Zacks Small-Cap Research

March 24, 2015
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Vericel Corporation (VCEL-NASDAQ)

VCEL: Solid Q4 Results Keep Us Bullish On Vericel Corp…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	6/16/2014
Current Price (03/24/15)	$4.02
Target Price	**$6.50**

UPDATE

On March 23, 2015, Vericel Corporation (VCEL) reported financial results for the fourth quarter and full year ending December 31, 2014. This was the second full quarter of operations for the company's recently acquired Cell Therapy & Regenerative Medicine ("CTRM") business. Results exceeded expectations and we believe are representative of strong and improving fundamentals at the company.

Below we outline some of the key strategies and initiatives that management has planned for 2015 and conclude with our thoughts on why we believe investment in Vericel Corp. makes sense at this level. We believe the shares are worth $6.50, representing 65% upside in 2015.

SUMMARY DATA

52-Week High	**$6.49**
52-Week Low	**$2.61**
One-Year Return (%)	**-27.95**
Beta	**1.08**
Average Daily Volume (sh)	**83,685**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$87**
Short Interest Ratio (days)	**2.68**
Institutional Ownership (%)	**46**
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 2015 Estimate	**N/A**
P/E using 2016 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)
2014	0 A	4.4 A	9.7 A	14.7 A	28.8 A
2015	12.8 E	12.7 E	12.1 E	16.2 E	53.7 E
2016					66.5 E
2017					79.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$1.02 A	-$0.71 A	-$0.82 A	-$0.10 A	-$1.72 A
2015	-$0.14 E	-$0.14 E	-$0.16 E	-$0.08 E	-$0.51 E
2016					-$0.02 E
2017					$0.31 E

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WHAT'S NEW

On March 23, 2015, Vericel Corporation (VCEL) reported financial results for the fourth quarter and full year ending December 31, 2014. This was the second full quarter of operations for the company's recently acquired Cell Therapy & Regenerative Medicine ("CTRM") business.

Revenues: Total revenues for the quarter were approximately $14.7 million, and were comprised of approximately $11.4 million of net sales of Carticel® implants and surgical kits and approximately $3.3 million of net sales of Epicel® grafts and biopsy kits. Revenues exceeded both our expectations of $11.2 million and Street consensus forecasts of $10.7 million thanks to upside from both products. It was clearly a solid quarter for the company.

Total revenues for the full year 2014 were $28.8 million, comprised mainly of $22.3 million in Carticel sales and $6.0 million in Epicel sales. Revenues for 2014 included approximately seven months of the CTRM business. On the fourth quarter earnings call management noted that Carticel sales grew by 13% year-over-year and total revenues grew by 9% year-over-year compared to the fourth quarter 2013 when the CTRM business was under control of Sanofi-US.

Management did not provide guidance for 2015 on the earnings call. Instead, management chose to provide revenue breakdown percentages by quarter for the last several years. This was no doubt done because both Carticel and Epicel have some seasonality to them and management did not want to let the solid fourth quarter numbers noted above overly inflate Street expectations for 2015. For example, Carticel, an elective surgery product, has historically seen strong uptake at the end of the year when insurance deductibles have likely been met and yearly flex spending accounts need to be used up before they expire. Over the past several years, one-third of Carticel sales typically are generated in the fourth quarter. The first and third quarters of the year are the weakest. Epicel sales are strongest over the winter months due to the use of things like electric blankets, space heaters, and fireplaces / wood-burning ovens. Management noted that roughly 56% of Epicel sales are generated in the first and fourth quarters of the year, with the third quarter being the weakest at only 20%.

For 2015, we see Carticel sales ramping slowly throughout the year. Although the product clearly has some seasonality to it, we believe management is doing the right things to grow the underlying business beyond seasonal fluctuations. For example, Carticel use is heavily concentrated within small number orthopedic surgeons. Vericel has nearly doubled the size of its sales force to target these top surgeons and increase their use of the product. Management is also getting these top surgeons involved with peer-to-peer networking programs so more of their fellow colleagues start using the product. Within the orthopedic segment, Vericel is focusing on military surgeons with Carticel. This makes sense to us, as the ideal Carticel candidate is a younger and more active patient. Finally, Vericel raised the price of Carticel by 7% in January 2015. As a result of the above initiatives, we see Carticel sales in 2015 growing to $42.0 million. This is roughly 20% growth over the pro forma 2014 numbers.

We see Epicel sales growing to $11.4 million in 2015, up a similar 20% pro forma from 2014 levels. Epicel growth in the coming quarters will be driven by a combination of increase penetration and eventual price increases. We remind investors that under Sanofi-US, Epicel was being promoted by one sales representative. That's right – one! Vericel has increased that number to three, with plans to add more reps in 2015 as the product grows. There are approximately 120 major burn centers in the U.S. were a product like Epicel is used. Almost 50% of Epicel use comes from only a handful of these centers. Each year there are between 2,000 and 2,500 patients that might qualify for the product. Current penetration of Epicel is only around 6%, so if management can drive uptake and awareness with a new promotional campaign we think the return on investment will be quite handsome.

Epicel is a product marketed under a Humanitarian Device Exemption (HDE). Previously, the U.S. FDA placed profit restrictions on products under a Humanitarian Use Device (HUD). That is not the case anymore. Vericel only needs to collect and package existing data on the use of Epicel in a pediatric population and present the application to the FDA for review. On the fourth quarter conference call management noted that around one-third of Epicel commercial use is in patients less than 21 years old, and about 30-40% of the historic clinical data are in pediatric patients. Management has already submitted a pre-meeting briefing package to the FDA and will have a face-to-face meeting with the agency in the coming months. After that meeting, assuming positive outcome, Vericel will file an amendment to the HDE to request a waiver of the profit restriction clause. Turnaround on that submission is 75 days. If all goes well, the price of Epicel (and profits from the product sales) will be going up by the end of the year.

Gross margin: Gross margin was 54.1% in the fourth quarter 2014, up nicely from the 42.7% in the third quarter and the -13.0% margin in the second quarter. Expansion of the gross margin is a key metric in helping Vericel achieve profitability for the newly acquired CTRM business. As we've noted in previous reports, the CTRM business was under-managed and neglected at Sanofi-US, rolled up within a significantly larger organization. Costs were high, efficiency was low; there was no P&L oversight. The first thing that management did to improve the gross margin, specifically with respect to Carticel, was to change the compensation package for the sales force to remove the incentive to have a biopsy done when it is unlikely it will lead to an implant.

For example, approximately 1,000 orthopedic surgeons performed biopsies for Carticel in 2013; however, only 422 surgeons actually implanted the product. That means 60% of the time Sanofi booked cost with no revenue offset. For instance, when the surgeon takes the biopsy the cells are sent to the Cambridge facility where they are expanded. They are then cryopreserved while the company waits for the Carticel order. No order means the company experienced wasted cost. Management tells us approximately 50% of the total cost of goods on Carticel is the first-pass expansion process on the cells.

We believe the low implant-to-biopsy ratio was due to two reasons: poor incentivizing and lack of understanding from the surgeon on the ideal Carticel candidate. Both of these fall on the sales reps. Specifically, Sanofi was incentivizing sales reps on biopsies instead of implants. Vericel management recently put an end to that practice. Now, sales reps will be incentivized on implants, which makes sense because this is when the company actually books revenue. Physicians will also be educated on the ideal Carticel patient so that biopsies are only taken if there is a strong intent that it will result in an implant. On the fourth quarter conference call management noted that the implant-to-biopsy ratio improved to 38% in the fourth quarter 2014, up from 34% when Vericel acquired the business from Sanofi-US.

Back at the manufacturing facility, cells will be cryopreserved before first-pass expansion, pulling out significant cost of waste from the process if an implant is never ordered. As noted above, we believe Carticel was a neglected asset at Sanofi. They obviously never did this sort of process optimization. The changes that Vericel management has made to the Carticel process, from point of sale to manufacturing, should lead to dramatic margin improvement throughout 2015. That means a business that was already throwing off cash at the end of 2014 will start throwing off more cash in 2015. Ultimately, we believe gross margin approach 60%. Raising the price of the product will certainly help, but the added benefits of increased scale and reducing waste will really drive home operating margin expansion in our view.

Net Loss / Income: Operating loss in the fourth quarter totaled $2.3 million, driven by $5.8 million in R&D and $4.5 million in SG&A. R&D expense was meaningfully higher than we expected, although management noted on the call that there was approximately $1.6 million in additional R&D expense in the fourth quarter due to the rapid pace of enrollment and increase size of the Phase 2b ixCELL-DCM study with ixmyelocel-T. Nevertheless, we think 2015 will be the last year for significant R&D expense at Vericel. The ixCELL-DCM study will offer data in the first quarter of 2016. If the data are strong, we expect Vericel to seek a licensing agreement with a larger organization that will likely handle the cost Phase 3 trial and commercialization of the product. If the data are not good, we expect management at Vericel to kill the product. Either way, R&D for 2016 will go down.

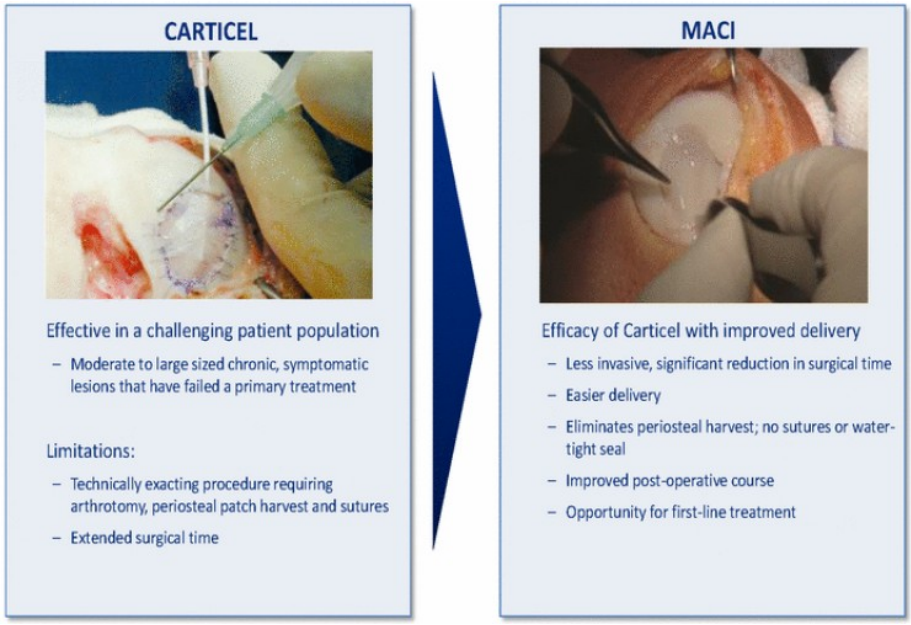
As far as SG&A, management is making hires to expand the sales force for both Carticel and Epicel. As a result, costs are going up. However, the company also closed the MACI® manufacturing facility in Denmark during the fourth quarter. All equipment has been sold and all employees let go. Vericel has an existing lease obligation on the facility until August 2015. These are the only ongoing costs for Vericel in Denmark. After that time, Denmark costs drop to zero. MACI manufacturing has been consolidated to Cambridge. According to management's guidance, closing down Denmark will save an estimated $1.4 million per year.

Net loss for the fourth quarter 2014 was $2.4 million. On the fourth quarter call, management provided a breakdown for this loss between the newly acquired CTRM and legacy (largely ixmyelocel-T) operations. R&D activities and expenses associated with ixmyelocel-T lost the company approximately $4.0 million, whereas CTRM generated income of approximately $1.6 million. As noted above, we believe 2015 will be the last year of sizable R&D expense at Vericel. It is possible that the company will need to conduct another Phase 3 trial in the U.S. with MACI in 2016, but the cost of this program will be far less than the Phase 2b ixCELL-DCM or Phase 3 REVIVE-CLI studies that the old Aastrom initiated. It is clear to us that Vericel is keenly focused on the CTRM business and driving the company to profitability with its existing resources.

Cash & Profits: As of December 31, 2014, Vericel Corp. reported cash and investments of approximately $30.3 million. We remind investors that the company raised gross proceeds of approximately $40.3 million in September 2014 through a public offering of common stock. On the company's fourth quarter call, management stated that they expect to be able to achieve cash flow positive operations with the existing cash balance. Based on our financial model, which forecasts cash flow positive operations around the middle of 2016, we believe the stated goal is achievable with still an estimated $12+ million in cash on hand.

As noted above, the company's goal is to report data from the Phase 2b ixCELL-DCM study in the first quarter 2016. If the data are positive, we believe the company will move quickly to secure a development and commercialization partnership for the drug. This will likely come with a sizable upfront payment, meaningful potential development, regulatory, and commercialization milestones, and royalties on product sales. This could be a potential game-changer for Vericel, as an influx of non-dilutive cash in 2016, coupled with the existing commercial business turning cash flow positive, will allow management to enter into additional M&A or licensing transactions to significantly expand the commercial business in 2017 and beyond.

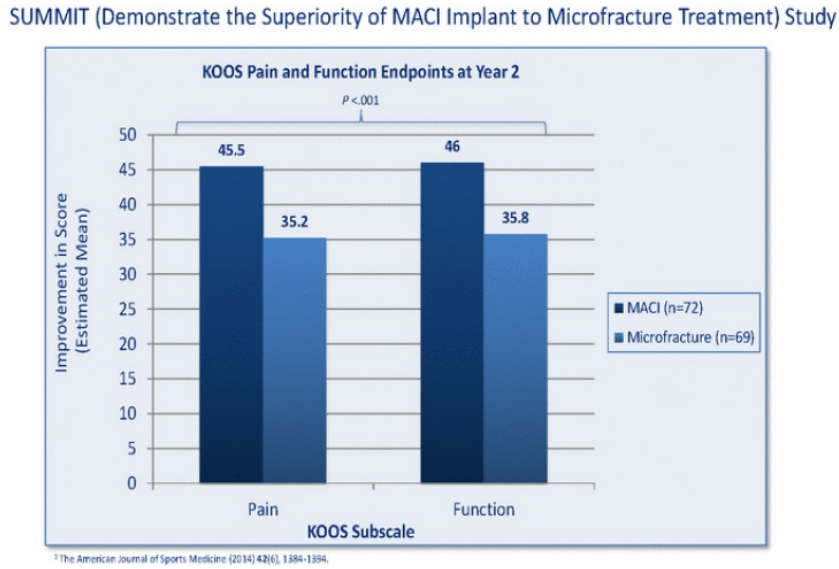
The Pipeline: MACI™ (matrix-induced autologous chondrocyte implant) is a third-generation autologous chondrocyte implant product currently marketed for the treatment of focal chondral cartilage defects in the knee in the European Union since 1998. According to Vericel, the advantage of MACI™ is that 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.



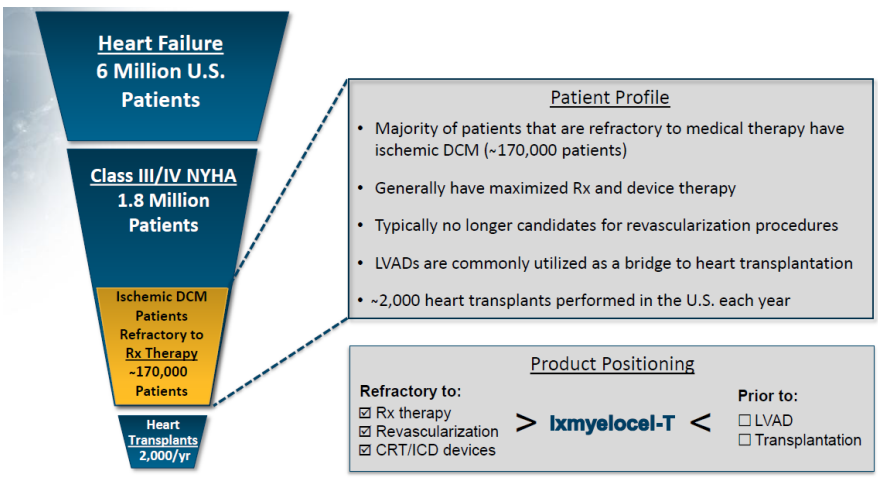
Management's goal is to bring MACI to the market in the U.S., as well as reintroduce the product in Europe. To us, MACI™ looks like represents a potential replacement product for Carticel® as well as an opportunity to expand the market for autologous cartilage repair products. Currently, Vericel has 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 Vericel has a chance to sit down with the FDA and determine the steps necessary to get MACI™ approved. This is scheduled to happen in the second quarter 2015.

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 $40+ million in revenues for the company right now. Based on the product characteristics, we believe MACI™ could effectively double the revenue opportunity. For example, in September 2014, Vericel 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). There are some 80,000 microfracture procedures in the U.S. each year. We believe MACI™ has improved economics to Vericel as well, which should allow for greater profitability as sales ramp.



With ixmyelocel-T, the Phase 2b ixCELL-DCM program continues on plan. Full enrollment was announced in January 2015. Enrollment took place at 30+ centers. It is clear to us based on the data Vericel 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 very soon, 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 Vericel 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, someone with an acute interest in interventional cardiology, if the data are good.

We believe Vericel can partner for this indication for $25 to $50 million upfront, $100+ million regulatory, and $250+ million in backend milestones, plus a handsome double-digit royalty on sales. We apply a 25% discount rate and 20% probability of success to arrive at a current NPV for the program of around $35 million. Should the program fail, we believe Vericel will kill ixmyelocel-T altogether. This mean, as noted above, regardless of success of failure, Vericel should be done spending significant R&D dollars are ixmyelocel-T in 2016.

Valuation: In the fourth quarter 2014, Vericel reported that CTRM provided $1.6 million in positive cash contribution. We expect profitability of CTRM to improve dramatically in the coming quarters based on a number of the above implementations we've outlined. As a result, we now believe that CTRM can generate $7 to 8 million in positive EBITDA in 2015 on revenues of approximately $53 million.

The pharmaceutical industry average Price / Sales ratio is 4.5x based on forward twelve month numbers. The ratio for Price / EBITDA is 13.0x based on forward twelve month numbers. This would seem to suggest that CTRM, should it generate $7 to 8 million in positive EBITDA in 2015 is worth between $90 and $105 million in value. We have already stated that we believe ixmyelocel-T for ischemic DCM is worth $35 million in value based on a probability-adjusted NPV analysis described above.

Vericel's current market capitalization is around $100 million. If we take the mid-range on our valuation for CTRM at $97.5 million and add in $35 million for ixmyelocel-T and $30 million in cash as of December 31, 2014, we arrive at a target valuation of $162.5 million, or ~$6.50 per share. That represents +65% upside. As a result, we would be buyers of the stock at today's price.

PROJECTED FINANCIALS

Vericel Corp.
Income Statement

Vericel Corp.	Dec-13	Dec-14	Mar-15	Jun-15	Sep-15	Dec-14	Dec-15	Dec-16	Dec-17
	2013 A	2014 A	Q1 E	Q2 E	Q3 E	Q4 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%*
Carticel	*$35.2*	**$22.3**	**$9.5**	**$10.0**	**$10.0**	**$12.5**	**$42.0**	**$47.0**	**$50.0**
YOY Growth	*0.0%*	-	-	-	-	*9.6%*	*88.3%*	*11.9%*	*6.4%*
Epicel	*$7.1*	**$6.0**	**$3.2**	**$2.6**	**$2.0**	**$3.6**	**$11.4**	**$16.0**	**$21.0**
YOY Growth	-	-				*9.1%*	*90.0%*	*40.4%*	*31.3%*
MACI	*$1.6*	**$0.2**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$3.0**	**$8.0**
YOY Growth	-	-					-	-	-
Marrow Donation, LLC	**$0**	**$0.3**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.3**	**$0.5**	**$0.5**
YOY Growth									
Ixmyelocel-T	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-
Total Revenues	**$0**	**$28.8**	**$12.8**	**$12.7**	**$12.1**	**$16.2**	**$53.7**	**$66.5**	**$79.5**
YOY Growth	-	-	-	-	-	*10.2%*	*86.5%*	*23.8%*	*19.5%*
Cost of Product Sales & Rentals	$0	$17.3	$6.4	$5.9	$5.4	$7.0	$24.7	$27.6	$30.6
Product Gross Margin	-	*39.9%*	*50.0%*	*53.0%*	*55.0%*	*57.0%*	*53.9%*	*58.5%*	*61.5%*
Research & Development	$15.1	$21.3	$5.2	$5.4	$5.5	$5.8	$21.9	$17.5	$15.0
Selling, General, and Admin	$5.9	$13.8	$4.6	$4.8	$5.2	$5.5	$20.1	$22.5	$25.0
Operating Income	($21.0)	($23.5)	($3.4)	($3.5)	($4.0)	($2.1)	($13.0)	($1.1)	$8.9
Operating Margin	-	-	-	-	-	-	-	-	*11.2%*
Other Income (Expenses)	$5.3	$3.6	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5
Pre-Tax Income	($15.6)	($19.9)	($3.3)	($3.4)	($3.9)	($2.0)	($12.6)	($0.6)	$9.4
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)	($19.9)	($3.3)	($3.4)	($3.9)	($2.0)	($12.6)	($0.6)	$9.4
Net Margin	-	-	-	-	-	-	-	-	*11.8%*
Reported EPS	**($5.18)**	**($1.72)**	**($0.14)**	**($0.14)**	**($0.16)**	**($0.08)**	**($0.51)**	**($0.02)**	**$0.31**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	3.0	11.6	24.0	24.5	25.0	26.0	24.9	27.5	30.0

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

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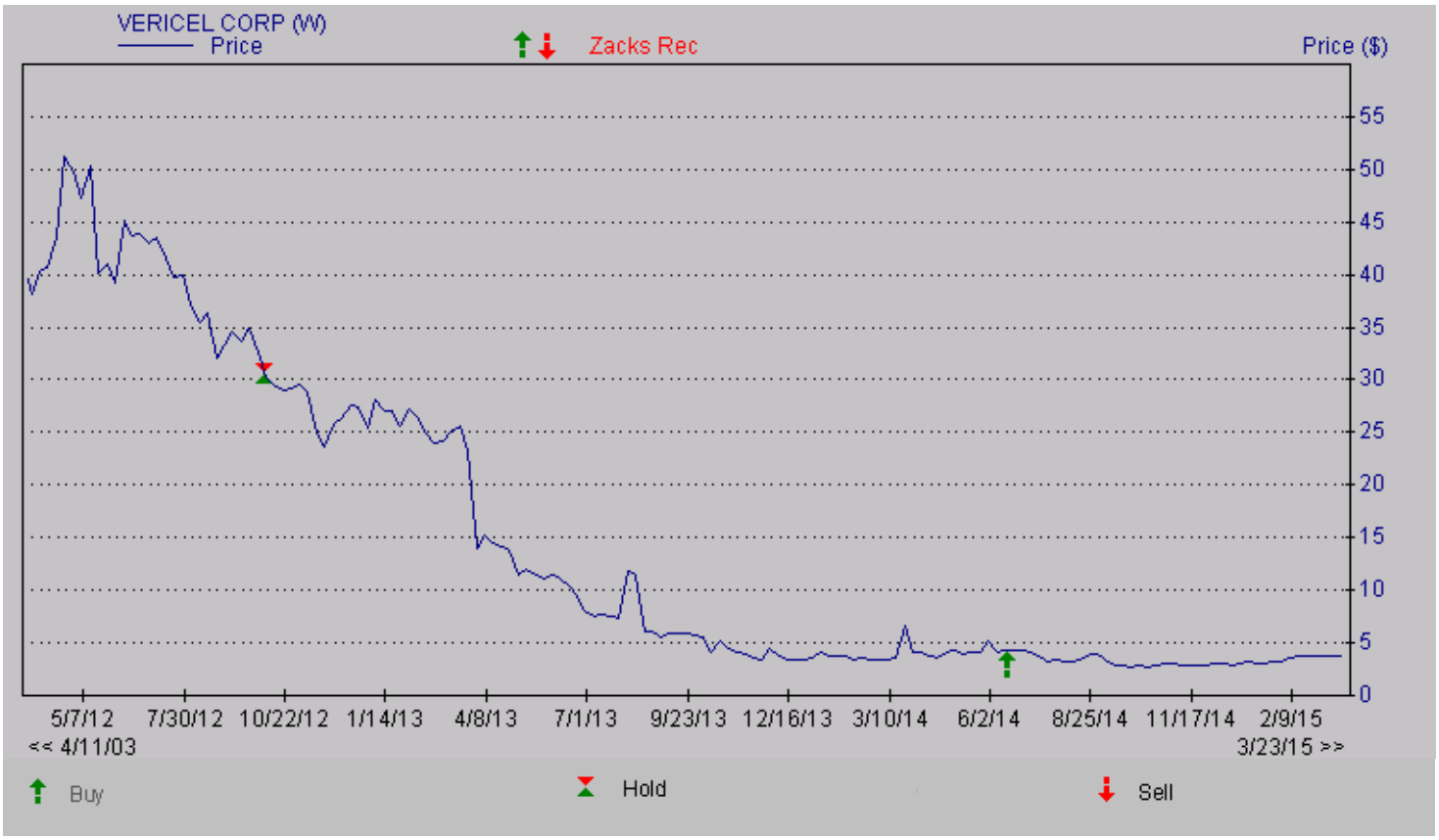

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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