Zacks Small-Cap Research

August 13, 2015
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Vericel Corporation (VCEL-NASDAQ)

VCEL: Solid Q2 Financial Results. Expect Continued Revenue Growth in 2H 2015

Current Recommendation	**Buy**
Prior Recommendation	Buy
Date of Last Change	5/15/2015
Current Price (08/13/15)	$3.32
Target Price	**$6.00**

UPDATE

On August 12, 2015, Vericel Corporation (VCEL) reported financial results for the second quarter ending June 30, 2015. This was a complete year of operations for the company's recently acquired Cell Therapy & Regenerative Medicine ("CTRM") business. Results beat our estimates. The underlying trends look on track. We see Vericel as having improving fundamentals and a very low valuation.

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 $6.00, representing nearly 100% upside in 2015.

SUMMARY DATA

52-Week High	**$3.96**
52-Week Low	**$2.61**
One-Year Return (%)	**-1.48**
Beta	**1.05**
Average Daily Volume (sh)	**32,933**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$82**
Short Interest Ratio (days)	**3.95**
Institutional Ownership (%)	**44**
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	10.8 A	13.6 A	10.6 E	15.8 E	50.8 E
2016					57.5 E
2017					68.0 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	-$0.20 A	-$0.09 A	-$0.14 E	-$0.03 E	-$0.47 E
2016					-$0.14 E
2017					$0.16 E

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WHAT'S NEW

On August 12, 2015, Vericel Corporation (VCEL) reported financial results for the second quarter ending June 30, 2015. Since its acquisition of the Cell Therapy & Regenerative Medicine ("CTRM") business last year, the company has shown financial as well as operational progress.

Revenues: Total revenues for the quarter were approximately $13.4 million, and were comprised of approximately $9.1 million of net sales of Carticel implants and surgical kits, $4.3 million of net sales of Epicel grafts and biopsy kits, and $0.2 million in sales from Marrow Donation, LLC. The revenue growth of both Carticel and Epicel was approximately 31% over the prior period in 2014. The total Carticel and Epicel net product revenues increased approximately 17% in 1H 2015 as compared to the same period in 2014. Revenues came in better than our estimates, as we expected total revenues of $11.5 million, based on $8.2 million in Carticel sales and $3.2 million in Epicel sales. The strong quarterly growth in revenues was primarily contributed by sales volume, the associated price increase for both Epicel and Carticel, and the sales and marketing initiatives associated with the core products. The company noted on the call that both Epicel and Carticel have significant growth potential and expects utilization to increase as physicians become interested in the technology. Management reiterated their plan for the second half of 2015, which is to improve their sales strategy that could serve as a catalyst in ramping up product utilization and revenue.

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, with sales accounting for around 21-22% of the total year for each quarter. 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 during the first quarter earnings call that roughly 56% of Epicel sales are generated in the first and fourth quarters of the year, split equally between the two quarters, with the third quarter being the weakest at only 20% of the total year.

Carticel:
We have made some adjustments to our financial model based on the results from the second quarter. Importantly, despite seasonality, management believes they can achieve year-over-year sales growth in both Carticel and Epicel throughout 2015. We think the 4% growth seen with Carticel is a good baseline for the upcoming quarters. As such, for 2015, we see Carticel sales ramping slowly throughout the year, posting total sales of $34.9 million. We have accounted for the seasonality and slower summer months in our model, which results in a sequential decline between the second and third quarter 2015, and model the fourth quarter 2015 to be up just over 4% from the very strong fourth quarter 2014.

With Carticel, management is undertaking the following initiatives to drive growth:

- ✓ Firstly, the company has greatly increased its promotional efforts around the product, and even implemented a peer-to-peer marketing program that kicked off in April 2015. This was a web-based national meeting with approximately 500 orthopedic surgeons and clinical support staff. According to management, the program was very well received and created a renewed interest in the product. We expect this program to continue in 2015, as well as expand to training sessions where experienced Carticel surgeons and assist their fellow physicians in gaining comfort with 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. Management's goal is to reach a total of 1,000 healthcare providers in the coming quarters.

- ✓ The second key initiative is adding to the Carticel sales force. For example, for the first time since Vericel acquired CTRM, all 21 sales territories for Carticel are now filled. Management commented on the second quarter call that additional sales personnel may be added in 2015 based on profitability.

- ✓ On the pricing front, Vericel raised the price of Carticel by 7% in January 2015. We discuss the process improvements in greater detail below when we analyze the gross margin line.

Epicel

With Epicel, the story is similar, with growth coming from increased promotional efforts, an increased sales force, and the goal to eventually raise the price and expand the patient population.

- ✓ In terms of the increased promotional effort, Vericel has increased the number of Epicel sales staff to four sales representatives. We remind investors that under Sanofi-US, Epicel was being promoted by only one sales representative. Vericel increased that number to four as of July 2015. Management commented on the call that they might increase the number of sales 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.

- ✓ The call detail with Epicel is interesting. Management is targeting centers that have previously used Epicel, between 2010 and 2013, but did not use the product – for whatever reason – in 2014. Vericel is going back to these centers and re-introducing the product. The barrier to use is low because the surgeons likely already have experience with the product, and thus management considers this "low hanging fruit" with respect to driving uptake. In time, once this segment has been effectively targeted, management will start promoting Epicel to surgeons at centers that have never used the product before.

- ✓ The final aspect of the Epicel growth plan is to expand the product label to include pediatric patients. The current label includes only adult use, even though Epicel has significant pediatric use since approved in 2007. In fact, 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. The reason Vericel wants to expand the label to include pediatric patients is because 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), limiting the profits that can be obtained through commercial sale by selling the price roughly equal to the cost to produce. 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 via an HDE supplement. Following discussions with the FDA, management plans to submit an HDE supplement to the regulatory agency in the fourth quarter of 2015 to revise the labeled indications for use of Epicel to specifically include pediatric patients, to add pediatric labeling for Epicel, as well as 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.

In terms of Epicel sales, for 2015 we think Vericel will see significant year-over-year growth acceleration for the product. Even with seasonality baked into our forecast, we see Epicel doing $14.5 million in sales in 2015, growing to $17.5 million in 2017. We believe our 2017 estimate can be easily beat if the pediatric amendment to the HDE is approved by the FDA.

Gross margin: Gross margin was close to 50% of total net revenues for the core therapeutics business in the second quarter of 2015. 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. This number was not given (we asked) first quarter, management only commented that they are "on track" with maintaining the improvements noted last year.

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 both products, Carticel based on demand and Epicel based on the amended label, will certainly help, but the added benefits of increased scale and reducing waste will really drive home operating margin expansion in our view.

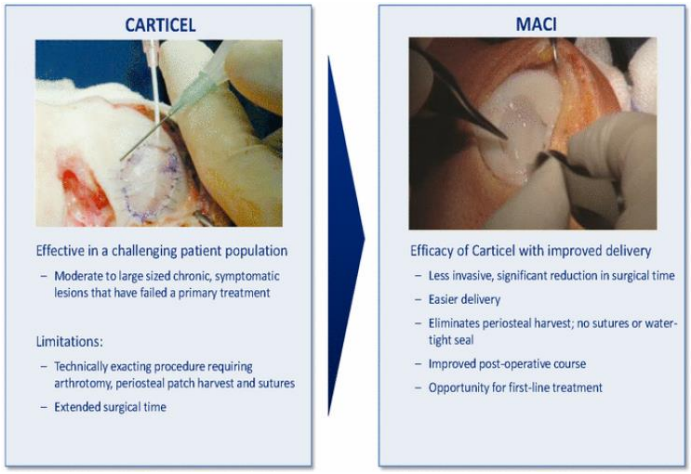
Net Loss / Income: Operating loss in the second quarter totaled $2.3 million, driven by $3.4 million in R&D and $5.6 million in SG&A. R&D expense declined in the quarter as the Phase 2b ixCELL-DCM study with ixmyelocel-T completed enrollment in January 2015. The ixCELL-DCM study will offer data in the 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 increase in SG&A, management hired representatives to expand the sales force for both Carticel and Epicel. However, management noted that new sales reps and expanding the promotional effort will only be undertaken on a profitable nature, so we think the SG&A run-rate for the second quarter 2015 is a good basis for what to expect the remainder of the year, and we still think the entire company can approach operating cash flow breakeven levels in 2016.

Net loss for the second quarter 2015 was $2.2 million, or $0.16 per share. 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 June 30, 2015, Vericel Corp. reported cash and investments of approximately $20.2 million. Operating and investing burn for the second quarter 2015 was $2.2 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. 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. A failure of the Phase 2b ixCELL-DCM study means the R&D line drops likely greater than 50% next year and the commercial operation has 100% of management's attention going forward. We see the outcome of this trial as a win / no big deal type event.

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.

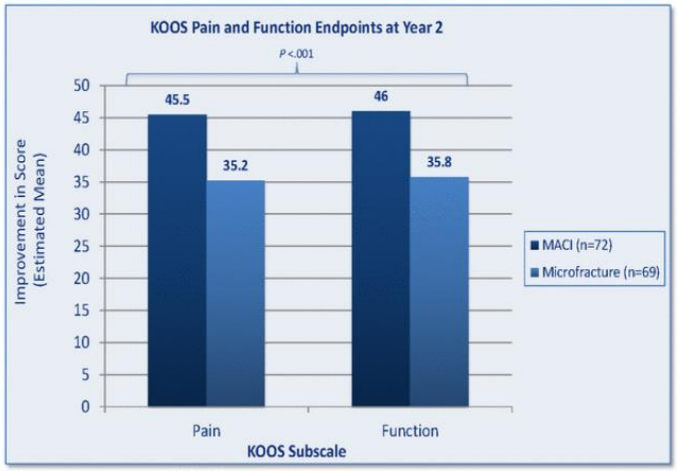


Management's goal is to bring MACI to the market in the U.S., as well as reintroduce the product in Europe. To us, MACI™ looks like represents a potential replacement product for Carticel® as well as an opportunity to expand the market for autologous cartilage repair products. Currently, Vericel has 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. On the earnings call, management announced their plans following discussions with the FDA to submit a Biologics License Application (BLA) to the FDA by the end of 2015 for MACI.

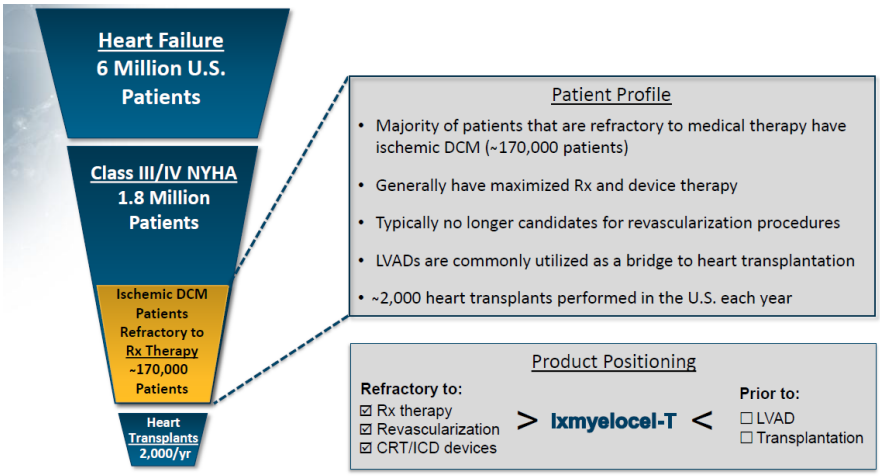
The opportunity for MACI™ in the U.S., where reimbursement procedures are already in place, is significant. MACI™ looks like a superior version of Carticel®, a product doing $40+ million in revenues for the company right now. Based on the product characteristics, we believe MACI™ could effectively double 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.

SUMMIT (Demonstrate the Superiority of MACI Implant to Microfracture Treatment) Study



[1]The American Journal of Sports Medicine (2014) 42(6), 1384-1394.

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: We continue to believe that Vericel Corp. is being under-valued by the market. Above we've outlined why we think ixmyelocel-T, even with only a 20% chance at success in the current Phase 2b study, is worth $35 million in value. That's $1.20 per share. We have done a similar kind of analysis with MACI, essentially believing the product is a more desirable, larger, and more profitable version of the Carticel product that is currently on the market and expected to generate sales in 2015 of roughly $30 million. If Carticel peak sales are $45-50 million in the U.S., then MACI peak sales are likely $75-100 million. At this time we do not yet know if another Phase 3 trial is necessary, but even if Vericel does have to conduct a U.S. Phase 3 program with the product, we still think MACI has a NPV of $20 million, or $0.80 per share.

The remaining valuation comes from the existing commercial business, which we believe is worth another $100 million in value, or $4.00 per share. We arrive at this number by applying a combination of valuation multiples to our projected 2015 numbers. For example, our value for the commercial business equates to only 2x projected sales, well below the industry average 4-5x.

Vericel's current market capitalization is around $80 million. If we sum-up our valuation of $100 million for CTRM, $30 million for ixmyelocel-T, $20 million for MACI, we arrive at a target valuation of $150 million, or $6.00 per share. And we note this number does not include the $20.2 million in cash as of June 30, 2015. As a result, we would be buyers of the stock at today's price.

Vericel Corp.
Income Statement

Vericel Corp.	Dec-14	Mar-15	Jun-15	Sep-15	Dec-14	Dec-15	Dec-16	Dec-17
	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E
R&D Agreements / Grants	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	0.0%	0%	0%
Carticel	$22.3	$7.1	$9.1	$7.7	$11.9	$35.8	$38.5	$42.0
YOY Growth	-	4.0%	13.8%	2.7%	4.4%	6.2%	7.5%	9.1%
Epicel	$6.0	$3.6	$4.3	$2.8	$3.8	$14.5	$15.5	$17.5
YOY Growth	-	4.0%	126.3%	55.6%	15.2%	50.3%	6.9%	12.9%
MACI	$0.2	$0	$0	$0	$0	$0	$3.0	$8.0
YOY Growth	-					-	-	-
Marrow Donation, LLC	$0.3	$0.1	$0.2	$0.1	$0.1	$0.5	$0.5	$0.5
YOY Growth								
Ixmyelocel-T	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-					-	-	-
Total Revenues	$28.8	$10.8	$13.6	$10.6	$15.8	$50.8	$57.5	$68.0
YOY Growth	-	-	-	-	7.4%	76.2%	13.3%	18.3%
Cost of Product Sales & Rentals	$17.3	$5.6	$6.9	$5.1	$7.4	$25.0	$25.3	$28.6
Product Gross Margin	39.9%	48.7%	49.3%	52.0%	53.0%	50.8%	56.0%	58.0%
Research & Development	$21.3	$4.4	$3.4	$3.6	$3.7	$15.1	$12.5	$10.0
Selling, General, and Admin	$13.8	$5.5	$5.6	$5.6	$5.6	$22.3	$24.0	$25.0
Operating Income	($23.5)	($4.6)	($2.3)	($3.7)	($0.9)	($11.6)	($4.3)	$4.4
Operating Margin	-	-	-	-	-	-	-	6.5%
Other Income (Expenses)	$3.6	($0.3)	$0.1	$0.1	$0.1	$0.0	$0.5	$0.5
Pre-Tax Income	($19.9)	($4.9)	($2.2)	($3.6)	($0.8)	($11.6)	($3.8)	$4.9
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	($19.9)	($4.9)	($2.2)	($3.6)	($0.8)	($11.6)	($3.8)	$4.9
Preferred Stock Dividend	($5.9)	($1.6)	($1.7)	($1.7)	($1.8)	($6.7)	$0	$0
GAAP EPS	**($3.18)**	**($0.27)**	**($0.16)**	**($0.21)**	**($0.10)**	**($0.74)**	**($0.14)**	**$0.16**
Net Margin	-	-	-	-	-	-	-	7.3%
Adjusted EPS	**($1.72)**	**($0.20)**	**($0.09)**	**($0.14)**	**($0.03)**	**($0.47)**	**($0.14)**	**$0.16**
YOY Growth	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	11.6	23.8	23.8	25.0	26.0	24.6	27.5	30.0

Source: Zacks Investment Research, Inc. *Anita Dushyanth, PhD*

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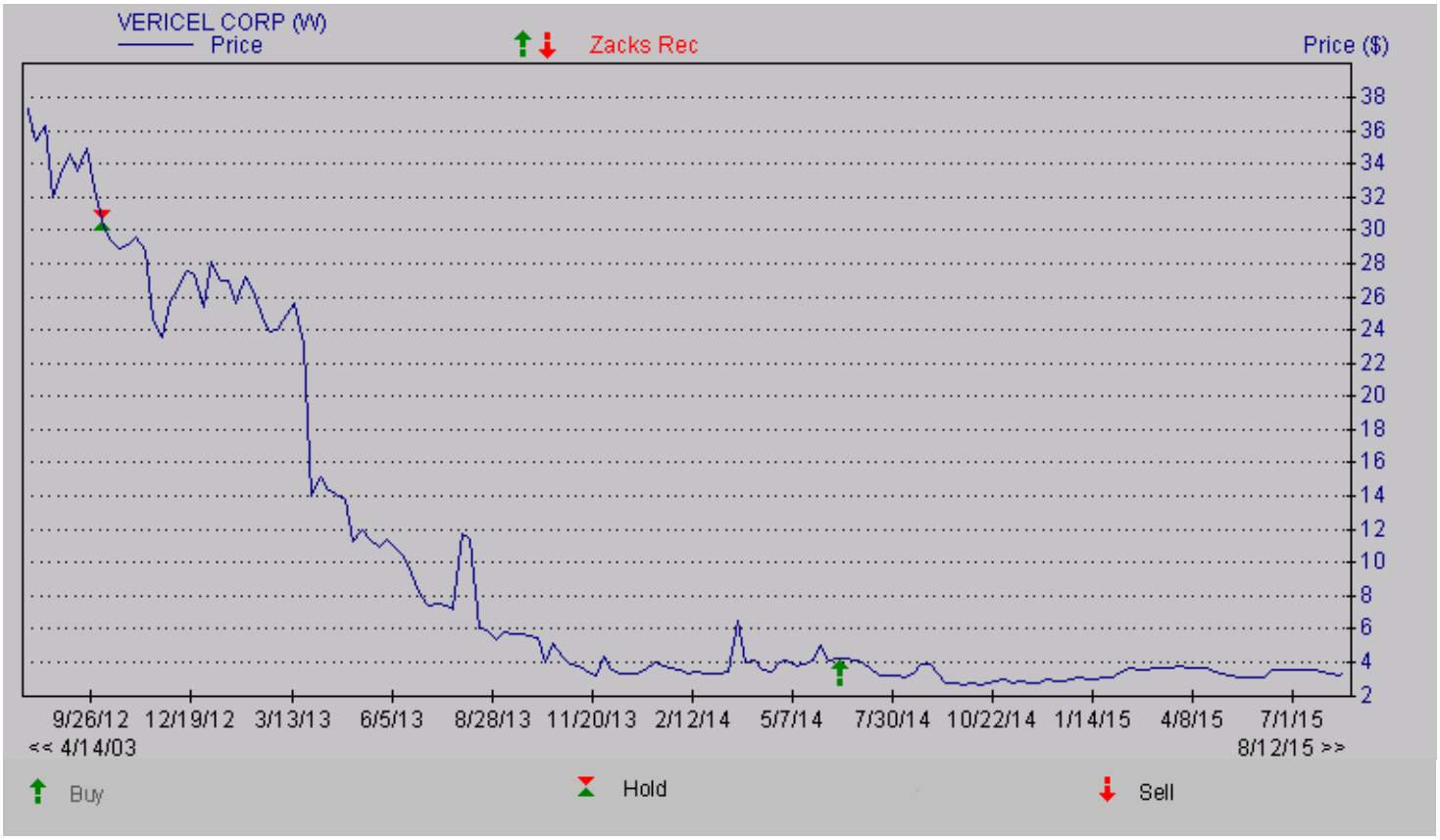
HISTORICAL ZACKS RECOMMENDATIONS



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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.