Zacks Small-Cap Research

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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Waiting For REVIVE Enrollment To Accelerate…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/05/2012
Current Price (11/09/12)	$1.45
Target Price	**$2.50**

UPDATE

We continue to rate shares of Aastrom Bio 'Neutral'.

Although we believe the shares remain an attractive long-term investment in the biotech sector, we see a number of issues that are expected to continue to weigh on the shares over the near-term. These issues include: the slower-than-expected enrollment in phase 3 REVIVE, the need for capital in the first half of 2013, and the search for a new CEO.

Accordingly, we see the stock trending side-ways for the better part of the next year; thus a more neutral position with respect to the stock price is warranted.

SUMMARY DATA

52-Week High	**$2.75**
52-Week Low	**$1.44**
One-Year Return (%)	**-41.80**
Beta	**0.13**
Average Daily Volume (sh)	**102,108**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$63**
Short Interest Ratio (days)	**11.07**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**1**
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 2012 Estimate	**N/A**
P/E using 2013 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)
2011	0 A	0 A	0 A	0 A	0 A
2012	0 A	0 A	0 A	0 E	0 E
2013					0 E
2014					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.13 A	-$0.26 A	-$0.05 A	-$0.07 A	-$0.51 A
2012	-$0.25 A	-$0.22 A	-$0.17 A	-$0.23 E	-$0.86 E
2013					-$0.91 E
2014					-$0.75 E

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WHAT'S NEW

Financial Results

On November 8, 2012, Aastrom Biosciences reported financial results for the third quarter ended September 30, 2012. The company did not report any revenues for the third quarter 2012, nor has the company reported revenues for any quarter this year. This was in-line with expectations.

Net loss for the third quarter totaled $7.2 million, driven by $6.1 million in R&D and $2.1 million in SG&A. Both line items were in-line with expectations. The company also recorded a net gain of $2.2 million associated with the change in fair value of warrant liability and a $1.2 million expense for the accretion of convertible preferred stock. The net loss equated to $0.17 per share. This was slightly better than our expectations for an EPS loss of $0.21 per share. As of October 31, 2012, Aastrom had 43.8 million basic shares outstanding.

...CEO To Retire...

On October 4, 2012, we learned that Aastrom's president and CEO, Tim Mayleben, plans to retire once the company can hire a successor. As a result, the Aastrom board of directors has initiated a search for a new CEO.

We are disappointed that Mr. Mayleben will be leaving the company. He has been instrumental in turning Aastrom around over the past few years and driving ixmyelocel-T from early-stage development into phase 3 trials for critical limb ischemia and phase 2b for dilated cardiomyopathy. But more importantly, in our conversations with Tim, he was adamant about cleaning up Aastrom's capital structure and bringing long-term investors to the story at shareholder friendly terms. The March 2012 financing which secured a net $37.6 million was an example of this commitment. Although he will continue to serve as a member of the board of directors after the transition, it remains to be seen whether or not the new CEO will be as committed to building shareholder value the way Mr. Mayleben has been. Mr. Mayleben holds 133,000 shares of common stock.

...Capital Needs...

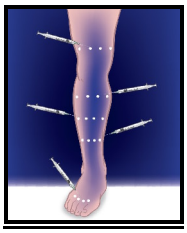
Aastrom exited the third quarter ended September 30, 2012 with $21.1 million in cash and investments. Cash use in the third quarter was $7.7 million, consistent with the $8.1 million used in the second quarter 2012. For the fourth quarter, we suspect cash usage again will be around $8 million. Therefore, we model cash at the end of the year (December 31, 2012) at around $13 million. We think Aastrom will require another round of financing at some point during the first half of 2013.

Although the valuation remains attractive, we are concerned that the slow enrollment and lack of catalysts on the clinical front, noted below, may make it difficult to secure funding on such shareholder friendly terms as the $37.6 million noted above form the March 2012 financing. We also view the CEO transition as a potential hurdle to raising cash. The new CEO needs to be in place long enough that both existing and new shareholders feel comfortable with the direction of the company. Aastrom needs to find a new CEO soon, and begin shopping around for financing early next year. We see this as a major drag on the stock until completed.

Recommendation

We currently rate shares of Aastrom Bio 'Neutral' with a $2.50 fair value calculation. Our concerns over the slow enrollment to date in RENEW and the potential need for cash in the first half of 2013, all while also searching for a new CEO, keep us at a 'Neutral' rating. Our $2.50 target is derived by DCF and can be found at the back of this report.

Phase 3 REVIVE Update



On February 29, 2012, Aastrom Bio announced it had begun patient recruitment in its phase 3 clinical trial, REVIVE, designed to assess the efficacy and safety of ixmyelocel-T in the treatment of patients with critical limb ischemia (CLI). REVIVE will be conducted at 80 sites in the U.S. and will include 594 CLI patients who have no option for revascularization, and also have existing tissue loss due to ischemia. REVIVE will be the largest randomized, double-blind, placebo-controlled, multicenter study ever conducted in patients with CLI, larger than Sanofi's failed phase 3 TAMARIS study conducted in 525 patients.

Patients will be followed for a total of 18 months, including 12 months from randomization for efficacy and an additional six months for safety. The primary endpoint of REVIVE is amputation-free survival at 12 months (AFS-12). The trial is being conducted under a Special Protocol Assessment (SPA) from the U.S. FDA. REVIVE has also been granted Fast Track designation for CLI. Secondary endpoints include adverse events at 18 months, wound closure at 12 months, and incidence of major adverse cardiac events (MACE), including myocardial infarction, chest pain hospitalization, or stroke.

...Slow Enrollment...

On May 9, 2012, Aastrom noted the first patient had been enrolled in the program. On the company's second quarter update call on August 7, 2012, Aastrom noted that 10 patients had been enrolled. On yesterday's third quarter call, the number grew to only 26 patients. A pace of 16 patients over 3 months is clearly behind schedule, and management expressed their disappointment with enrollment numbers to date.

That being said, management does expect enrollment to accelerate in the coming months. Back in August, the majority of the clinical sites, especially many of the ones management expects to be most active, were just beginning to screen patients. Setting up the sites and opening enrollment seems to be taking longer than expected. Management has a goal in mind for each site – a pace of enrollment in terms of patients per month. On the third quarter update call, CEO Tim Mayleben noted that some sites were hitting this goal, but the majority were not. At this point, it remains to be seen whether or not Aastrom can bring the majority of sites up to its desired pace or if there is an underlying problem with the trials design – i.e. enrollment criteria is too strict and / or the independent steering committee is taking too long to adjudicate patients.

Aastrom expects that enrollment will accelerate once these high enrolling sites come on. CEO Tim Mayleben noted on the third quarter call that the ratio of enrolled patients to screened patients to started out very low, but has been slowly improving. We suspect that as both physicians and enrollment centers become more comfortable with the entry criteria for REVIVE, enrollment will improve. To date, the biggest reason for patients being screened by not accepted into REVIE is end-stage renal disease.

Enrollment numbers to date are clearly behind schedule. When the trial initiated management guided to full enrollment in 18 to 24 months. From today, we believe enrollment will still take upwards of 24 months. That means enrollment to complete around the third quarter 2014, with data around mid-2015.

...Statistical Powering Is Key...

The trial is 90% powered to show superiority of ixmyelocel-T over the control (no cells). Management used an assumed treatment effect of 36% to design the trial (12% numerical separation). We remind investors that in the phase 2b RESTORE program, ixmyelocel-T showed a 62% risk reduction vs. the control (p=0.0032).

For the powering assumptions for REVIVE, management used an event rate for the control group of 34.5%, while expecting that ixmyelocel-T will come in around 22.2%.

Key Phase 3 Statistical Assumptions

Pivotal Phase 3 No-option protocol key statistical assumptions
- Ixmyelocel-T AFS event rate – 22.2%
- Placebo/control AFS event rate – 34.5%
- Assumed treatment effect – 36%

	Amputation and Death Event Rate – RESTORE-CLI*			
Treatment Group	**Interim #1**	**Interim #2**	**Final Analysis**	**Wounds at BL**
Ixmyelocel-T	22%	25%	25%	21%
Control	50%	29%	33%	44%

We think ixmyelocel-T works. Therefore, the biggest risk we see with REVIVE is control group doing better than management's assumption, which was based on the TAMARIS and RESTORE-CLI studies. We note, however, that during Aastrom's RESTORE-CLI program, at the company's second interim update, the control group event rate (29%) was trending below what was seen after the first interim update (50%). This, essentially, worked itself out by the end of the trial, where the event rate was 33% for the control. It is also the reason why management has instituted a strict entry criteria looking for patients with confirmed tissue loss - a true "no option" population.

Aastrom will have a blinded interim update after the first 297 patients have been enrolled in REVIVE and completed the 6 month follow-up. Management can add patients to the trial based if the overall blinded data is showing an event rate lower than expectations. An overall event rate lower than expect could mean the control is doing better, the treatment group is doing better, or both are doing better than the powering assumptions. We like the fact that management has baked in this blinded look after 297 patients; it provides the ability to enhance the power of REVIVE if necessary. We expect this to take place around early 2014.

We also note at the data safety monitoring board (DSMB) will be monitoring the trial with unblinded data. The DSMB can stop the trial at any time for safety or efficacy reasons. Efficacy reasons can include futility, or clear statistical separation prior to enrolling the 594 patients.

We estimate the cost at around $30 million ($45-50k per patient). We expect that REVIVE will complete enrollment around the middle of 2014. We are expecting data in early 2015. This should put Aastrom in position to file the New Drug Application (NDA) late 2015, putting U.S. FDA action for the NDA of ixmyelocel-T for CLI late 2016.

…Previous Data Supports Our Optimism…

In November 2011, Aastrom reported the final analysis from the phase 2b RESTORE-CLI trial. The RESTORE-CLI clinical trial assessed the safety and ability of ixmyelocel-T, Aastrom's expanded, bone marrow-derived cellular therapy, to restore damaged tissue in a lower extremity affected by critical limb ischemia (CLI). The results include the final analysis from all 86 randomized patients.

The primary endpoint of RESTORE-CLI was time to first occurrence of treatment failure, defined as major amputation, all-cause mortality, doubling of total wound surface area from baseline, or de novo gangrene. A total of 48 patients were treated with ixmyelocel-T and 24 received a placebo. Adverse event rates in both groups were similar. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure (p =0.0032) with wounds at baseline resulted in a 77% risk reduction in time to first occurrence of treatment failure (p=0.0002) and a positive trend in the REVIVE endpoint of amputation-free survival (61% risk reduction, p=0.0915).

A post hoc analysis of the subgroup of 45 patients yielded impressive separation between the ixmyelocel-T group and the control. The Rutherford-5 AFS rate for the ixmyelocel-T group was 79%, lower than the AFS rate for the overall ixmyelocel-T population at 75%. Results showed even further separation from the control, which showed an AFS rate of 56%, down from the overall control population at 67%. This is a 61% risk reduction (hazard ratio of 0.391). Results were not statistically significant (p=0.0915), but we note the small sample size of only 45 patients, and remind investors that the phase 3 REVIVE program will be nearly 600 patients. And, we remind investors that Aastrom and the U.S. FDA came to an agreement for a Special Protocol Assessment (SPA) on the REVIVE program in July 2011.

All in all we are pleased with the final results from RESTORE-CLI. We think the trial demonstrates excellent proof-of-concept in patients with no option CLI, especially those with confirmed tissue loss. The design of REVIVE is solid. If Aastrom can reproduce similar results in REVIVE to what was presented at AHA on November 14, 2011, we believe the trial will be successful. Full data from RESTORE-CLI was published in the Journal of Molecular Therapy in March 2012 (doi:10.1038/mt.2012.52).

Phase 2a DCM Study Encourages

On May 10, 2012, Aastrom Bio presented the 12-month follow up results from the phase 2a dilated cardiomyopathy (DCM) study at the Society for Cardiovascular Angiography and Interventions (SCAI) Scientific Sessions. The data presentation, entitled "Safety and Efficacy of Ixmyelocel-T, An Expanded Patient-Specific Mixed Cell Therapy, in Dilated Cardiomyopathy" highlighted injection of Aastrom's expanded multicellular therapy using J&J's NOGA/MyoSTAR transendocardial catheter.

…Design Background…

The phase 2a program enrolled 22 patients with ischemic or non-ischemic DCM that had no other options available for revascularization (meaning the next available options are surgical – a heart transplant or LVAD). The study took place at three centers all in the U.S. Patients were randomized 2:1 to receive Ixmyelocel-T + standard of care vs. standard of care alone. Below we highlight some of the more important baseline characteristics of these 22 patients:

	Ixmyelocel-T Group (n=15)	Control (n=7)
Body Mass Index	28.8	27.5
Ejection Fraction (from echo)	23.9	22.3
NYHA III/IV	14/1	6/0
Ischemic / Non-Ischemic DCM	9 / 6	3 / 4

The primary endpoint of the study was safety, with a planned interim analysis conducted when all subjects completed 6 months. There was also a planned final analysis conducted when all subjects completed 12 months, with control patients being able to crossover to the Ixmyelocel-T group after 6 months.

…Safety Improved…

As noted above, a total of 22 subjects were randomized. One subject in the control with NIDCM withdrew prior to day-1 so was not included in the safety assessment. One subject in the Ixmyelocel-T group with NIDCM discontinued due to heart failure on day 322.

	Ixmyelocel-T Group (n=15)	Control (n=7)
12 Month Completers	14 (93%)	5 (83%)

Investigators concluded that transendocardial injection of Ixmyelocel-T was well tolerated in patients with DCM. In fact, management noted that the tolerability of the procedure was significantly better than the previous study (IMPACT-DCM) conducted by Aastrom in which patients received the cells via a minithoracotomy. Adverse events were similar between the Ixmyelocel-T and control group, a clear positive considering the control group underwent no transendocardial injection procedure. We strongly feel that use of the NOGA/MyoSTAR transendocardial catheter is the superior delivery option for cell therapy.

Secondary objectives were included to investigate signs of efficacy, including:

- ✓ Major Adverse Cardiovascular Events (MACE) – The key clinical endpoint
- ✓ Cardiopulmonary stress and 6-minute walk – Key functional endpoints
- ✓ Echo and left-ventricle ejection fraction (LVEF) – Key structural endpoints
- ✓ New York Heart Associate (NYHA classification) – Subjective / Quality of Life endpoints

…Proof-Of-Concept Evident…

Proof-of-Concept was clearly evident by analyzing the data. Given the small size of the trial, no results are statistically significant, but the signs point to a reduction in MACE and improvement in quality of life measures with Ixmyelocel-T. Also, similar to the IMPACT-DCM results, the data shows an improved outcome for the IDCM patients far greater than for the NIDCM patients. We believe that efficacy observations related to structural and functional end points including major adverse cardiovascular events (MACE), New York Heart Association (NYHA) functional classification, 6-minute walk distance were consistent with improved function of impaired myocardium.

The key clinical endpoint is MACE. Below (Figure-1) is a graphical representation of the Time to First Occurrence of MACE. The results show an observational benefit in favor of the Ixmyelocel-T group, although not statistically significant due to the small number of patients (n=19) completing the study. The data in Figure-2 shows the clear separation of benefit for patients with IDCM verses NIDCM.

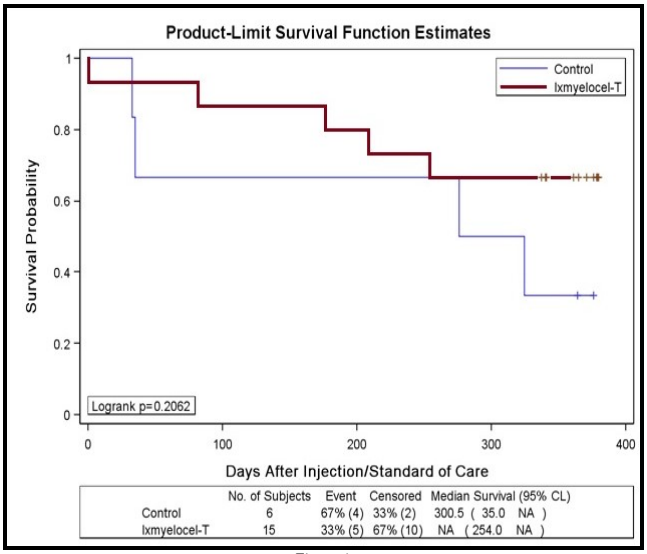


Figure-1

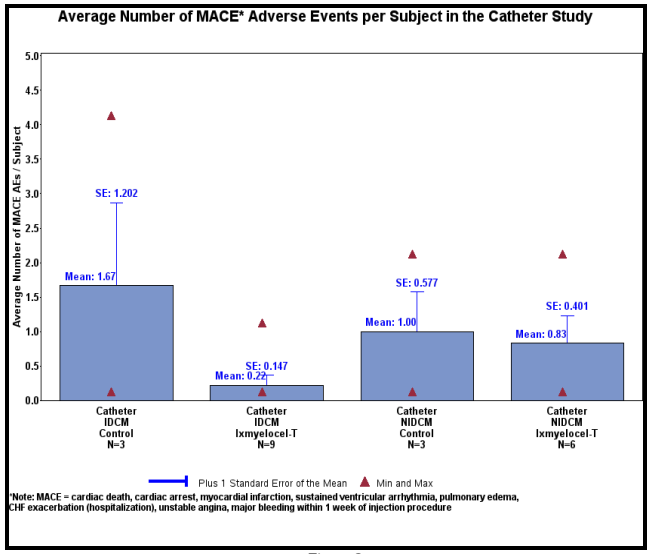


Figure-2

Additional functional and quality of life benefits also trended in favor of the Ixmyelocel-T group, specifically in patients with IDCM. However, no noticeable benefit in ejection fraction was observed in either group.

	IDCM	NIDCM	Control
Improvement in NYHA Class…			
@ 3 Months	7 of 9	3 of 6	0 of 5
@ 6 Months	7 of 9	3 of 6	1 of 5
@ 12 Months	9 of 9	2 of 5	0 of 5
Improvement in 6-Minute Walk Test…			
@ 3 Month	8 of 9	4 of 6	0 of 5
@ 6 Months	7 of 9	5 of 5	4 of 5
@ 12 Months	6 of 9	2 of 4	1 of 5
Increase in Echo Ejection Fraction…			
@ 3 Months	4 of 7	1 of 6	1 of 4
@ 6 Months	5 of 7	2 of 6	1 of 4
@ 12 Months	1 of 5	2 of 5	2 of 4
MACE Adverse Events…			
Average Per Subject	0.22	1.00	1.11

…Phase 2b ixCell-DCM Finally Underway…

Earlier in the year, Aastrom met with the FDA to outline the design and necessary endpoints for a phase 2b study. Management noted on the third quarter call on November 8, 2012 that patient screening has begun and the first patients should be enrolled soon. A quick check to Clinicaltrials.gov (Identifier number NCT01670981) shows patient recruitment is open.

The trial, called ixCELL-DCM (formerly RENEW-DCM), will be randomized, placebo-controlled program using the NOGA/MyoSTAR transendocardial catheter, seeking to enroll about 108 ischemic DCM patients at around 15 to 20 sites all in the U.S. Identifying the right sites and investigators for ixCELL-DCM will be key to its success.

The primary endpoint of the study will be major adverse cardiovascular events (MACE), with 80% powering for statistical significance. Secondary endpoints are expected to include cardio-pulmonary function through imaging, exercise capacity, 6-minute walk test, and safety. We view this as a "registration quality" study, as the data should give Aastrom – and potential partners – a clear sign on the profile of Ixmyelocel-T before proceeding into phase 3. We expect 12 months to enroll, with top-lie data expected early 2014. We estimate the trial will cost Aastrom around $5 million ($50k per patient).

…DCM Backgrounder…

DCM is a condition in which the heart becomes weakened and enlarged, and cannot pump blood efficiently. The expansion of the heart and the decreased function results in poor blood circulation and affect the lungs, liver, and other body systems. In patients with DCM, the left or right ventricular systolic pump function of the heart becomes impaired, leading to progressive cardiac enlargement and hypertrophy, a process called remodeling.

There are an estimated 200k to 250k people living (prevalence) in the U.S. with DCM, with roughly 20,000 new cases (incidence) each year. About one in three cases of congestive heart failure (CHF) is due to DCM. The 1-year survival rate for a patient diagnosed with DCM is roughly 75%. The 5-year survival rate drops to only 30% because many patients with DCM go un-diagnosed until the disease has progressed to the most severe stages.

As a general rule for idiopathic DCM, after 1-year, 1/3rd of patients exhibit improved cardiac function, 1/3rd have stable cardiac dysfunction, and 1/3rd progress to significant cardiac dysfunction. These 1/3rd that progress to severe cardiac dysfunction will require a heart transplant. We remind investors that the FDA has granted Orphan Drug designation to Aastrom for use of its ixmyelocel-T in patients with DCM.

Standard of care for patients with DCM is often to treat secondary co-morbid conditions such as hypertension or renal failure. As such, patients with DCM are often prescribed angiotensin-converting enzyme (ACE) inhibitors, diuretics, beta-blockers, and sometimes digitalis. Anticoagulants may also be used. Artificial pacemakers and left ventricular assist devices (LVADs) may be used in patients with intra-ventricular conduction delay, and implantable cardioverter-defibrillators in those at risk of arrhythmia. These forms of treatment have been shown to improve symptoms and reduce hospitalization. They can cost upward of $75,000 each, and many patients will require re-implantation or an upgraded or new device in a year.

However, for patients with advanced disease who are refractory to medical therapy, cardiac transplantation is the only option. LVAD are commonly known as a "bridge to transplantation". The problem however, and the reason this is such as a significant medical problem, is that only about 2,000 heart transplants are done in the U.S. each year. That means of the estimated 150k NYHA Class III or IV patients with dilation, over 95% will never get a transplant. Accordingly, this is why mortality rates start to rise dramatically after a patient has been diagnosed with DCM.

Preclinical Studies

Aastrom has been working diligently, both internally and with outside investigators, to improve its understand of the mechanism of action and market potential for ixmyelocel-T. Earlier in the year, management reported results of preclinical research demonstrating the ability of ixmyelocel-T to protect heart tissue from damage in a murine model of heart failure in a poster presentation at the 18th Annual International Society for Cellular Therapy Meeting.

Just recently, outside investigators at the University of Michigan School of Dentistry and the Michigan Center for Oral Health completed a study in patients who required jawbone reconstruction. The positive results from the clinical trial were recently published in the peer-reviewed journal *Cell Transplantation* and showed that patients receiving ixmyelocel-T tolerated the treatment well, and had greater bone density and quicker bone repair than those who received traditional bone generation therapy.

The majority of investor focus is currently on the phase 3 REVIVE trial. But we think Aastrom's ixmyelocel-T represents a pipeline-product. The ixCELL-DCM trial is finally underway, and recent preclinical work suggests that Aastrom's platform has broad application in potentially several new areas of regenerative medicine. We think this presents upside to investors and potential partners.

PROJECTED FINANCIALS

Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-10	Dec-11	Mar-13	Jun-12	Sep-12	Dec-12	Dec-12	Dec-13	Dec-14	Dec-15
	2010 A	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E	2015 E
R&D Agreements / Grants	**$0.3**	**$0**	**$0**	**$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**	**$0**
YOY Growth		*0.0%*	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Total Revenues	**$0.3**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth		-	-	-	-	-	-	-	-	-
Research & Development	$15.1	$21.3	$6.8	$7.1	$6.1	$7.0	$27.0	$35.0	$35.0	$35.0
% R&D		-	-	-	-	-	-	-	-	-
Selling, General, and Admin	$6.2	$7.7	$1.8	$2.2	$2.1	$2.2	$8.3	$8.3	$8.5	$8.6
% SG&A		-	-	-	-	-	-	-	-	-
Operating Income	($21.0)	($29.1)	($8.6)	($9.3)	($8.2)	($9.2)	($35.3)	($43.3)	($43.5)	($43.6)
Operating Margin		-	-	-	-	-	-	-	-	-
Other Income (Expenses)	($4.7)	$9.4	($1.2)	$0.7	$1.0	($0.8)	($0.2)	($2.0)	($1.5)	($1.0)
Pre-Tax Income	($25.7)	($19.7)	($9.7)	($8.6)	($7.2)	($10.0)	($35.5)	($45.3)	($45.0)	($44.6)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($25.7)	($19.7)	($9.7)	($8.6)	($7.2)	($10.0)	($35.5)	($45.3)	($45.0)	($44.6)
Net Margin		-	-	-	-	-	-	-	-	-
Reported EPS	**($0.91)**	**($0.51)**	**($0.25)**	**($0.22)**	**($0.17)**	**($0.23)**	**($0.86)**	**($0.91)**	**($0.75)**	**($0.64)**
YOY Growth		-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	28.3	38.6	38.7	38.9	43.3	43.8	41.2	50.0	60.0	70.0

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

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Aastrom Biosciences
DCF Model

Aastrom Bio (ASTM)	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Global Ixmy-T CLI Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$39**	**$139**	**$266**	**$399**	**$541**	**$690**
YoY Growth	-	-	-	-	-	-	*257%*	*90%*	*50%*	*35%*	*28%*
Global Ixmy-T DCM Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$47**	**$119**	**$196**	**$278**	**$364**
YoY Growth	-	-	-	-	-	-	-	*156%*	*65%*	*42%*	*31%*
Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$8**	**$37**	**$77**	**$119**	**$164**	**$211**
YoY Growth	-	-	-	-	-	-	*376%*	*107%*	*55%*	*37%*	*29%*
Licensing & Collaborative	**$0**	**$0**	**$0**	**$25**	**$55**	**$30**	**$25**	**$10**	**$10**	**$10**	**$10**
Revenues (in Millions)	**$0**	**$0**	**$0**	**$25**	**$55**	**$38**	**$62**	**$87**	**$129**	**$174**	**$221**
YoY Growth	-	-	-	-	-	*-31%*	*65%*	*40%*	*48%*	*35%*	*27%*
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
R&D	*$27*	*$35*	*$35*	*$30*	*$25*	*$25*	*$25*	*$10*	*$15*	*$21*	*$27*
SG&A	*$8*	*$8*	*$9*	*$9*	*$9*	*$10*	*$10*	*$11*	*$11*	*$12*	*$12*
Other Expenses	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
EBITDA	($35)	($43)	($44)	($14)	$21	$3	$27	$66	$102	$141	$182
Depreciation and amortization	*$1*	*$1*	*$1*	*$2*	*$2*	*$3*	*$3*	*$4*	*$4*	*$5*	*$5*
EBIT	**($36)**	**($44)**	**($45)**	**($15)**	**$18**	**$0**	**$23**	**$62**	**$98**	**$136**	**$177**
EBITDA margin	-	-	*#DIV/0!*	*-61.6%*	*33.2%*	*0.1%*	*37.7%*	*71.0%*	*75.8%*	*78.4%*	*80.0%*
Cash Taxes	$0	$0	$0	$0	$0	$0	$0	$0	($10)	($41)	($53)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*10.0%*	*30.0%*	*30.0%*
Balance Sheet											
Capital Expenditures	$0	$5	$5	$5	$5	$4	$3	$2	$1	$0	($1)
Working Capital	$2	$2	$3	$3	$4	$4	$5	$5	$6	$6	$7
Interest & Other Expenses	($0)	($2)	($2)	($1)	($1)	$0	$1	$1	$2	$2	$3
Non-Cash Adjustments	($1)	($1)	($1)	($2)	($2)	($2)	($2)	($2)	($2)	($3)	($3)
Capital demployed	**$1**	**$4**	**$5**	**$5**	**$6**	**$6**	**$6**	**$6**	**$6**	**$6**	**$5**
ROIC	*-6648.6%*	*-1170.3%*	*-956.0%*	*-251.9%*	*328.6%*	*46.8%*	*449.7%*	*1130.9%*	*1808.6%*	*2562.7%*	*3401.8%*
Discounted Cash Flow											
Net Income	($36)	($44)	($45)	($15)	$18	$0	$23	$62	$88	$95	$124
Depreciation and amortization	$1	$1	$1	$2	$2	$3	$3	$4	$4	$5	$5
Net Cash Changes	($1)	($4)	($5)	($5)	($6)	($6)	($6)	($6)	($6)	($6)	($5)
Post-Tax Operating Cash Flow	**($36)**	**($47)**	**($48)**	**($19)**	**$14**	**($3)**	**$21**	**$60**	**$87**	**$95**	**$124**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**($36)**	**($47)**	**($48)**	**($19)**	**$14**	**($3)**	**$21**	**$60**	**$87**	**$95**	**$124**

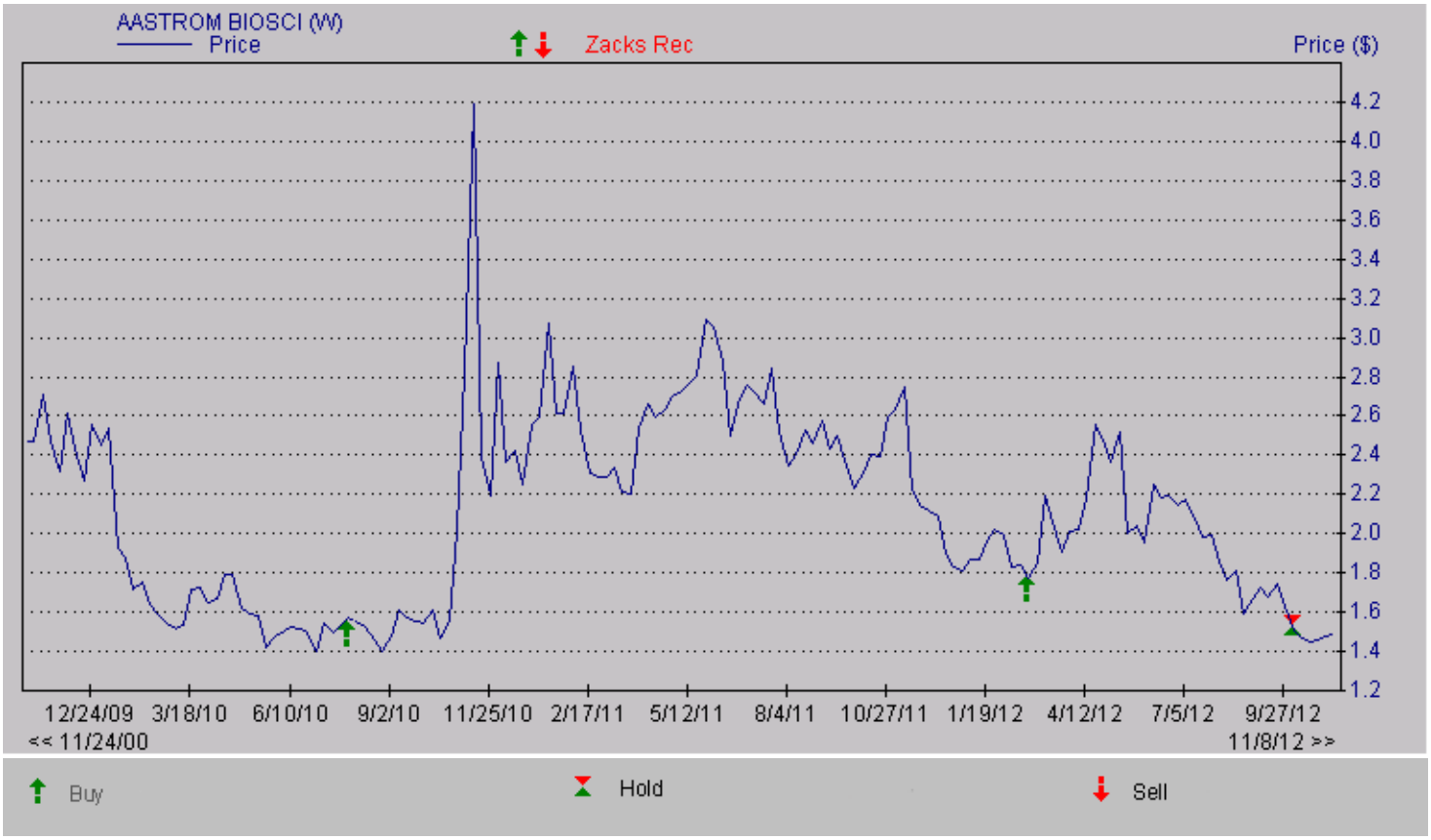
Assumptions	
Beta:	1.22
Equity Risk Premium:	6.0%
Risk Free Rate:	1.8%
Firm Risk Premium:	150.0%
Discount Rate:	**16.8%**

Valuation	
10-Year Model:	($11.8)
Terminal Growth:	3.0%
Terminal Value:	$163.7
Net Cash - LT Debt:	$13.1
Firm Value:	**$165.0**

Price Target	
Basic Outstanding:	43.8
Warrants / Options:	8.6
Preferred Stock:	12.3
Fully Diluted:	64.7
Target Price:	**$2.55**

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

HISTORICAL ZACKS RECOMMENDATIONS



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