Zacks Small-Cap Research

November 13, 2014
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Aastrom Biosciences, Inc. (ASTM-NASDAQ)

ASTM: Aastrom Fundamentals Continue To Improve; Reiterate Buy Rating…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	6/16/2014
Current Price (11/13/14)	$2.82
Target Price	**$6.50**

UPDATE

On November 14, 2014, Aastrom Biosciences reported results for the third quarter of 2014. These included a full quarter of operations for the newly acquired CTRM business. Total revenues for the quarter were $9.7 million. The company reported a net loss of $6.9 million, or $0.82 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	**$6.49**
52-Week Low	**$2.61**
One-Year Return (%)	**-27.47**
Beta	**1.12**
Average Daily Volume (sh)	**123,212**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**4.06**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**32**
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	9.7 A	11.8 E	25.9 E
2015					49.1 E
2016					57.8 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	-$0.82 A	-$0.16 E	-$1.86 E
2015					-$0.52 E
2016					-$0.03 E

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WHAT'S NEW

Third Quarter Financial Results

On November 13, 2014, Aastrom Biosciences, Inc. (ASTM) reported financial results for the quarter of 2014 ending September 30, 2014. Results in the quarter included a 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 third quarter 2014 were approximately $9.7 million, and were comprised of approximately $7.5 million of net sales of Carticel® implants and surgical kits, approximately $1.8 million of net sales of Epicel® grafts and biopsy kits, $0.2 million sales of MACI™, and $0.2 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.

Revenues in the quarter were flat with the same period in 2013, only we note that Aastrom was able to achieve these revenues with slightly fewer sales representatives than what Sanofi had at the end of 2013. For example, the current Carticel® sales force is 20 full-time representatives, down 3 from when Aastrom took over the business. Management believes that they may add back some representatives in 2015. We expect a strong uptick in revenues in the fourth quarter 2014 for a number of reasons:

1) As we come to the end of the year, many patients have met their insurance deductibles or have flexible spending accounts they need to use. Elective procedures tend to have strong fourth quarters based on the dynamics of the insurance market. Carticel® typically has had a strong fourth quarter under Sanofi.
2) As the weather turns colder, people begin to use space heaters or electrical blankets. Increase use of heating elements tends to lead to an increase in burns, which drives use of Epicel®.
3) Additionally, Aastrom has recently raised the price of Epicel® and increase the sales force promoting the product from one to three full-time representatives.

Gross margin in the third quarter was 42.7%. We expect continued improvement in the gross margin line over the next several quarters as Aastrom gains efficiencies on manufacturing and scale at the Cambridge facility. Ultimately, we believe Aastrom can see gross margin approach 60% by the end of 2015.

Operating expenses in the third quarter totaled $12.1 million and were driven by $7.8 million in R&D and $4.3 million in SG&A. We note R&D included a $3.2 million charge related to a settlement agreement with Verigen that eliminates all future milestone payments (was approximately $15.8 million) related to the development and commercialization of MACI™ in the United States. R&D specific to CTRM totaled $0.8 million. SG&A expense in the third quarter totaled $4.3 million, of which $1.9 million was attributable to CTRM. During the quarter, Aastrom noted that costs associated with the manufacturing facility in Denmark totaled $0.4 million. This facility will be fully shut down by the end of the year.

Aastrom reported a net loss of $6.9 million, or $0.82 per share in the third quarter 2014. Backing out the $3.2 million Verigen agreement and net loss would have been $3.8 million, or $0.52 per share. This was right in-line with our expectations. Contribution from CTRM totaled $1.0 million. This number would have been $1.4 million backing out the facility in Denmark. We view these as highly impressive results. Many investors baulked at the acquisition of CTRM earlier in 2014. In its first full quarter under Aastrom control, CTRM reported positive EBITDA of $1.0 million, with a clear path to make it significantly higher in the coming quarters. We discuss what CTRM might be worth in our report below.

As of September 30, 2014, the company had $37.6 million in cash and cash equivalents, compared to $7.3 million at the end of June 2014. During the third quarter, Aastrom raised approximately $37.4 million in net proceeds from an underwritten sale of common stock run by Ladenburg Thalmann & Co. In the public offering, Aastrom sold 15.784 million shares of stock to the public at $2.55 per share. We model that Aastrom will exit 2014 with roughly $35 million in cash on the books. We suspect operating burn in 2015 will be around the $10 million mark, meaning that cash at year end 2015 should still be $15 million. If the CTRM business ramps to our expectations, Aastrom may be in position to report breakeven operations, notwithstanding moving ixmyelocel-T into a Phase 3 study alone, in 2016. This is something both new and long-term Aastrom investors should be excited about, and the primary reason we continue to be positive on the stock.

CTRM Off To A Great Start

As can be seen from the reported revenue numbers, Aastrom is off to a great start in regards to Carticel® and Epicel® sales. Above we outlined three reasons why results in the fourth quarter should be even better. In addition, Aastrom is looking to engage with the FDA to determine the steps necessary to get MACI™ approved for use in the U.S. We hope to have an update in this regard early 2015. On the company's third quarter conference call, management would not provide financial guidance for 2015, instead stating that they would like to get two full quarters of CTRM operations under their belt. We expect management to provide financial guidance for 2015 on the company's year-end 2014 conference call in March 2015.

…Carticel®…

Carticel® sales in the third quarter totaled $7.5 million. We estimate this represented approximately 220 surgeries. Management noted that surgeries in the fourth quarter could increase by 100 over the third quarter due to the dynamics of the insurance market – i.e. patients meeting their yearly deductible and/or having money left over in their flexible spending accounts. We note that elective procedures tend to uptick in the fourth quarter of the year.

We believe the ultimate patient population for Carticel® in the area of 60,000, with an emphasis on younger patients with larger cartilage defects who may benefit from Carticel® treatment. We see this as a largely unpenetrated population, thus creating a situation where there are robust expansion opportunities exist for Aastrom. For example, even penetration of only 1% of this population would contribute an additional $20+ million in revenue to Aastrom's top-line. 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. For 2015 we see Carticel® sales approaching $40 million in the U.S.

…MACI™…

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.

In September 2014, Aastrom presented three year data from the SUMMIT Extension Study of MACI™ at the 2015 American Academy of Orthopedic Surgeons annual meeting. Two-year results from the initial Phase 3, randomized, controlled SUMMIT trial demonstrated that patients with symptomatic articular cartilage defects of the knee who were treated with MACI™ showed greater improvement over baseline compared to patients treated with microfracture (Saris D, et al. Am J Sports Med. 2014).

To us, MACI™ looks like 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 without having to file for a new application. 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 next few months.

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.

…Epicel®…

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 has made is to increase 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 relative to what Sanofi sold the product for in 2013. 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.

In the meantime, we expect Epicel® sales to increase in the coming quarters thanks to enhanced promotion from Aastrom. Aastrom acquired one sales representative when they bought CTRM from Sanofi earlier in the year. They have since increased that number to three. The strategy is to go back to burn centers that previously used Epicel® prior to Aastrom acquiring CTRM but have since stopped, likely because of a lack of promotion. We believe that Aastrom can book $12.5 million in Epicel® sales in 2015. We expect an uptick in the fourth quarter 2014 based on seasonality of the product – i.e. more burns occur as the weather turns colder.

Valuing CTRM

In the third quarter 2014, Aastrom reported that CTRM provided $1.0 million in positive cash contribution. This number would have been $1.4 million without the Denmark facility. Denmark will be fully shut-down by the end of 2014. We also expect profitability of CTRM to improve in the coming quarters as Aastrom increases promotion and gains efficiencies in manufacturing.

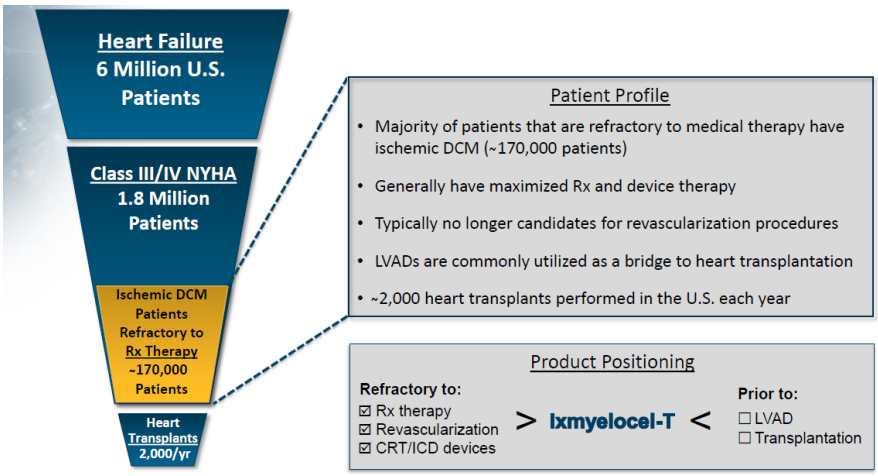
We had previously believed that CTRM would do +$5 million in EBITDA in 2015. Based on the $1.0 million that was reported, and likely $1.4 million that would have been reported backing-out Denmark, this number now looks too conservative. We think it is possible CTRM does $6-7 million in positive EBITDA in 2015. For 2015, we project near $50 million in revenues from CTRM. If these numbers hold, then Aastrom is vastly undervalued today.

For example, the pharmaceutical industry average Price / Sales ratio is 5.5x based on trailing twelve month numbers. The ratio for Price / EBITDA is 16.0x based on trailing twelve month numbers. This would seem to suggest that CTRM, should it generate $50 million in revenues and $6.5 million in positive EBITDA in 2015 is worth between $80 and $105 million in value.

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 80% 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 in the first quarter 2016.



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.

Conclusion

We believe ixmyelocel-T for ischemic DCM is worth $30 million in value based on a probability-adjusted NPV analysis described above. Management has laid out an aggressive yet comprehensive plan to turn around the newly acquired CTRM business; and in the company's first full quarter of reported results they hit the ball out of the park, generating $9.7 million in revenues and $1.0 million in positive cash contribution. We believe the company is executing on its aggressive plan. For 2015 we project $49.1 million in revenues and $6.5 million in positive EBITDA from CTRM. Using current pharmaceutical industry averages of 5.5x sales and 16.0x EBITDA (see below) we believe that CTRM is worth between $80 and $105 million.

Company	Price / Sales	Price / Earnings	Price / EBITDA
GlaxoSmithKline plc	2.9	14.7	11.1
Sanofi-aventis	3.0	14.5	9.7
Eli Lilly and Co	3.6	21.1	15.0
Pfizer Inc.	3.8	13.6	9.0
Merck & Co. Inc.	4.0	16.7	11.1
Johnson & Johnson	4.1	17.5	12.1
Cubist Pharma	4.7	39.5	27.2
AbbVie, Inc.	5.2	15.2	14.6
Valeant Pharma	5.4	13.0	11.6
Actavis plc	5.5	14.8	18.8
Bristol-Myers Squibb	6.1	32.4	22.7
Amgen Inc.	6.3	17.5	14.6
Shire plc	6.9	17.5	15.4
Gilead Sciences Inc.	7.9	10.9	12.4
Allergan Inc.	8.3	22.8	25.1
Biogen Idec Inc.	8.5	22.2	18.5
Celgene Corporation	11.7	22.2	32.0
AVERAGE	**5.7**	**19.2**	**16.5**
AVERAGE (w/o Hi & Lo)	**5.5**	**18.4**	**16.0**

Valuing Aastrom Bio	Calculated Value
Ixmyelocel-T (Phase 2b DCM)	$30 Million
CTRM Business ($80-105M range)	$80 Million
Cash & Investments (Sept 30th)	$37.6 Million
TOTAL VALUE	$147.6 Million
Basic Shares Outstanding	~ 23.0 Million
TARGET PRICE	$6.41 / Share
Current Price	$2.75 / Share
UPSIDE TO TARGET	125%

Even taking the low-end of this range at $80 million is more than the company's current market capitalization at around $65 million. Adding in $30 million for ixmyelocel-T and $37.6 million in cash we arrive at a target valuation of $147.6 million, or $6.41 per share. That represents +125% upside over the next twelve months. It is clear that after the acquisition of CTRM Aastrom is a different and new company. In fact, they are seeking to change their name to Vericel Corporation and move the headquarters from Ann Arbor, MI to Cambridge, MA. We would be buyers of the stock at today's price.

PROJECTED FINANCIALS

Aastrom Biosciences
Income Statement

Aastrom Biosciences	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Dec-15	Dec-16
	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
R&D Agreements / Grants	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*0%*	-	-	-	-	*0.0%*	*0%*	*0%*
Carticel	*$35.2*	*$7.9*	**$3.4**	**$7.5**	**$9.0**	**$19.9**	**$36.0**	**$39.0**
YOY Growth	*0.0%*	-	-	-	-	*0.0%*	*0.0%*	*0.0%*
Epicel	*$7.1*	*$2.5*	**$0.9**	**$1.8**	**$2.5**	**$5.2**	**$12.5**	**$16.0**
YOY Growth	-					-	-	-
MACI	*$1.6*	*$0.1*	**$0.0**	**$0.2**	**$0.0**	**$0.2**	**$0.0**	**$2.0**
YOY Growth	-					-	-	-
Marrow Donation, LLC	**$0**	**$0**	**$0.1**	**$0.2**	**$0.2**	**$0.5**	**$0.6**	**$0.8**
YOY Growth								
Ixmyelocel-T	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
Total Revenues	**$0**	**$0**	**$4.4**	**$9.7**	**$11.7**	**$25.8**	**$49.1**	**$57.8**
YOY Growth	-	-	-	-	-	-	*90.4%*	*17.7%*
Cost of Product Sales & Rentals	$0	$0	$5.0	$5.5	$6.3	$16.8	$22.5	$22.5
Product Gross Margin	-	-	*-13.0%*	*42.7%*	*46.2%*	*34.7%*	*54.2%*	*61.1%*
Research & Development	$15.1	$3.3	$4.4	$7.8	$4.5	$20.0	$20.0	$15.0
Selling, General, and Admin	$5.9	$1.4	$3.6	$4.3	$4.6	$13.9	$21.0	$25.0
Operating Income	($21.0)	($4.6)	($8.5)	($8.0)	($3.7)	($24.9)	($14.4)	($4.7)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Expenses)	$5.3	($1.4)	$3.9	$1.1	$0.0	$3.6	$2.0	$4.0
Pre-Tax Income	($15.6)	($6.0)	($4.6)	($6.9)	($3.7)	($21.3)	($12.4)	($0.7)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($15.6)	($6.0)	($4.6)	($6.9)	($3.7)	($21.3)	($12.4)	($0.7)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.18)**	**($1.02)**	**($0.71)**	**($0.82)**	**($0.16)**	**($1.87)**	**($0.52)**	**($0.03)**
YOY Growth	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	3.0	5.9	6.5	10.3	22.8	11.4	24.0	28.0

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

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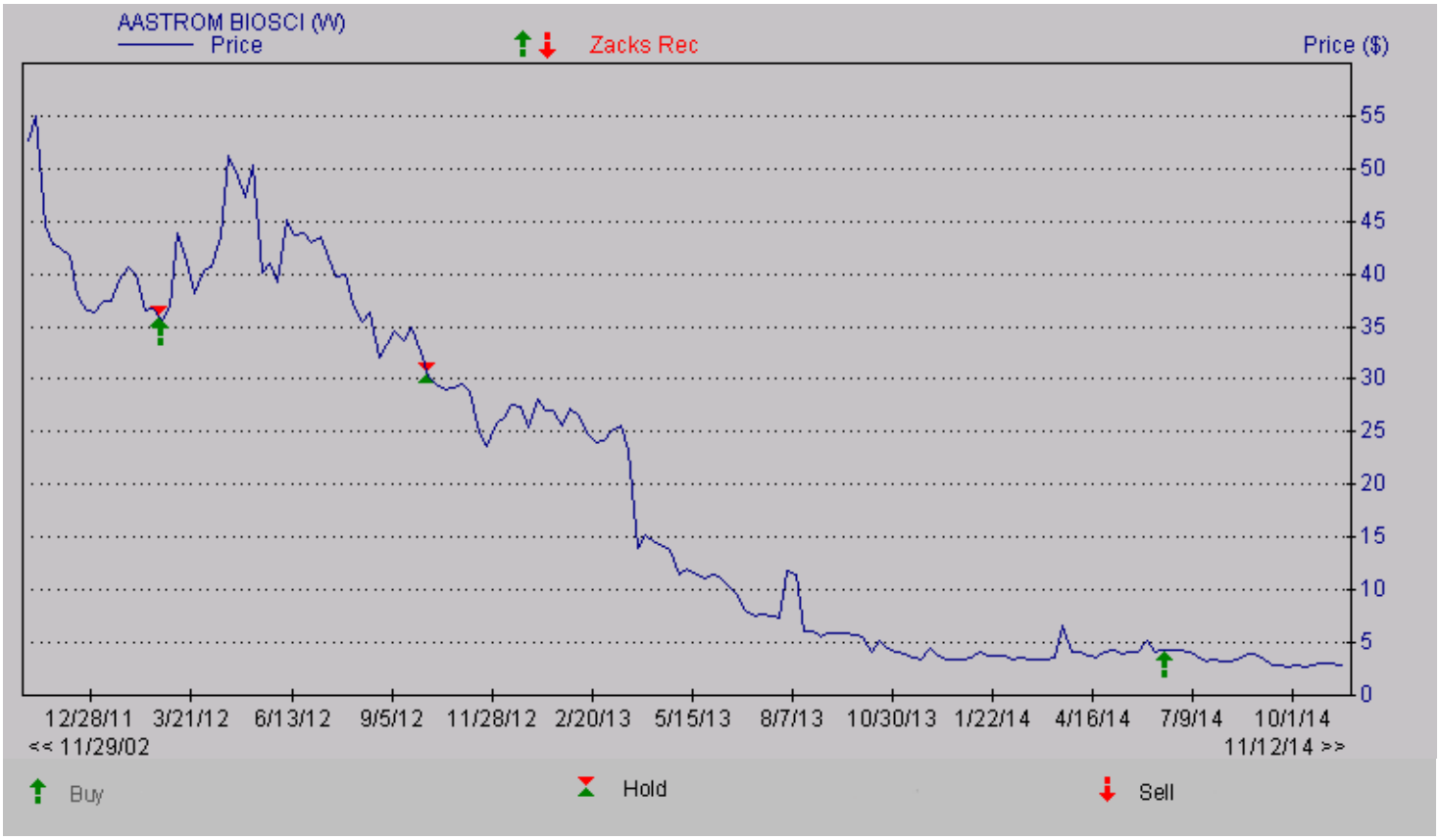

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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.8%, Hold/Neutral- 76.4%, Sell/Underperform – 5.9%. Data is as of midnight on the business day immediately prior to this publication.