Zacks Small-Cap Research

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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Sanofi Deal A Potential Game-Changer For Aastrom Bio…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/05/2012
Current Price (05/14/14)	$3.96
Target Price	**$5.00**

UPDATE

On April 21, 2014, Aastrom Biosciences announced an agreement to acquire Sanofi's Cell Therapy and Regenerative Medicine (CTRM) business, previously known as Genzyme Biosurgery Aps. The deal came at a purchase price of $6.5 million, with $4 million payable in cash from Aastrom to Sanofi at closing and $2.5 million payable in the form of a promissory note due 60 days later. On Aastrom's first quarter conference call, CEO Dominick Colangelo noted that he expects the deal to close late May 2014. We are racking our brains on this deal because – on the cusp – it looks like a 'Home Run'. If our back-of-the-envelope numbers are correct, Aastrom's stock could double once the financials are made public. We have the stock on watch for an upgrade.

SUMMARY DATA

52-Week High	**$15.48**
52-Week Low	**$3.21**
One-Year Return (%)	**-75.15**
Beta	**0.82**
Average Daily Volume (sh)	**524,936**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**0.98**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**22**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 E	0 E	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$3.03 A	-$2.14 A	-$0.75 A	-$0.65 A	-$5.18 A
2014	-$1.02 A	-$0.74 E	-$0.72 E	-$0.73 E	-$1.73 E
2015					-$2.47 E
2016					-$2.25 E

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WHAT'S NEW

Financial Results

On May 15, 2014, Aastrom Biosciences, Inc. (ASTM) reported financial results for the first quarter ended March 31, 2014. The company did not report meaningful revenues in either the quarter or during the full year 2013. This was in-line with expectations. Net loss in the quarter totaled $6.0 million, or $1.02 per share. Loss was driven by $3.3 million in R&D and $1.4 million in SG&A. The company also recorded a $1.4 million non-cash charge associated with the change in fair-value of the warrant liability. The current value of the outstanding warrant liability on the balance sheet is $2.0 million as of March 31, 2014. Actually operating burn during the quarter totaled $4.7 million.

Aastrom exited March 31, 2014 with $8.1 million in cash and investments. We remind investors that the company current has an At-The-Market (ATM) financing facility in place with MLV, LLC dating back to June 2011. It allows for the sale of registered securities up to $20.3 million. From inception of the agreement through March 31, 2014, the company has raised total gross proceeds of $10.7 million, which includes $5.5 million in gross proceeds raised during the first quarter 2014. We expect the company to utilize the remaining $9.6 million via the ATM in the near future. We believe the company's goal is to maintain cash at roughly two quarters runway – or at least $8 million – until the release of the top-lined from the truncated REVIVE-CLI Phase 3 study around the middle of the year. If the data is positive, this could give the company an opportunity to raise additional new capital.

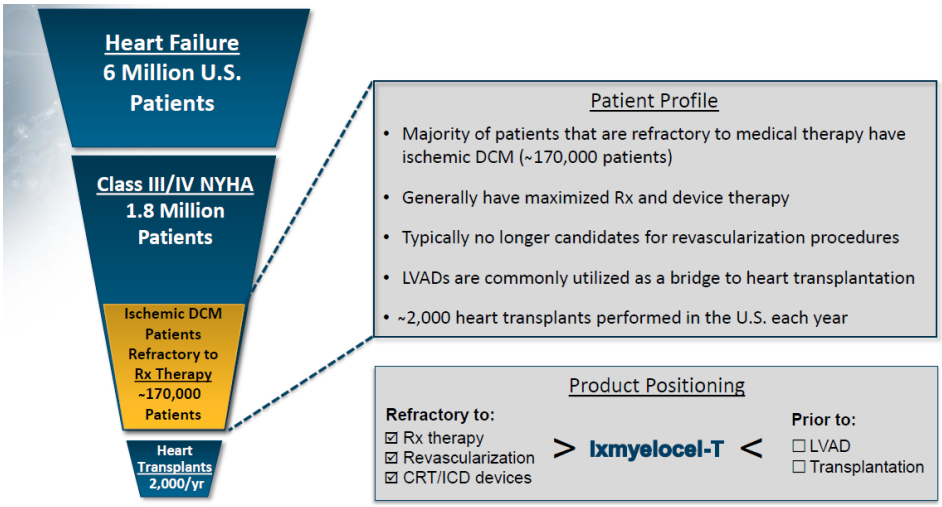
In terms of raising future cash beyond the ATM, we note that on January 21, 2014, the company entered into a common stock purchase agreement (CSPA) with Lincoln Park Capital Fund, LLC (Lincoln Park) to sell to Lincoln Park up to $15.0 million in shares of its common stock, subject to certain limitations, from time to time over the 30-month period. Terms allow for Aastrom to sell, at its sole discretion, up to 50,000 shares of common stock in regular purchases, increasing to amounts of up to 100,000 shares depending upon the closing sale price of the common stock. Lincoln Park buys the shares at the 10 business day trading average for Aastrom stock, and has a floor price of $2.50 per share.

DCM Program Continues

Not much new to update shareholders on with respect to the Phase 2b ixCELL-DCM active clinical program with ixmyelocel-T. Enrollment has progressed at 30+ centers so far, and we believe will be completed by the middle of 2014. DSMB clearance for the first group of patients enrolled took place in April 2014, with the committee recommending no changes to the protocol. This is a good sign.

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.

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

Assuming this data are positive, we believe Aastrom will be able to partner the drug for a Phase 3 trial to start in 2016. We believe the Phase 3 trial will take a similar two years to enroll and report data, putting the potential NDA in 2018 and approval in 2019. Approximately 0.6% of the U.S. adult population is classified NYHA Class III/IV. Approximately 15% of these patients have DCM and approximately 60% are considered ischemic in nature (source: American Heart Association). This equates to a target patient population of around 170,000, consistent with the graphic shown above.

If we model 5% peak market penetration in 2024, with ixmyelocel-T priced at $75,000 per course of treatment, this equates to peak U.S. sales of $600 million. We believe sales outside the U.S. will total $400 million, bringing peak worldwide sales of ixmyelocel-T in DCM to $1.0 billion. Given the suspected commercialization price for DCM around $75,000 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. That's the beauty of having an orphan drug designation. Those impressive economics are sure to attract a pharmaceutical partner if the data is good. We believe Aastrom can partner for this indication for $25 million upfront, $75 million regulatory, and $250 million in backend milestones plus 20% royalty on sales. We apply a 25% discount rate and 20% probability of success to arrive at a current NPV for the program of $30 million. Aastrom's market capitalization is only $24 million.

…CLI Program Shelved…

During the first quarter conference call, management reported that they have conducted a preliminary analysis of data from patients in the REVIVE-CLI study. We remind investors that this study was originally planned to enroll roughly 600 patients, but management halted recruitment at 41 patients back in March 2013 because of exceeding costs and slow enrollment. Analysis of the 41 patients showed positive trends in amputation-free survival and wound closure in the ixmyelocel-T treated group consistent with previous results seen in the Phase 2 RESTORE-CLI study. Although the positive trends were in-line with expectations, the trial was not of sufficient size to demonstrate statistical significance. Further clinical testing of ixmyelocel-T in CLI will only move forward with the assistance of a development and commercialization partner. We have removed all value for ixmyelocel-T in CLI from our financial model.

Sanofi Deal A Game-Changer For Aastrom

However, the biggest news of the year came on April 21, 2014, when Aastrom Biosciences announced an agreement to acquire Sanofi's Cell Therapy and Regenerative Medicine (CTRM) business, previously known as Genzyme Biosurgery Aps. The deal came at a purchase price of $6.5 million, with $4 million payable in cash from Aastrom to Sanofi at closing and $2.5 million payable in the form of a promissory note. On Aastrom's first quarter conference call, CEO Dominick Colangelo noted that he expects the deal to close late May 2014.

We believe this deal as the potential to be a game-changer for Aastrom. Through the CTRM acquisition, Aastrom is acquiring global commercial rights to three marketed autologous cell therapy products:

- **Carticel®** (autologous cultured chondrocytes) is an autologous chondrocyte implant (ACI) currently marketed in the United States for the treatment of articular cartilage defects. The product is administered by orthopedic surgeons after obtaining a cartilage biopsy from which the patient's chondrocytes cells that produce cartilage are isolated and expanded into GMP manufacturing process. The cells are implanted in the cartilage defect under a periosteal flap where they produce new cartilage. The therapeutic advantage of this approach is that autologous chondrocyte produce the hyaline cartilage that is naturally present in the knee rather than fibrous cartilage, which is the case with other approaches. There have been more than 22,000 implants performed since first approved in 1997.

- **MACI®** (matrix-induced autologous chondrocyte implant) is a third-generation ACI product currently marketed in the European Union since 2013. The product is manufactured similarly to Carticel® whereby chondrocytes are isolated from a cartilage biopsy and expanded after which they are on to a collagen membrane. The seeded membrane is trimmed to the size of the cartilage defect and fixed in the defect with fibrin glue. According to Aastrom, the advantage of MACI® is that it delivers the efficacy of Carticel®, with a dramatic improvement in ease of use for the physician and a reduced rehabilitation protocol for the patient. The implant procedure for MACI® is much less invasive and thus results in a meaningful reduction in the post-operative recovery time for the patient. There have been more than 10,000 patients treated with MACI® to since first approved outside the U.S. in 1998.

- **Epicel®** (cultured epidermal autografts) is a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area. It is the only approved autologous epidermal product available for large total surface area burns. Epicel® is produced by isolating and expanding keratinocytes, which are the predominant cell type in epidermis or outer layer of the skin obtained from a biopsy of a patient's healthy skin. We believe the product is a much needed and important treatment option for patients with severe burns given the lack of alternative treatment options for patients with full thickness burns. Epicel® is a relatively small product though, used in only around 100 patients per year. It is only approved for use as a humanitarian use device in the U.S. and supplied to patients outside the U.S. on a named-patient basis.

Revenues of these three products totaled $44 million in 2013, with the majority coming from Carticel®. Sales in 2013 are consistent with the previous few years. However, we point out to investors that these assets have been considered low priority at Sanofi-aventis (SNY). There has been minimal effort, if any, to growth this business or streamline the operations. Aastrom believes there is sizable "low-hanging fruit" with respect to increasing revenues and increasing operating profit from the business. And according to management, the business is generating positive operating income as of right now. Aastrom will acquire the entire operations from Sanofi, including two manufacturing facilities (one in Cambridge, MA and the other in Denmark), roughly 200 employees, and $4.3 million in positive working capital.

This seems like an incredible opportunity for Aastrom. Upon the close of the transaction, Aastrom will pay Sanofi $4.0 million in cash. They will then immediately take ownership of $4.3 million in positive working capital, meaning net-net Aastrom will see an increase in working capital on day one. We have no idea what the two manufacturing facilities are valued at, but we suspect that Aastrom will also see a big spike in total assets and shareholder equity as a result of the transaction. Aastrom will owe Sanofi $2.5 million 60 days after the deal closes. All-in, the net cost of the transaction is $2.2 million, astonishingly low. Given that Aastrom still has roughly $10 million on its ATM and $15 million on its CPSA with LPC, we believe the company has sufficient capital to execute the transaction.

Aastrom has commented publicly that acquiring the CTRM business from Sanofi will provide a platform to generate operating income to support the development of the internal pipeline, which includes ixmyelocel-T. Again, Aastrom has stated publicly that division has assets to generate positive operating income. On $44 million in revenues, if

CTRM offers only 10% operating margins – which seems low – it would generate $4.4 million in positive operating income to Aastrom in year one. Is it possible that Aastrom just acquired $4.4 million in positive operating income per year, with enormous opportunity to both grow revenues and streamline the operations, for net 0.5x earnings?

If Aastrom can improve the operating margin on CTRM to 20% and grow revenues even only 10% in 2015 to $50 million, Aastrom could be generating $10 million in positive operating income from this transaction. Two potential wildcards that could derail this thesis include potential disruption to the business during the transition period and management of the business once under-house at Aastrom. We address these issues below:

- We see little risk in disruption and believe the transaction will be seamless for Aastrom. We believe this because Aastrom is acquiring the entire division, which includes all three products, two manufacturing facilities and 200 employees. For these employees and this business, it will be simply a name-change on day one. The revenues from the three products have been fairly stable over the past few years and, if anything, we think Aastrom will place far more strategic vision and emphasis on growing the brand that Sanofi did. CTRM was simply an after-thought for Sanofi. For Aastrom, it's a golden opportunity.

- In terms of Aastrom leaders, new CEO Dominick Colangelo brings direct experience in acquisitions, development, and commercialization in fibrovascular, metabolic and cardiovascular diseases during his tenure at Eli Lilly (LLY). Mr. Colangelo was Director of Strategy and Business Development for Lilly's Diabetes Product Group and also served as a founding Managing Director of Lilly Ventures. COO Daniel Orlando brings more than 20 years of commercial product preparation and launch experience. His previous role was Vice President of Business Development for North and South America at Takeda Pharmaceuticals. CMO Dr. David Recker brings more than 20-years of drug development experience, previously serving as Senior Vice President of clinical sciences at Takeda Global Research and Development. However, the recent hire we find most interesting is Dr. Ross Tupo to the role of CSO. Dr. Tupo served as Vice President of Stem Cell and chemokine biology at Genzyme, where he directed R&D programs for Carticel® and Epicel®. On Aastrom's first quarter conference call, CEO Colangelo noted that Dr. Tupo, "Now has the opportunity 20-years later to support the products he developed early in his carrier and rejoined a business that he helped to create."

The deal is expected to close in a few weeks (guidance is late May 2014). After the deal closes, Aastrom should provide guidance for the business and make available pro-form income statement for all to see. These could take a month to prepare, but we fully expect that Aastrom will disclose more numbers and more detail than we currently have in the press release announcing the closing of the transaction. As of right now, we are left doing some guessing, extrapolating, and a little detective work to try to ascertain the true value of CTRM. However, the thing that we find most perplexing is the acquisition price. Based on our preliminary analysis, CTRM could be worth as much as $30 million, conservatively. Aastrom is picking it up for net $2.2 million. As noted above, Aastrom's current market value is $24 million. What's missing?

Conclusion

We believe ixmyelocel-T for ischemic DCM is worth $30 million in value. The current market capitalization is only $24 million – attractive but not attractive enough to make us want to buy the stock based on this alone. However, when we do our back-of-the-envelope calculation on CTRM, we arrive at a similar $30 million value. That makes Aastrom worth $60 million total, or around $9.25 per share – extremely attractive. We are eagerly awaiting an update from the company once the deal closes because if our back-of-the-envelope calculations are correct, Aastrom stock is set to, at the very least, double over the near term.

PROJECTED FINANCIALS

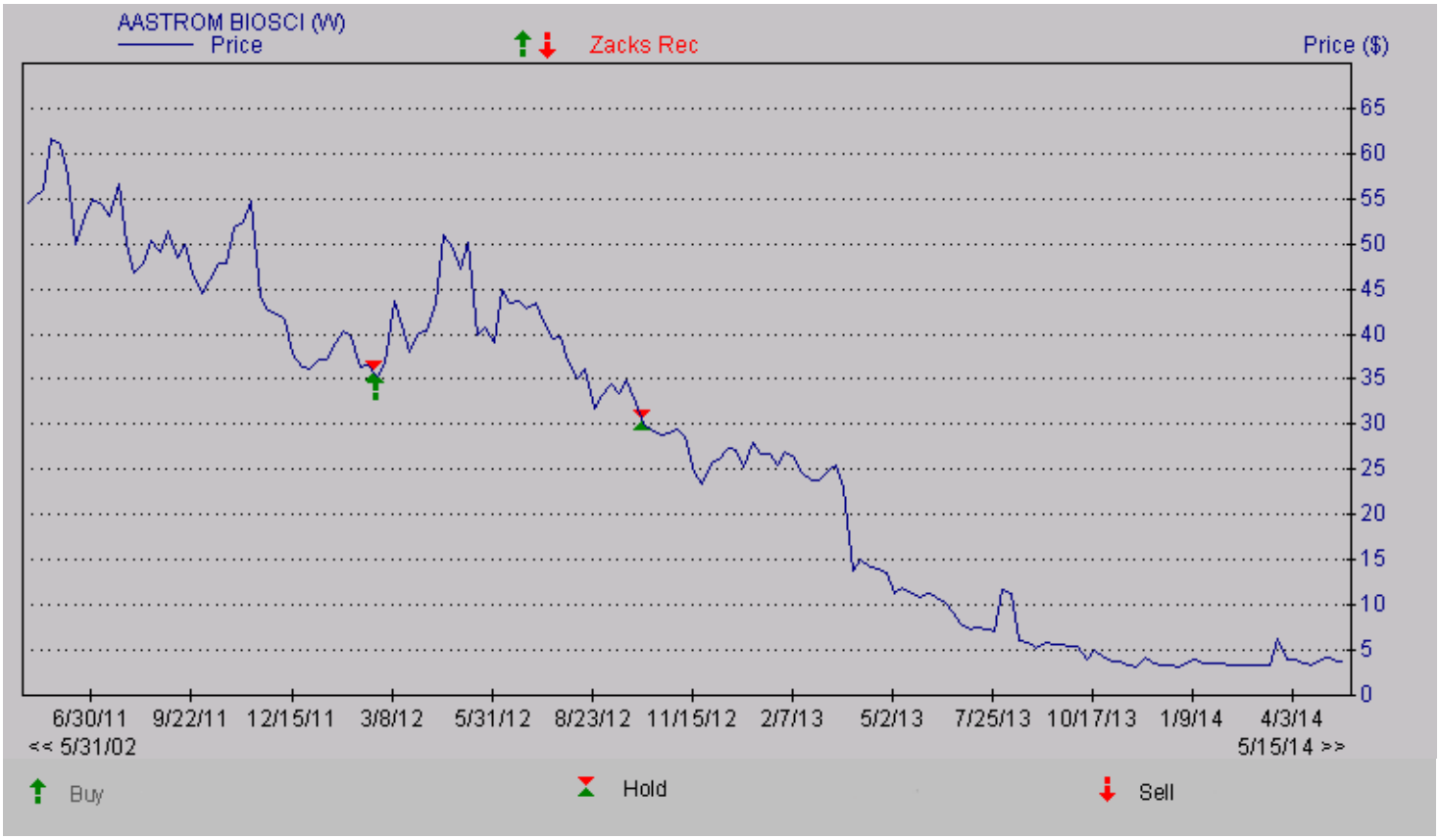
Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-12	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Dec-15	Dec-16
	2012 A	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
R&D Agreements / Grants	**$0.021**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0.0%*	*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	$26.0	$15.1	$3.3	$3.5	$3.5	$3.6	$13.9	$15.0	$16.0
% R&D	-	-	-	-	-	-	-	-	-
Selling, General, and Admin	$7.8	$5.9	$1.4	$1.4	$1.4	$1.5	$5.7	$6.0	$6.5
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($33.8)	($21.0)	($4.6)	($4.9)	($4.9)	($5.1)	($19.5)	($21.0)	($22.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Income (Expenses)	$4.3	$5.3	($1.4)	$0.0	$0.0	$0.0	($1.4)	$0.0	$0.0
Pre-Tax Income	($29.5)	($15.6)	($6.0)	($4.9)	($4.9)	($5.1)	($20.9)	($21.0)	($22.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($29.5)	($15.6)	($6.0)	($4.9)	($4.9)	($5.1)	($20.9)	($21.0)	($22.5)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($14.31)**	**($5.18)**	**($1.02)**	**($0.74)**	**($0.72)**	**($0.73)**	**($1.73)**	**($2.47)**	**($2.25)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	2.1	3.0	5.9	6.6	6.8	7.0	6.7	8.5	10.0

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

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