Zacks Equity Research

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January 20, 2011
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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: IMPACT-DCM Data Shows Proof-of-Concept. Near SPA For Phase 3 CLI.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/08/2010
Current Price (01/20/11)	$2.57
Target Price	**$4.00**

UPDATE

We are reiterating our 'Outperform' rating on shares of Aastrom Bio following a meeting with management in January 2011. Below we analyst the interim data from the IMPACT-DCM program and outline the plans forward in both DCM and CLI. We believe the markets misconceptions on both the DCM data and the path forward in CLI has created a buying opportunity in the shares.

We are lowering our target to $4 (from $5) based on the 10 million share offering late last year. Our target valuation for the company, a market capitalization of $145 million, remains in place. We would be buyers of the stock up to the $4 level as we see 2011 as the pivotal year for Aastrom Bio.

SUMMARY DATA

52-Week High	**$4.20**
52-Week Low	**$1.34**
One-Year Return (%)	**55.32**
Beta	**-0.02**
Average Daily Volume (sh)	**2,605,615**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$112**
Short Interest Ratio (days)	**0.97**
Institutional Ownership (%)	**10**
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 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**13 of 161**

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 A	0 E	0 E	0 E	0 E
2012					0 E
2013					0 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	-$0.21 A	-$0.21 E	-$0.23 E	-$0.27 E	-$0.92 E
2012					-$1.00 E
2013					-$0.97 E

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

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WHAT'S NEW

IMPACT-DCM Data

This morning at the Sixth International Conference on Cell Therapy for Cardiovascular Disease, Aastrom Bio presented interim data from the first 40 patients at 6-months from the company's IMPACT-DCM program. As a reminder, the phase II IMPACT-DCM (surgical) program looked at the safety and efficacy of direct injection of TRCs into damaged areas of the myocardium. The trial was a prospective, open-label program with a crossover extension study for the control patients.

Baseline patient characteristic show a good distribution between both ischemic and non-ischemic subjects, with the majority of patients having significantly impaired ejection fraction (<30%) and are classified as NYHA III. These are "no option" patients heading towards transplant.

IMPACT-DCM Baseline Characteristics

	TRC Group (n=24)	Control (n=15)
Ischemic / Non-Ischemic	12 / 12	7 / 8
Ejection Fraction	28.4%	25.8%
NYHA Class-III	96%[1]	100%
Male / Female	60% / 40%	73% / 27%
Mean Age	60	58
Mean BMI	29	30

1 patient was NYHA Class IV

…Proof-Of-Concept Clearly Evident…

Proof-of-Concept is clearly evident by analyzing the data. Given the small size of the trial, no results are statistically significant, but the signs point to a quality of life benefit with TRCs. This will be explored further in a larger-scale phase IIb program to start later in 2011. The data notes an improved outcome for the ischemic DCM patients vs. the non-ischemic DCM patients.

	TRC Group	Control
Improvement in NYHA Class…		
@ 1 Month	67%	14%
@ 3 Months	67%	9%
@ 6 Months	79%	20%
@ 12 Months	85%	40%
Improvement in 6-Minute Walk Test…		
@ 1 Month	45%	42%
@ 6 Months	68%	50%
@ 12 Months	77%	60%
Improvement in Septal Thickness…		
@ 6 Month	58%	62%

…Safety Assessment Looks Clean…

Given the baseline characteristics of very sick patients, that fact that there were no discontinuations due to adverse events and that events were pretty similar between the control and TRC group is highly encouraging. Post-surgery, there was no difference in the incidence of AEs across the TRC and control groups.

	TRC Group	Control
Patients with Any AE	96%	93%
Discontinuations Due To AE	0%	0%
Serious AE	60%	60%
All Cause Mortality	12%	13%
Post-Op AEs per Patient	~7	~7

Management will present full data from this program at the 12-month timeframe during the second quarter 2011.

…Cather-DCM Continues…

Management is also continuing enrolling patients in the phase II Catheter-DCM study to determine the safety and tolerability of administering expanded autologous cell therapy via a catheter (J&J's NOGA) to patients with heart failure due to dilated cardiomyopathy. This trial completed enrollment at 23 patients in December 2010. Interim 6 month data from the Catheter study should be available in the third quarter 2011. The next step in DCM will be for Aastrom to meet with the U.S. to outline the design for a phase IIb study.

We expect the phase IIb program will be a fully-control catheter program using the NOGA device. The trial will most likely seek to enroll about 100-150 patients with clearly objective endpoints such as heart function, 6-minute walk test, VO_2 max, exercise capacity, or MACE. This will be large enough to clearly provide a roadmap for the phase III program, which we expect management will secure an SPA. We remind investors that the FDA has granted Orphan Drug designation to Aastrom for use of its TRCs in DCM. We are tentatively modeling this program to start in the calendar fourth quarter 2011, with data late 2012.

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.

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 3 or 4 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.

CLI Update

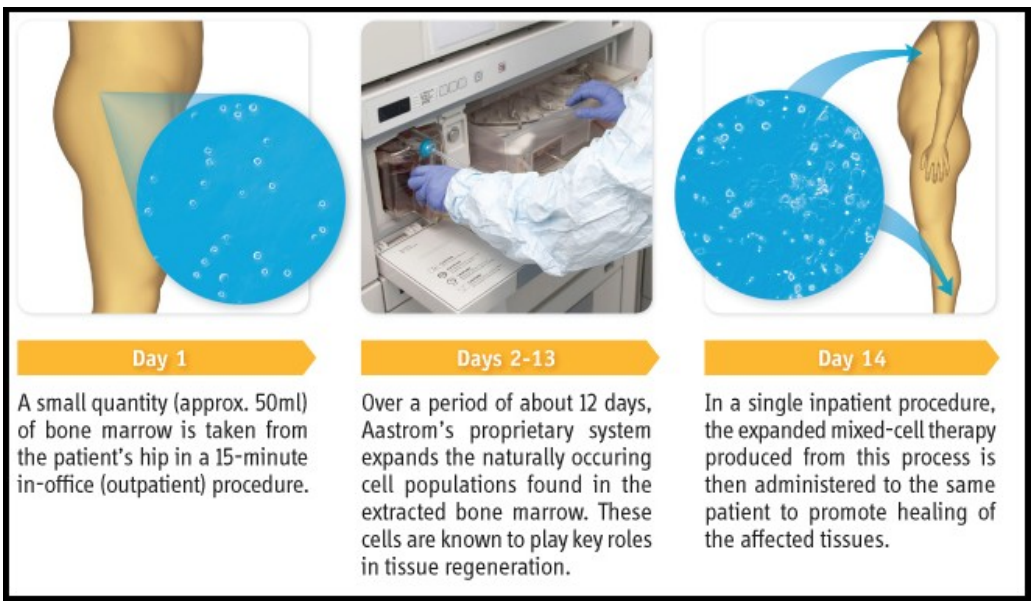
Aastrom Bio and the U.S. FDA continue to have a back-and-forth dialogue on the planned special protocol assessment (SPA) for the phase III CLI program. We remind investors that the first-draft of the SPA was filed in October 2010 and that it is normal to have several re-filings of the application before a finalized protocol is agreed upon by the agency. In fact, this is the purpose of the SPA, to work closely with the FDA to design the exact trial the agency would like to see in order to qualify for approval.

We met with Aastrom's CEO, Tim Mayleben and CFO, Scott Durbin, in early January 2011 to obtain an update on the planned phase III CLI program. Based on our conversation with management, we expect the finalized SPA to come in around the second quarter 2011 and include 2 phase III trials. Aastrom has received U.S. FDA Fast Track development status for this program. We assume:

- CLI-301-NO: This program will seek to enroll 500 patients with severe CLI. These "no option" patients must have confirmed tissue loss and disease progression to qualify for enrollment. We expect the primary endpoint of the program to be amputation-free survival at 12-months (AFS-12). Other endpoints will include major amputation, de novo gangrene, wound size, and all cause mortality. Management is targeting 70-80 clinical sites around the U.S. and Canada for enrollment. The goal will be to create a central adjudication committee that will oversee the entry criteria and decision to amputate. We are extremely pleased to see AFS at 12 months be the proposed primary endpoint. In the previous RESTORE-CLI phase IIb program management looked at AFS at 6 months. We believe the extra 6 months allows for greater separation between the treatment and control groups – as a reminder the event rate in RESTORE-CLI was lower than expected, so pushing the endpoint out to 12 months show allow for a clear efficacy determination. We expect this trial to begin enrollment in the third quarter 2011.

- CLI-302-POOR: This program will see to enroll 250 patients with moderate CLI. These "poor option" patients will have disease progression with a clear path toward amputation. We believe the FDA wants to see AFS-12 as the primary endpoint for this program as well. Management was hoping to include revascularization or MALEFS (major amputation limb event free survival) as an endpoint, but it seems clear the FDA is looking for AFS-12 as the key outcome here. This trial clearly presents more risk than the "no option" program. The risk here is that the AFS-12 event rate is too low to show clear separation between TRC and the control.

There have been rumblings lately about the potential risk of treating with TRCs given the 2-week processing time between bone-marrow aspiration and re-injection. As a reminder, Aastrom's TRC is an autologous cell therapy, meaning cells are taken from the patient, processed over 2-weeks for amplification, and then re-injected. Allogenic cell therapies (see Athersys, Pluristem, or Osiris) use donor cells that have been processed to remove immunogenicity. These products can be injected in sick patients without having to wait the 2-weeks for processing and amplification.



We have heard concerns that during the phase III program patients may enroll (intent-to-treat) and then die or decide to amputate in the 2-weeks between bone marrow aspiration (Day-1) and re-injection (Day-14). Management would like to begin the ITT population on re-injection (Day-14) and the FDA seems intent on counting patients for the ITT population on aspiration (Day-1). In RESTORE-CLI, there were 14 patients that enrolled (Day-1) but never proceeded to injection (Day-14).

- ✓ Some did not meet entry criteria upon further review prior to bone aspiration.
- ✓ Some could not tolerate the bone aspiration.
- ✓ Some of the bone aspirate was contaminated or could not be expanded under Aastrom's technology.
- ✓ Some had amputations in-between the bone aspiration and the injection (2-weeks).
- ✓ Some had significant adverse events in-between the bone aspiration and the injection (2-weeks).
- ✓ Some provided bone aspirate for expansion, but never returned for injection.

Nevertheless, we see this as a non-issue. The phase III CLI program will seek to enroll 750 patients total. That means potentially as many as ~125 patients will not receive therapy. However, as long as the randomization between placebo and test group is in-place, it should have no effect on the statistical outcome. Aastrom should still have data from its phase III program of 600+ patients.

Phase IIb RESTORE-CLI

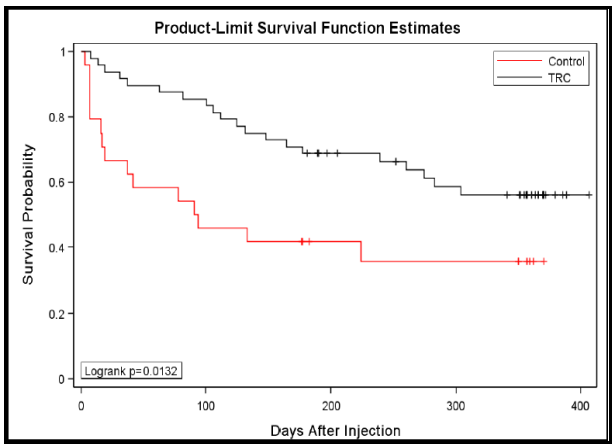
On November 18, 2010 at the VEITHsymposium satellite event in NYC, Dr. Richard Powell, principal investigator for the RESTORE-CLI program, presented an update from all 72 patients who completed the study at 6 months.

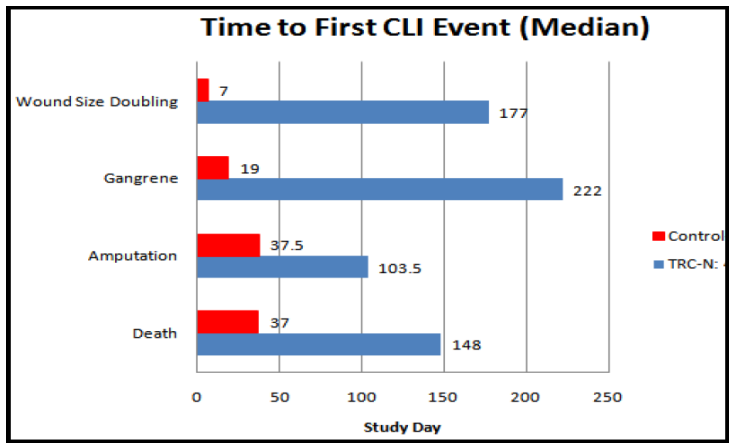
On Time To Treatment Failure…

Efficacy Assessment on ITT Population – TOTAL

Parameter	TRC (n=48)	Control (n=24)	
Amputation	21%	25%	
De Novo Gangrene	13%	21%	
Doubling in Wound Size	19%	29%	
All Cause Mortality	6%	4%	
Treatment Failure	42%	63%	*p = 0.0132*

Results for the primary endpoint of the phase IIb program were statistically significant for Time to Treatment Failure at p = 0.0132. The graph below shows the clear separation between TRC and the control for the entire population. The bar chart breaks down the individual components of Treatment Failure, where we see that each was meaningfully in-favor of TRC vs. the control.





Conclusion: The Time to Treatment Failure composite endpoint was clearly a success in RESTORE-CLI. The p-value of 0.0132 is incredibly strong considering only 72 patients were included. We would have liked to see better data with respect to "Death" and "Amputation", but these are things we expect will continue to separate upon the final analysis of the program expected in May 2011.

On Amputation Free Survival…

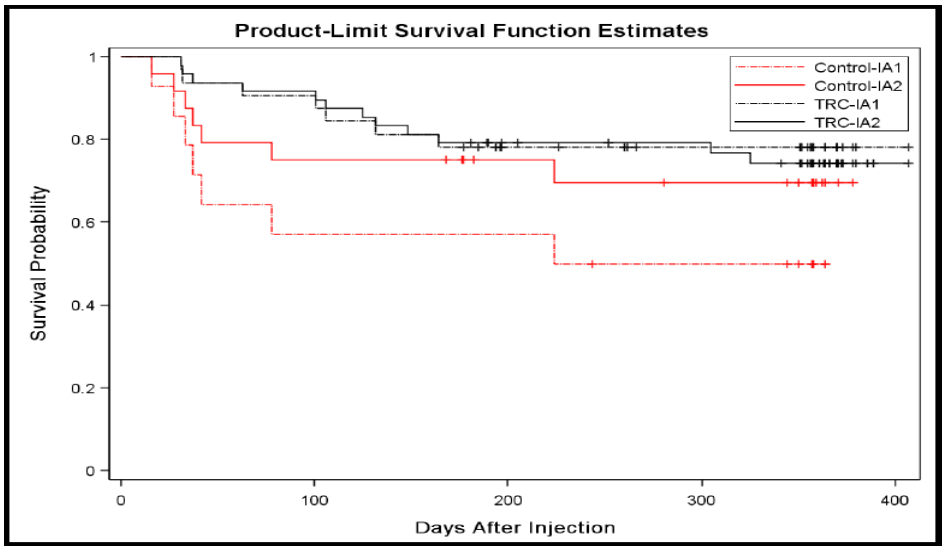
Efficacy Assessment on ITT Population – TOTAL

Parameter	TRC (n=48)	Control (n=24)	
Amputation Free Survival @ 12-Months	75%	71%	*p = 0.5541*

The results from RESTORE-CLI show a favorable trend, but failed to meet statistical significance. We believe this was due to a number of factors. Mainly, the control group at the backend of the trial responded significantly better than expected. Some reasons why:

- Patients may have skewed a little "less sick" as the trial completed enrollment. A less sick population will certainly have less events (MACE, amputation, death) in a 12-month time period. Management noted that of the 10 new control patients that were added between the 1st and 2nd analysis, there were no events during months 7-12. Just 2 or 3 events, which you would assume given the ~30% net event rate, would have made the endpoint statistically significant at p<0.05.

- Amputations are subjective and a placebo effect was clearly evident. Pain scores are a major contributor to the decision to amputate. Things like de novo gangrene and wound size are clearly not subjective and showed statistical significance in favor of TRC. However, pain is subjective and with less reported pain it is possible physicians were delaying amputations accordingly. This is something we expect will mitigate as the trial progresses to the final analysis. Placebo response does not actually delay disease progression.



Conclusion: The chart above clearly shows the big change in control response from the 1st to 2nd update. We are encouraged by the fact that TRC behaved remarkably consistent throughout the trial. We assume management can alleviate some of the placebo effect in the phase III trial through:

- ✓ Better patient selection
- ✓ A centralized adjudication committee for amputations (less subjective)
- ✓ Enrollment criteria
- ✓ Standardized care

If TRC offers up an amputation free survival rate of ~75%, while the control trends to the expected ~65%, the phase III trial will most definitely meet statistical significance with 500+ patients.

On Safety Assessment…

Patients that did undergo the procedure generally responded well. Adverse events (AEs) were high, as expected, but nothing was significantly higher in the TRC group vs. the control.

Safety Assessment on ITT Population - TOTAL

Parameter	TRC (n=53)	Control (n=24)
Number (%) with Adverse Events	46 (87%)	22 (92%)
Number of Deaths	3 (6%)	1 (4%)
Number (%) with Serious Adverse Events	23 (43%)	12 (50%)
Number (%) Withdrawal due to AE	1 (2%)	0

…SPA Under Review…

In mid-October 2010, Aastrom announced that it had submitted a special protocol assessment (SPA) on the company's 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. We expect the back-and-forth between Aastrom and the FDA to continue into the second quarter 2011. If all goes well, we expect the first phase III trial to begin in the third quarter 2011. As noted above, we are expecting 2 trials, one with 500 “no option” patients and the second with 250 “poor option” patients.

The primary endpoint will be amputation-free survival at 12 months (AFS-12), with secondary endpoints including amputation, 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. Site selection and enrollment criteria will be instrumental to the success of the program. Enrollment should take between 12 to 18 months to complete.

The total cost should be roughly $25 million, or $30-40k 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. In late October 2010, Aastrom Bio signed a new strategic manufacturing partnership with ATEK Medical. ATEK will supply the disposable cassettes used during the cell therapy procedure. The relationship puts a more comprehensive and long-term supply agreement into place ahead of the phase III program. This should work to alleviate supply or logistic issues that could materialize during the program.

Also in October 2010, the U.S. FDA granted a Fast Track designation to Aastrom’s cell therapy development program for CLI. 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%.

…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.

RECOMMENDATION & VALUATION

Two Potential Meaningful Opportunities…

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 from a phase IIb program, RESTORE-CLI, on FDA-validated endpoints for CLI – major amputation and amputation-free survival. The U.S. FDA has granted Aastrom 'Fast Track' designation for the CLI indication. We expect the phase III program to begin under a special protocol assessment (SPA) during the second half of 2011.

Major Amputations: 160,000 / year
→ Savable by ASTM's cell therapy: 50%
→ Market share: 20%
→ Cost: $50k / treatment ➔ Peak Sales: $800 Million

NPV Assumptions CLI Program: Upfront payment of $40 million in 2012 with significant backend regulatory and sales-related milestone, plus 20% royalty on sales. FDA approval in 2014, with peak in 2019 and a risk adjustment rate of 50%.

Value of CLI Program ➔ $85 million

✓ For DCM, management has demonstrated promising trends from IMPACT-DCM, which show meaningful improvements in NYHA function class, quality of life, and other functional parameters for patients on therapy. The U.S. FDA has granted Aastrom 'Orphan Drug' designation for the DCM indication.

Living with DCM: 200,000 / year
→ Savable by ASTM's cell therapy: 50%
→ Market share: 25%
→ Cost: $50k / treatment ➔ Peak Sales: $500 Million

NPV Assumptions DCM Program: Upfront payment of $30 million in 2013 with significant backend regulatory and sales-related milestone, plus 20% royalty on sales. FDA approval in 2015 with peak sales level in 2019, and a risk adjustment rate of 65%.

Value of DCM Program ➔ $30 million

Total Technology Value for Aastrom Bio: $115 million + $30 million in cash = $145 million market capitalization. Based on roughly 38 million shares outstanding, we see fair-value at $4 per share. We reiterate our Outperform rating on the stock.

EVENTS TO WATCH

EVENTS TO WATCH	TIMING
Full 12-Month Data from RESTORE-CLI	Q2-2011
Full 12-Month Data from IMPACT-DCM	Q2-2011
Finalized SPA with FDA on Phase III CLI Program	Q2-2011
Interim 6-Month Data from Catheter-DCM	Q3-2011
Meet with FDA to Design Phase IIb for DCM (Catheter)	Q3-2011
Initiate 1st Phase III CLI Program in "No Option" Patients	Q3-2011
Initiate Phase IIb in DCM	Q4-2011
Initiate 2nd Phase III CLI Program in "Poor Option" Patients	2012
Data From Phase IIb DCM	2012
Data From Phase III CLI	2013

PROJECTED FINANCIALS

Aastrom Biosciences
Income Statement

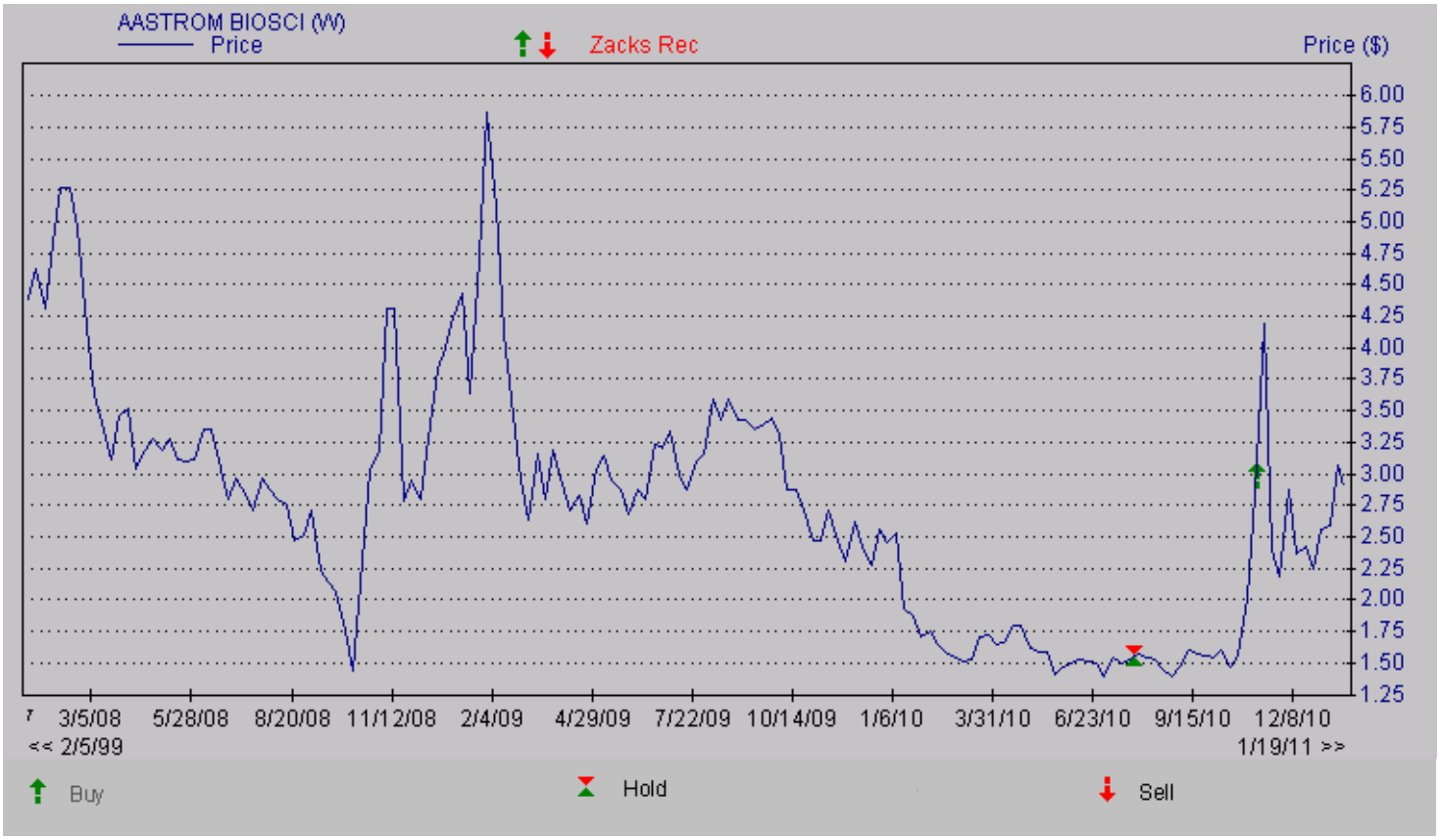
Aastrom Biosciences	Jun-10	Sep-10	Dec-10	Mar-11	Jun-11	Jun-11	Jun-12	Jun-13	Jun-14
	2010 A	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
R&D Agreements / Grants	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0%*	-	-	-	-	*0%*	*0%*	*0%*	*0%*
Product Sales & Rentals	**$0.089**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*
Total Revenues	**$0.089**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*-51.1%*	-	-	-	-	*-100.0%*	-	-	-
Cost of Product Sales & Rentals	$0.034	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*0%*	-	-	-	-	-	-	-	-
Research & Development	$12.658	$4.167	$4.250	$5.000	$6.000	$19.417	$25.000	$25.000	$20.000
% R&D	*14222.5%*	-	-	-	-	-	-	-	-
Selling, General, and Admin	$5.201	$1.686	$1.700	$1.750	$1.800	$6.936	$7.250	$8.000	$9.000
% SG&A	*5843.8%*	-	-	-	-	-	-	-	-
Operating Income	($17.804)	($5.853)	($5.950)	($6.750)	($7.800)	($26.353)	($32.250)	($33.000)	($29.000)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Income (Expenses)	$0.075	$0.020	$0.026	$0.055	$0.045	$0.146	$0.120	$0.130	$0.200
Pre-Tax Income	($17.729)	($5.833)	($5.924)	($6.695)	($7.755)	($26.207)	($32.130)	($32.870)	($28.800)
Taxes & Other Charges	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($17.729)	($5.833)	($5.924)	($6.695)	($7.755)	($26.207)	($32.130)	($32.870)	($28.800)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.72)**	**($0.21)**	**($0.20)**	**($0.17)**	**($0.20)**	**($0.77)**	**($0.80)**	**($0.73)**	**($0.58)**
YOY Growth	-	-	-	-	-	-	-	-	-
FAS-123R Expense	$0.7	$0.2	$0.2	$0.2	$0.3	$0.9	$1.1	$1.5	$2.0
Weighted Ave. Shares Out	24.7	28.3	30.0	39.0	39.2	34.1	40.0	45.0	50.0

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

Please note that Aastrom plans to change its corporate reporting to calendar year-end starting in 2011.
Therefore, the fiscal Q2-11 which ended on December 31, 2010 will now become the Q4-2010 and the new fiscal 2011 will begin January 1, 2011.

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HISTORICAL ZACKS RECOMMENDATIONS



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