Zacks Equity Research

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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: SPA Filed, FDA Grants Fast Track for CLI…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	07/28/2010
Current Price (10/20/10)	$1.52
Target Price	**$2.50**

UPDATE

It's been a busy week for Aastrom Bio. On Monday the company announced the U.S. FDA had granted its cell therapy for CLI "Fast Track" designation. This morning, the company announced it has filed a special protocol assessment (SPA) for the planned phase III trial in CLI. We expect the FDA will respond in 60 days, and if the protocol is agreed upon, Aastrom should be in position to initiate the program in early 2011.

We view Aastrom as the premier stem cell play for cardiovascular indications. However, more data is needed before investors can be confident in the story. Our price target is $2.50 per share.

SUMMARY DATA

52-Week High	**$2.95**
52-Week Low	**$1.34**
One-Year Return (%)	**-48.11**
Beta	**-0.14**
Average Daily Volume (sh)	**312,627**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**3.21**
Institutional Ownership (%)	**14**
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 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**73 of 141**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0.07 A	0.02 A	0 A	0 A	0.09 A
2011	0 E	0 E	0 E	0 E	0 E
2012					0.10 E
2013					0.10 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.18 A	-$0.21 A	-$0.16 A	-$0.18 A	-$0.72 A
2011	-$0.18 E	-$0.18 E	-$0.19 E	-$0.19 E	-$0.74 E
2012					-$0.90 E
2013					-$0.93 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

FDA Grants Fast Track Status for CLI…

On October 18, 2010, the U.S. FDA granted a Fast Track designation for Aastrom's critical limb ischemia (CLI) cell therapy development program. The FDA's fast track program is designed to facilitate the development and expedite the review of new drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. CLI clearly falls into this category.

- Critical limb ischemia (CLI) affects approximately 1 million people in the U.S. each year -- roughly 2% of the population over the age of 50. Over 25% of patients with PAD will eventually development CLI. CLI is defined as inadequate blood flow to the limbs, and if left untreated can result in tissue loss, gangrene, amputation and death. In fact, CLI leads to an average of 150,000 major limb amputations each year. CLI has a high mortality rate: 20% after 6-months after initial diagnosis and 25% after 12-months. Nearly 30% of all patients who undergo a major limb amputation will require another amputation at some point in the future. The mortality rate post-amputation remains high, at roughly 25%.

Fast track-designated drugs and biologics ordinarily qualify for priority review, thereby expediting the review process. In addition, the designation may allow Aastrom to submit portions of the biologic license application (BLA) on a rolling submission basis. For a company of Aastrom's size, it's a significant benefit in our view.

…Aastrom Submits SPA for Phase III CLI Program…

Two days after the U.S. FDA granted Fast Track status, Aastrom announced that it had submitted a special protocol assessment (SPA) describing the company's proposed phase III clinical development program in CLI. The SPA allows for close consultation with the agency on the protocol design and necessary endpoints for approval in the CLI indication. If the FDA concurs with the protocols outlined in the SPA, we expect that Aastrom will be in position to initiate the phase III program in early 2011.

We expect that the phase III program will look similar to the phase IIb RESTORE-CLI program. Management may focus the patient population to be more homogeneous in nature to lower variability and risk. We expect there to be two phase III trials in the program, with in the area of 500 patients total between two arms. The primary endpoint will most likely be amputation-free survival at 6 months, with secondary endpoints including amputation free survival at 12 months, de novo gangrene, wound healing, and all cause mortality. Enrollment should proceed faster than the phase IIb program now that management has identified the key wound care centers and vascular surgeons from the RESTORE-CLI program. We expect approximately 50 sites in the U.S. and Canada to participate.

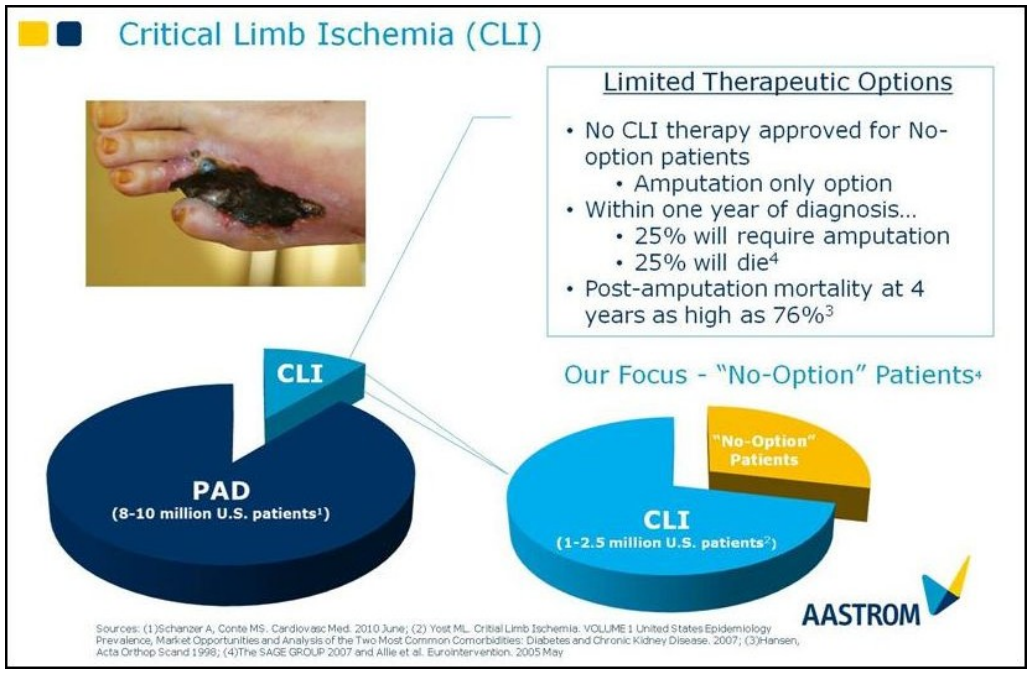
Our assumption is that this program will take up to two years to complete. The total cost should be roughly $15 million, or $30k per patient. We note this is relatively inexpensive for a pivotal phase III program. The design and costs are more in-line with a medical device than a small molecule pharmaceutical. The biggest impediment we see in enrollment would be a potentially competing CLI program from an oral small molecule or medical device company and funding.

…Market for CLI Remains Wide Open…

Therapeutic options for patients with CLI are limited. Besides being at significantly increased risk for heart attack, stroke or vascular death, patients with CLI often live with several other co-morbidities, including diabetes, angina, dyslipidemia, hypertension and renal disease. For less severe forms of PAD, physicians will typically recommend smoking cessation (when applicable), and changes to diet and exercise.

Medications such as aspirin, statins and clopidogrel (Plavix) are common first-line therapies for early-stage PAD. Many patients will also be on medications for diabetes and heart failure as well. However, once PAD progresses to the point of CLI, the only real options available to patients are surgical. Patients are passed from the cardiologist, diabetologist or podiatrist to the care of the vascular surgeon. Surgical procedures include percutaneous transluminal angioplasty, plaque excision, stenting and bypass grafting. Patients living with CLI suffer from severe pain as a result of the neuropathy, tissue loss and ischemia. The healthcare burden associated with PAD-related amputations in the U.S. is greater than $10 billion per year.

In September 2010, Sanofi-Aventis released top-line data from the company's phase III Tamaris trial evaluating its small molecule angiogenic gene therapy agent, NV1-FGF, in patients with CLI who were not eligible for revascularization (no option patients). The trial failed to achieve its primary endpoint in major amputations or all-cause mortality. Sanofi's failure leaves the door wide open for Aastrom's cell therapy as the leading pipeline candidate under development for CLI. At this time we are unsure of Sanofi's future plans with NV1-FGF. We note that should Sanofi decide to conduct another phase III program, it would create enrollment competition for Aastrom with its planned phase III program in 2011.



INVESTMENT THESIS

Two Potential Blockbuster Opportunities…

In July 2010, we initiated coverage of Aastrom Biosciences with a Neutral rating and $2.50 price target. Aastrom is pioneering the research effort on adult stem cells for therapeutic applications, specifically for the treatment of cardiovascular diseases such as critical limb ischemia (CLI) and dilated cardiomyopathy (DCM).

Aastrom's approach involves expansion of a patient's own stem and progenitor cells outside of the body to generate a cell product with significantly increased numbers of highly functional early-stage cells. These autologous cell products can then be used for the repair or regeneration of multiple human tissues. The company has developed a proprietary Tissue Repair Cell technology in which cells are derived from a small amount of bone marrow taken from a patient and expanded in culture to generate a unique cell mixture containing high doses of stem and progenitor cells. Due to the high number of stem and progenitor cells contained in a small volume, Aastrom's strategy seems particularly suitable for direct injection into the affected limb or myocardium.

Aastrom Biosciences has two clinical programs ongoing, one for vascular applications in critical limb ischemia (CLI), the most severe (end-stage) of peripheral arterial disease (PAD), and another for cardiac applications in dilated cardiomyopathy (DCM), the leading cause of heart transplantation.

- ✓ For CLI, management has presented very encouraging proof-of-concept data, as well as statistically significant interim results from a phase IIb program, RESTORE-CLI, on FDA-validated endpoints for CLI – major amputation and amputation-free survival. We have also seen encouraging preliminary data from an investigator-sponsored program conducted in Germany.

- ✓ For DCM, management has demonstrated promising trends from an interim analysis of IMPACT-DCM, which show meaningful improvements in NYHA function class for patients on therapy. The company has also made available encouraging case study data from compassionate use in Europe.

We view Aastrom Biosciences at the premier play for the application of adult stem cells for potential cardiovascular indications. While other stem cell companies such as Cytori Therapeutics (the market leader for cosmetic and reconstructive surgery) and Osiris Therapeutics (the market leader for inflammatory diseases) command higher market capitalizations, no other firm has as an advanced program for peripheral arterial disease or heart failure. Yet, despite the firm's advanced position for two potential billion-dollar "home run" indications, the market has yet to value Aastrom as a leader. We believe this is due to the company's novel approach, the high risk nature of the trials, and the fact that Aastrom must pave the way itself. As such, Aastrom Biosciences is in "show me" mode, and Aastrom must deliver before Wall Street will really start to pay attention. That being said, the next six to nine months is packed with catalysts from a clinical standpoint. We anticipate the first potential big catalyst for the shares, the final six-month data from all 86 patients in RESTORE-CLI, later this year.

For Additional Information, See Our Full Initiation Follow-Up Report From August 2010.

PROJECTED FINANCIALS

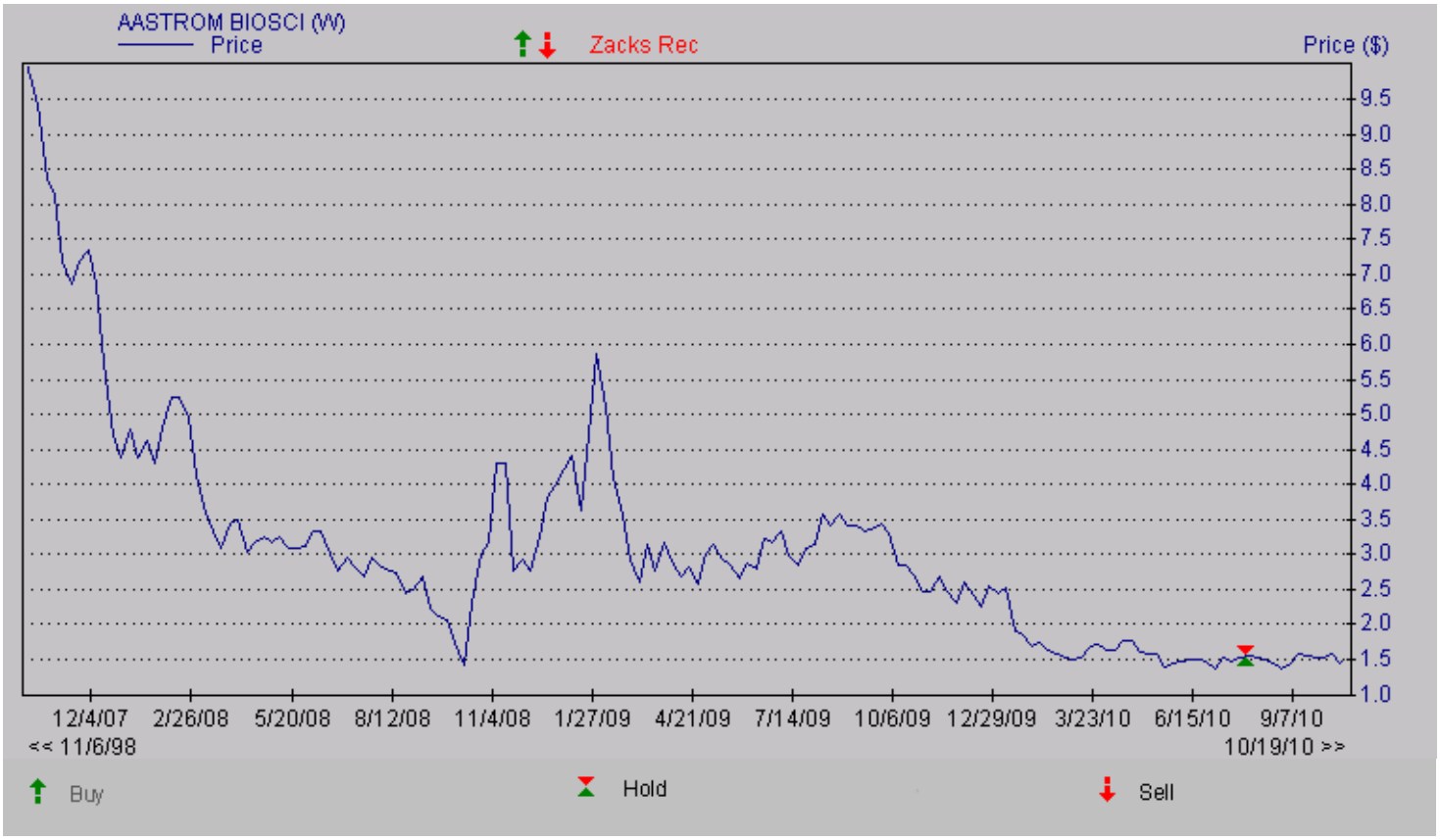
Aastrom Biosciences
Income Statement

Aastrom Biosciences	Jun-09	Jun-10	Sep-10	Dec-10	Mar-11	Jun-11	Jun-11	Jun-12	Jun-13	Jun-14
	2009 A	2010 A	Q1 E	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
R&D Agreements / Grants	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**
YOY Growth	-	*0%*	-	-	-	-	*0%*	*0%*	*0%*	*0%*
Product Sales & Rentals	**$0.182**	**$0.089**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.100**	**$0.100**	**$0.100**
YOY Growth	-	-	-	-	-	-	-	*#DIV/0!*	*0.0%*	*0.0%*
Total Revenues	**$0.182**	**$0.089**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.100**	**$0.100**	**$0.100**
YOY Growth	*-65.1%*	*-51.1%*	-	-	-	-	*-100.0%*	*#DIV/0!*	*0.0%*	*0.0%*
Cost of Product Sales & Rentals	$0.112	$0.034	$0	$0	$0	$0	$0	$0.040	$0.040	$0.040
Product Gross Margin	*38%*	*0%*	-	-	-	-	*#DIV/0!*	*60%*	*60%*	*60%*
Research & Development	$11.289	$12.658	$3.500	$3.700	$3.800	$4.000	$15.000	$22.500	$25.000	$20.000
% R&D	*6202.7%*	*14222.5%*	-	-	-	-	*#DIV/0!*	*22500.0%*	*25000.0%*	*20000.0%*
Selling, General, and Admin	$4.950	$5.201	$1.550	$1.550	$1.600	$1.650	$6.350	$6.500	$6.750	$7.000
% SG&A	*2719.8%*	*5843.8%*	-	-	-	-	*#DIV/0!*	*6500.0%*	*6750.0%*	*7000.0%*
Operating Income	($16.169)	($17.804)	($5.050)	($5.250)	($5.400)	($5.650)	($21.350)	($28.940)	($31.690)	($26.940)
Operating Margin	*-8884.1%*	*-20004.5%*	-	-	-	-	*#DIV/0!*	*-28940.0%*	*-31690.0%*	*-26940.0%*
Other Income (Expenses)	$0.223	$0.075	$0.025	$0.025	$0.025	$0.025	$0.100	$0.120	$0.130	
Pre-Tax Income	($15.9)	($17.729)	($5.025)	($5.225)	($5.375)	($5.625)	($21.250)	($28.820)	($31.560)	($26.940)
Taxes & Other Charges	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($15.946)	($17.729)	($5.025)	($5.225)	($5.375)	($5.625)	($21.250)	($28.820)	($31.560)	($26.940)
Net Margin	-	*-19920.2%*	-	-	-	-	*#DIV/0!*	*-28820.0%*	*-31560.0%*	*-26940.0%*
Reported EPS	**($0.89)**	**($0.72)**	**($0.18)**	**($0.18)**	**($0.19)**	**($0.19)**	**($0.74)**	**($0.90)**	**($0.93)**	**($0.75)**
YOY Growth	-	*-19.6%*	-	-	-	-	*3.4%*	*21.5%*	*3.1%*	*-19.4%*
FAS-123R Expense	$1.4	$0.5	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.6	$0.7
Weighted Ave. Shares Out	17.9	24.7	28.5	28.6	28.7	28.9	28.7	32.0	34.0	36.0

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

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HISTORICAL ZACKS RECOMMENDATIONS



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