Zacks Small-Cap Research

August 15, 2014
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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Initial Results from CTRM Look Encouraging…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	6/16/2014
Current Price (08/15/14)	$3.34
Target Price	**$6.50**

UPDATE

On August 14, 2014, Aastrom Biosciences reported results for the second quarter of 2014. These included one month of operations for the newly acquired CTRM business. Total revenues for the quarter were $4.4 million. The company reported a net loss of $4.6 million, or $0.71 per share.

Aastrom has implemented an aggressive strategic plan to get costs associated with CTRM under control. As a result of these initiatives, CTRM generated a positive contribution in the quarter, with management indicating additional areas for growth through this operation on the second quarter call.

We are encouraged by the initial month of operating results from the newly acquired business and are maintaining a Buy rating and $6.50 price target.

SUMMARY DATA

52-Week High	**$6.55**
52-Week Low	**$3.16**
One-Year Return (%)	**-44.35**
Beta	**1.09**
Average Daily Volume (sh)	**79,180**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**5.49**
Institutional Ownership (%)	**9**
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	4.4 A	11.1 E	12.1 E	27.6 E
2015					50.1 E
2016					53.5 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	-$0.71 A	-$0.50 E	-$0.49 E	-$2.60 E
2015					-$1.82 E
2016					-$0.54 E

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WHAT'S NEW

Financial Results

On August 14, 2014, Aastrom Biosciences, Inc. (ASTM) reported financial results for the second quarter of 2014. Results included one full quarter of operations for the company's recently acquired Cell Therapy and Regenerative Medicine (CTRM) business from Sanofi (SNY), previously known as Genzyme Biosurgery Aps. Total revenues for the quarter were approximately $4.4 million, and were comprised of approximately $3.4 million of net sales of Carticel® implants and surgical kits, approximately $0.9 million of net sales of Epicel® grafts and biopsy kits, and approximately $0.1 million of revenue from commercial sales of bone marrow generated by Marrow Donation, LLC. Aastrom only began commercial sales of bone marrow late in the second quarter. In fact, these revenues were generated from only about one month with Carticel® and Epicel®, and about one week with Marrow Donation, LLC.

Aastrom reported a gross loss of $0.6 million, which was the partial result of $2.4 million of charges in cost of goods sold associated with the restructuring of CTRM. Net loss in the quarter was $4.6 million, or $0.71 per share. The loss was driven by $4.4 million in R&D and $3.6 million in SG&A expenses. Other income for the second quarter was $3.9 million, and was primarily due to a bargain purchase gain of $3.6 million recorded upon the closing of the acquisition of CTRM.

As of June 30, 2014, the company had $7.3 million in cash and cash equivalents, compared to $8.1 million in cash and cash equivalents at December 31, 2013. During the second quarter Aastrom raised approximately $3.2 million in proceeds in the Lincoln Park equity line. We expect the company to remain active in the third quarter raising additional capital from this equity purchase agreement.

Room to Grow with CTRM

As can be seen from the reported revenue numbers, Aastrom is off to a good start in regards to Carticel® and Epicel® sales, however there is much that can be done to drive sales higher for both of these products. In addition, the company is looking to engage with the FDA to determine the steps necessary to get MACI approved for use in the U.S.

…Carticel® is a compelling treatment option for younger patients…

During the second quarter conference call management indicated that the $3.4 million in sales of Carticel® represented approximately 100 surgeries. They also indicated that there is a potential patient population of approximately 60,000 younger patients with larger cartilage defects who may benefit from Carticel® treatment, thus creating a situation where there are robust expansion opportunities. For example, even penetration of only 1% of this population would contribute an additional $20+ million in revenue to Aastrom's top-line.

This is an enormous opportunity. The target patient population for Carticel® is younger and more active, thus any treatment option for this population needs to be durable and ideally able to restore proper knee function. Carticel® was first approved in 1997, with over 20,000 patients treated thus far in the U.S. In addition, there is durability of repair data out to 20 years that demonstrates long-term benefits of the product and allows the patients to regain normal function of the knee over time.

Current first-line treatment for the target patient population is a microfracture, which involves a fracturing into the subchondral bone and induction of fibrous cartilage to form over the defect. However, that process is both biochemically and biomechanically inadequate to last a long period of time. Typically this type of procedure only provides relief for one to three years. This is due to the lack of formation of hyaline cartilage, which is found on the surface of the knee joint. This treatment is typically followed up by another microfracture or an osteochondral autograft, with an inevitable partial or total knee replacement to follow. This entire process typically takes 10 to 15 years – and hundreds of thousands of dollars – to play out.

The advantage of Carticel® is that it involves a robust biochemically and biomechanically correct repair tissue, meaning that the transplant induces formation of hyaline cartilage that is naturally present in the knee and typically results in restoration of function for the patients.

Data presented in 2008 at the American Academy of Orthopaedic Surgeon's annual meeting showed that almost 90% of patients treated with Carticel® who experienced improvement in knee function at an early follow-up sustained their improvement for up to almost 10 years. This data makes Carticel® a compelling choice for a younger patient looking for a long-term treatment option.

…Epicel® may become a for-profit product…

Epicel® was originally approved as a Humanitarian Use Device (HUD) in 2007. Only a small number of physicians are responsible for a majority of use with most of the business coming from a handful of burn centers in the U.S. Management estimates that as a share of burn bed's Epicel® is probably under 5% share. As a HUD product, Epicel cannot be sold for an amount that exceeds the costs of research and development, manufacturing / fabrication, and distribution.

One of the strategic moves Aastrom plan's to take is increasing the price of Epicel® to the maximum allowed under HUD. Based on conversations with management, this should result in a roughly 30% increase in price by the second half of the year. Epicel® sales in 2013 totaled $7.1 million. Stable operations and a 30% price increase should add over $2.0 million in to the top-line numbers in 2015.

Another strategy management is looking into in regards to Epicel® is converting the product from a HUD to a commercial product capable of being sold for a profit. The FDA Safety and Innovation Act (SIA) was enacted into law in 2012, and allows the makers of HUDs to make a profit so long as the device meets the following criteria:

- The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

- The device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

There are a number of children who benefit from treatment with Epicel®, thus the product most likely meets the requirements under the SIA. The process to gain approval for converting a HUD to a commercial entity involves a 75-day review period, and the company is currently in discussions with the FDA about the data that Sanofi had with regards to pediatric use. We are expecting they will be in position to file a package with the FDA soon. However, as with most things involving the FDA, there is an issue regarding exactly what the agency will review the application, as conversion of a HUD to a for-profit entity has only been done approximately five or six times in the past. There is not extensive experience or precedent to follow. It is certainly not impossible, but for this reason management was not able to put a timeline on when this process may occur.

…Looking to Relaunch MACI® in Europe and Determine the Path to Approval in the U.S.…

MACI® (matrix-induced autologous chondrocyte implant) is a third-generation autologous chondrocyte implant product currently marketed for the treatment of focal chondral cartilage defects in the knee in the European Union since 1998. 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. Specifically, the implant procedure involves only a mini-arthrotomy or arthroscopic delivery, eliminating the need for a periosteum harvest and sutures.

Management believes that MACI® represents a potential replacement product for Carticel® as well as an opportunity to expand the market for autologous cartilage repair products. Currently, Aastrom has halted sales of MACI® in Europe, and the company has a three year window in which to reintroduce the product. There are reimbursement challenges in Europe; however, the company believes that there are a number of countries where the product has great potential and thus they will continue to investigate the best path forward in that regard.

As far as gaining approval for MACI® in the U.S., the company is continuing to engage with the FDA to determine the path forward. Management is not certain whether the study that got MACI® approved in Europe is going to be sufficient to gain approval in the U.S. However, if another study is required, it is likely to be a smaller confirmatory study. With that said, nothing will be known for sure until Aastrom has a chance to sit down with the FDA and determine the steps necessary to get MACI® approved. This will likely happen in the second half of 2014.

The opportunity for MACI® in the U.S., where reimbursement procedures are already in place, is significant. MACI® looks like a superior version of Carticel®, a product doing $35+ million in revenues for CTRM right now. Based on the product characteristics, we believe MACI® could effectively double the revenue opportunity to Aastrom from CTRM. We believe MACI® has improved economics to Aastrom as well, which should allow for greater profitability as sales ramp.

Valuing CTRM

Below we've built a quick P&L for the CTRM business based on management's proposed strategic plan. It shows the business losing $33.6 million in income in 2013, roughly $20.4 million of which was pure cash. In 2015, management believes they can turn this around and generate positive cash flow from CTRM.

In Millions	2013		2015
Carticel®	$35.2	*Improve efficiency*	$40.5
Epicel®	$7.1	*Increase price >>>*	$9.2
MACI®	$1.6	*Eliminate >>>>>>>*	$0.0
Marrow Donation	-	*Acquired >>>>>>>*	$0.4
TOTAL REVENUES	**$43.9**		**$50.1**
Non-Cash Items (A&D, SBC)	$13.2		$13.2
MACI® R&D	$9.0	*Eliminate >>>>>>>*	-
Denmark Facility	$7.0	*Eliminate >>>>>>>*	-
Staff	$4.0	*Eliminate >>>>>>>*	-
TOTAL EXPENSES	**$77.5**		**$57.5**
CASH FLOW	**($20.4)**		**$5.8**

Source: Jason Napodano, CFA

…What CTRM Might Be Worth…

Valuing a division within a larger organization is a daunting task. Even if Aastrom management can get CTRM to cash flow positive operations in 2015 to the tune of $5+ million, that will not be enough to drive the entire organization to cash flow positive operations considering the research and development programs for ixmyelocel-T are costing an estimated $15 to 20 million per year to fund. And, because of the significant non-cash expense associated with CTRM (mainly depreciation and amortization), the division will not show a profit even if cash flow turns positive in 2015.

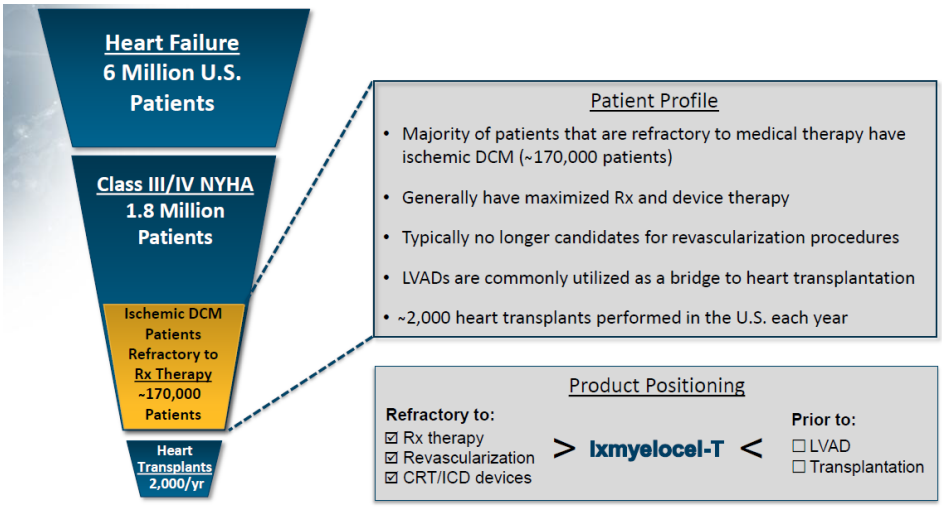
Below we present two commonly used applied valuation multiples based on comparisons with some of the pharmaceutical and biotechnology industry's largest players. Based on the table below, which includes some "high flyers" like Gilead, Biogen, Celgene, and Allergan, the average Price / Sales ratio for the top players in the industry is around 5.5x. On a Price / Cash Flow basis, the average is 16.4x. To be conservative, we've chosen not to value Aastrom on a Price / Sales ratio because the division is not profitable. However, as a point of reference, based on Aastrom's current market capitalization of $24 million, the stock is currently trading at 0.5x sales. If Aastrom were able to generate $5.4 million in positive cash flow from CTRM in 2014, as outlined in our rudimentary P&L above, applying a Price / Cash Flow multiple of 10x, which is roughly were the lowest quartile of companies in our valuation comparison table are trading, CTRM might be worth $50 million in value.

We admit $50 million in value seems aggressive, especially considering Aastrom has yet to demonstrate it can achieve $5+ million in positive cash flow per year from CTRM. However, based on the company's strategic plan and execution of that plan thus far, we do believe this level of financial achievement is possible in 2015. It looks like CTRM has been rather poorly run and/or neglected at Sanofi since the merger with Genzyme in 2011. We believe Aastrom has a good strategic plan to turn the operations around and significant "low-hanging fruit" exists to get the company started.

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, with the company reporting they have enrolled and treated more than half of the targeted 108 patients while remaining on track to complete enrollment of the study by the end of the year. 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.

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. Assuming enrollment is completed by the end of 2014, we expect top-line data from ixCELL-DCM by the end 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.

Conclusion

We believe ixmyelocel-T for ischemic DCM is worth $30 million in value, valued based on a probability-adjusted NPV analysis. Management has laid out an aggressive yet comprehensive plan to turn around the newly acquired CTRM business, and the first month of sales seems to indicate that the company is executing on the plan. If guidance and our projections hold, and the company can generate $5+ million in positive cash flow in 2015 through CTRM, then CTRM could be worth another $25 to $50 million in value, based on a 10x Price / Cash Flow ratio. The current market capitalization is only $24 million, making the stock attractive for share accumulation in our view. As such, we are maintaining our 'Buy' rating on the shares with a target of $6.50 per share.

PROJECTED FINANCIALS

Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Dec-15	Dec-16	Dec-17
	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E	2017 E
R&D Agreements / Grants	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0%*	-	-	-	-	*0.0%*	*0%*	*0%*	*0%*
Carticel	*$35.2*	*$7.9*	**$3.4**	**$9.0**	**$10.0**	**$22.4**	**$40.5**	**$43.0**	**$46.0**
YOY Growth	*0.0%*	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Epicel	*$7.1*	*$2.5*	**$0.9**	**$2.0**	**$2.0**	**$4.9**	**$9.2**	**$10.0**	**$11.0**
YOY Growth	-					-	-	-	-
MACI	*$1.6*	*$0.1*	**$0.0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-	-
Marrow Donation, LLC	**$0**	**$0**	**$0.1**	**$0.1**	**$0.1**	**$0.3**	**$0.4**	**$0.5**	**$0.5**
YOY Growth									
Ixmyelocel-T	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-	-
Total Revenues	**$0**	**$0**	**$4.4**	**$11.1**	**$12.1**	**$27.6**	**$50.1**	**$53.5**	**$57.5**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Product Sales & Rentals	$0	$0	$5.0	$5.0	$5.5	$15.5	$22.5	$21.4	$23.0
Product Gross Margin	-	-	*-13.0%*	*55.0%*	*54.5%*	*43.9%*	*55.0%*	*60.0%*	*60.0%*
Research & Development	$15.1	$3.3	$4.4	$4.0	$4.0	$15.6	$20.0	$15.0	$15.0
% R&D	-	-	-	-	-	-	-	-	-
Selling, General, and Admin	$5.9	$1.4	$3.6	$5.5	$6.0	$16.5	$25.0	$26.5	$28.0
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($21.0)	($4.6)	($8.5)	($3.4)	($3.4)	($20.0)	($17.4)	($9.4)	($8.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Income (Expenses)	$5.3	($1.4)	$3.9	$0.0	$0.0	$2.5	$2.0	$4.0	$5.0
Pre-Tax Income	($15.6)	($6.0)	($4.6)	($3.4)	($3.4)	($17.4)	($15.4)	($5.4)	($3.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($15.6)	($6.0)	($4.6)	($3.4)	($3.4)	($17.4)	($15.4)	($5.4)	($3.5)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($5.18)**	**($1.02)**	**($0.71)**	**($0.50)**	**($0.49)**	**($2.60)**	**($1.82)**	**($0.54)**	**($0.28)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	3.0	5.9	6.5	6.8	7.0	6.7	8.5	10.0	12.5

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

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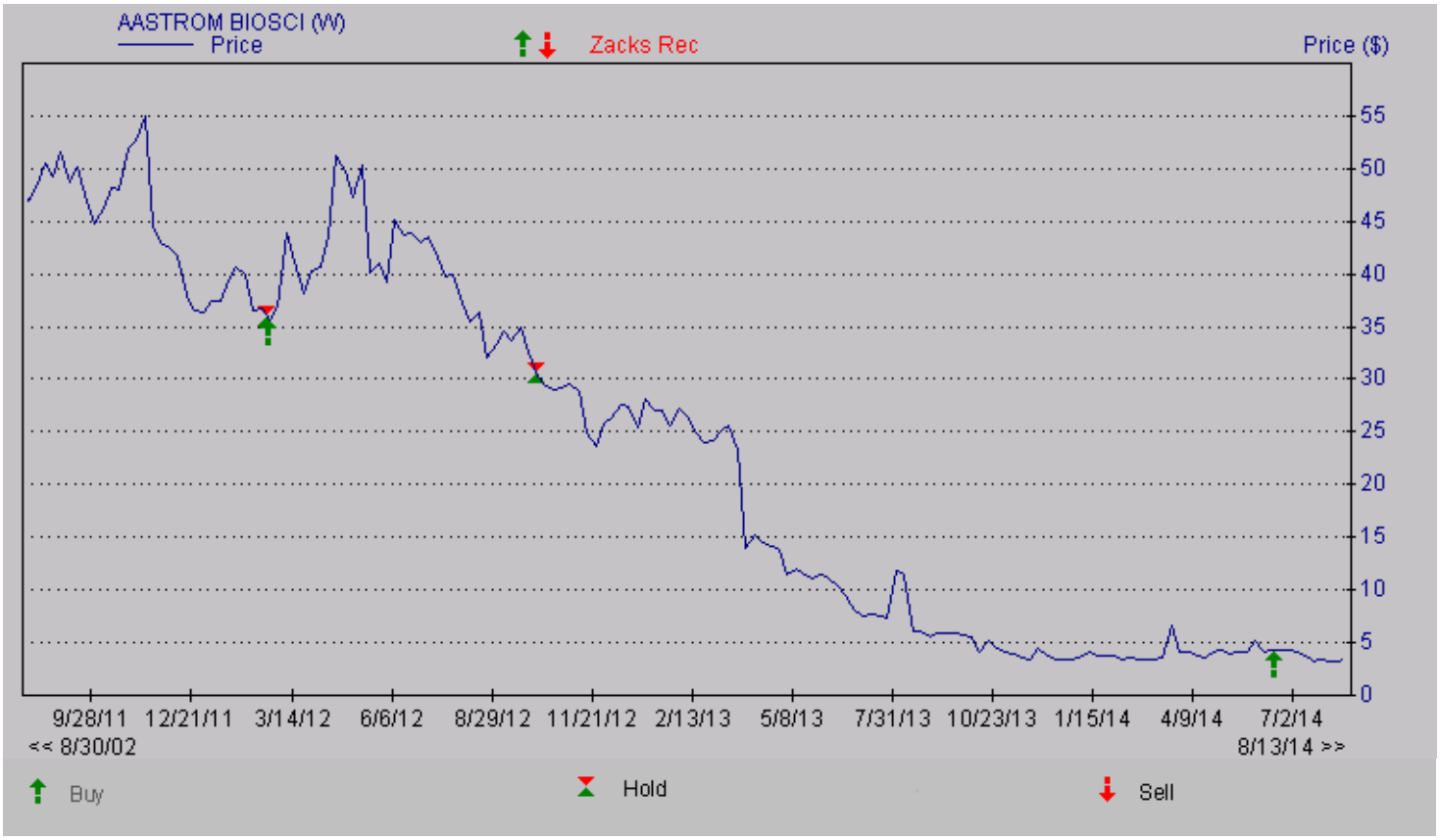

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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