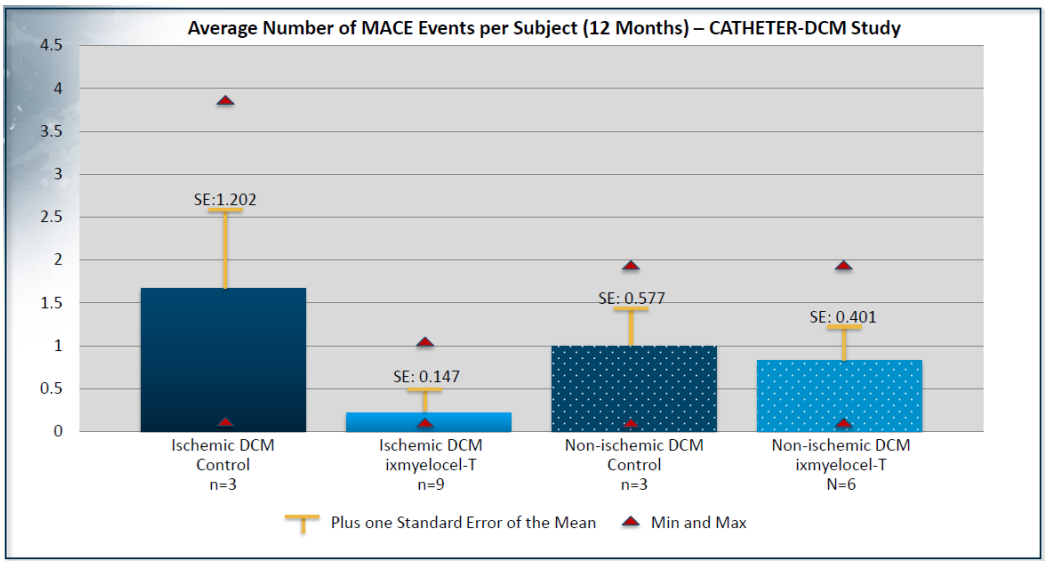
Aastrom Biosciences (ASTM)
Meeting took place with Dominick Colangelo, CEO, and Daniel Orlando, CCO.

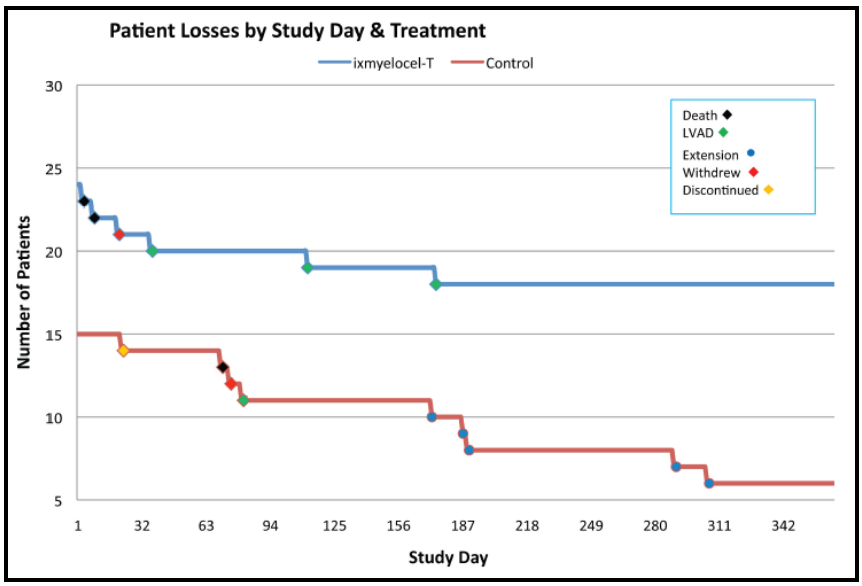
Aastrom has had a difficult past twelve months, no doubt. The shares declined by 88% in 2013. The decline in the shares was sparked by the company's decision in March 2013 to discontinue new enrollment the Phase 3 REVIVE-CLI trial and refocus efforts with Ixmyelocel-T on ischemic dilated cardiomyopathy. The decision came only a few weeks after Dominick Colangelo was appointed to the role of President and CEO. Though a painful decision, we believe it was the right decision given the difficulties of enrolling patients with severe critical limb ischemia into the REVIVE-CLI study, and the growing costs associated with the program.

According to management, the company's Phase 2b ixCELL-DCM study, initiated in April 2013, continues on plan. Enrollment has progressed at 36 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

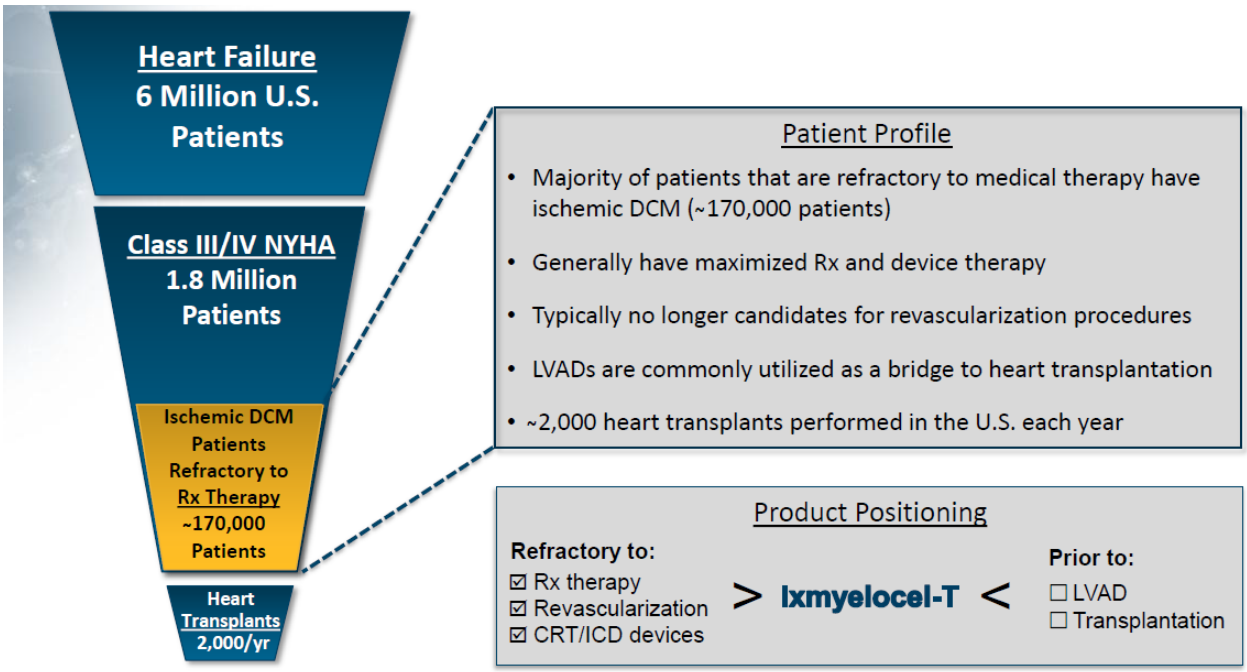






These were both small studies, so no statistically significant results can really be determined, but both trials pointed to a reduction in MACE and improvement in quality of life measures with Ixmyelocel-T vs. the control. Also, and similar for both studies, the data showed an improved outcome for the 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

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. 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.

The biggest revelation from our meeting with Aastrom was an in-depth discussion of the economics behind ixmyelocel-T. 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 $40,000 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. Over 170,000 target patients, 90% gross margin, orphan drug designation…those impressive economics are sure to attract a pharmaceutical partner if the data is good when the timing is right.

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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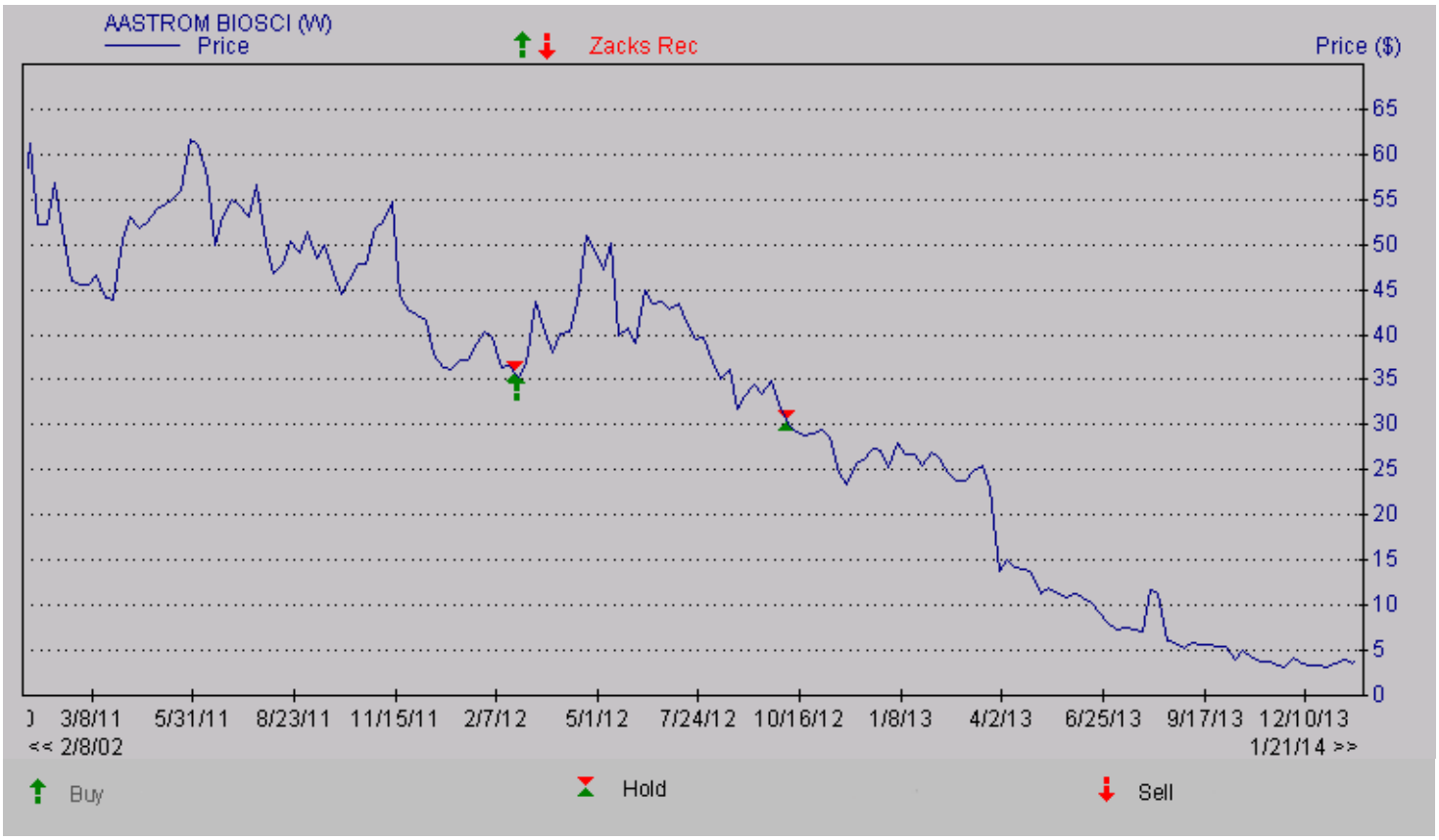

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