Zacks Small-Cap Research

January 26, 2015
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Vericel Corporation (VCEL-NASDAQ)

VCEL: Meeting With Vericel Management Reinforces Our Optimistic Call…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	6/16/2014
Current Price (01/26/15)	$3.10
Target Price	**$6.50**

UPDATE

On January 15, 2015, we had a chance to sit down for a face-to-face meeting with the senior management team at Vericel Corporation (VCEL). At the meeting, management laid out their plans for generating growth and driving profitability at the Cell Therapy and Regenerative Medicine (CTRM) business newly acquired from Sanofi in 2014. We were also provided with a brief update on the status of the Phase 2b ixCELL-DCM study with ixmyelocel-T for the treatment of ischemic dilated cardiomyopathy. 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 125% upside in 2015.

SUMMARY DATA

52-Week High	**$6.49**
52-Week Low	**$2.61**
One-Year Return (%)	**-16.44**
Beta	**1.18**
Average Daily Volume (sh)	**50,978**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$74**
Short Interest Ratio (days)	**7.77**
Institutional Ownership (%)	**0**
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	11.2 E	25.3 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	-$0.18 E	-$1.86 E
2015					-$0.52 E
2016					$0.15 E

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WHAT'S NEW

On January 15, 2015, we had a chance to sit down for a face-to-face meeting with the senior management team at Vericel Corporation (VCEL). At the meeting, management laid out their plans for generating growth and driving profitability at the Cell Therapy and Regenerative Medicine (CTRM) business newly acquired from Sanofi in 2014. We were also provided with a brief update on the status of the Phase 2b ixCELL-DCM study with ixmyelocel-T for the treatment of ischemic dilated cardiomyopathy. 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.

Third Quarter Financials Provide a Glimpse Into The Future

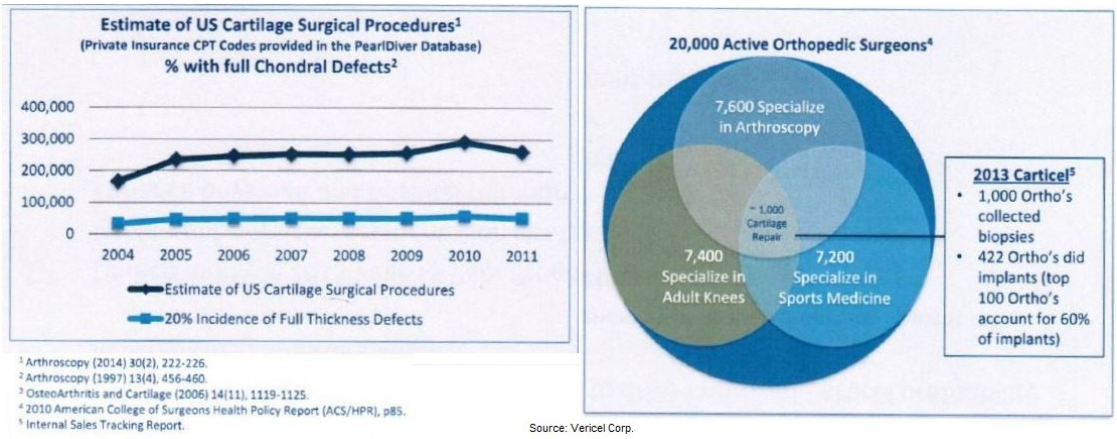
On November 13, 2014, Vericel reported financial results for the quarter of 2014 ending September 30, 2014. This was the first full quarter of operations for the company's recently acquired CTRM business. Total revenues for the quarter were approximately $9.7 million, and were comprised of approximately $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.

On their third quarter conference call, management noted that these revenues were flat with the corresponding period in 2013. We are expecting that when Vericel reports results for the fourth quarter 2014 there were will be a meaningful uptick sequentially from the third quarter numbers. Specifically, we model total revenues in the fourth quarter of $11.2 million (Street consensus is $10.7 million), a 15% sequential increase. For 2015, we believe total revenues will be between $45 and $50 million. The mid-range of this estimate equates to 22% annualized growth over the third quarter 2014. We expect management will provide financial guidance for 2015 when the company reports fourth quarter results in March 2015.

The third quarter numbers were good, but there are several initiatives being put into place that we believe will drive an impressive financial turnaround in 2015 even beyond what the market saw in the third quarter 2014.

Increased Penetration for Carticel: Carticel® sales in the third quarter 2014 totaled $7.5 million. Management has not broken out the number of procedures per quarter, but there are obviously two ways to drive the quarterly Carticel sales rate higher – drive more procedures and raise the price per implant. Based on data we've obtained (see below), the number of yearly procedures has been relatively consistent. Sanofi (previously Genzyme) has not been putting a concerted effort into driving use of the product over the past decade. In fact, Carticel has been a somewhat neglected asset at Sanofi. As a result, use of Carticel is heavily concentrated within small number orthopedic surgeons.

For example, in the U.S. there are an estimated 20,000 active orthopedic surgeons, roughly a third in arthroscopy, a third in sports medicine, and a third that specialize in knees. Within these sub-groups, about 1,000 collected biopsies for Carticel in 2013. Only 422 actually did implants, and of those, the top 100 surgeons account for 60% of the business. Vericel's focus in 2015 will be on driving use among these top 100 Carticel surgeons, as well as expanding use among the next 322 surgeons and then focusing on increasing penetration to the remaining several hundred surgeons that seem amenable or interested in the product but just aren't using it to the same extent as peers. Because of this, Vericel will make peer-to-peer networking programs a priority in 2015. The company will also implement a physician segmentation and targeting strategy in 2015 to help drive use of Carticel. For instance, Vericel is currently targeting military orthopedic surgeons with Carticel. This makes sense to us, as the ideal Carticel candidate is a younger and more active patient.



Increase Price for Carticel: A universal strategy for pharmaceutical and biotech companies selling any product is to raise the price each year. It's simple, yet effective. For 2015, Vericel recently took a 7% price increase on Carticel. The average revenue per procedure in 2015 should now run around $35,000 for Vericel.

Facilitating Reimbursement: Hand in hand with raising the price of a product is making sure reimbursement runs smoothly. There are formal medical policies in place that allow for coverage of Carticel with the 15 largest payers, including the top five national plans. These plans represent approximately 132 million individuals, or 98% of the commercial lives in the U.S. Part of Vericel's strategy in 2015 is to enhance physician and hospital reimbursement support. This will ensure that when Carticel is implanted, payment to Vericel comes at an efficient and timely manner.

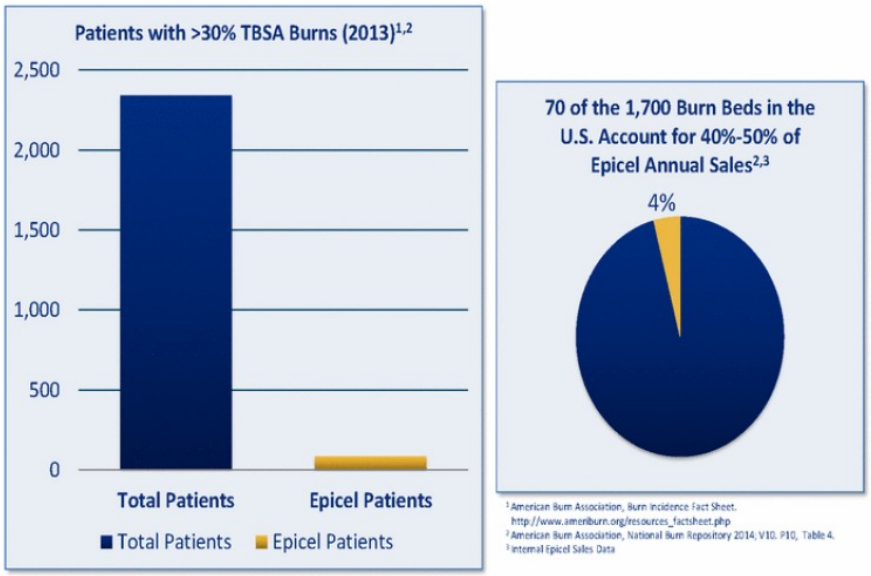
Increasing Carticel Profitability: Besides driving the topline for Carticel in 2015, management is keenly focused on increasing profitability of the business. As a reference, gross margin in the third quarter 2014 was 42.7%. We expect continued improvement in the gross margin line over the next several quarters as Vericel gains efficiencies on manufacturing and scale at the Cambridge facility. 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.

Above we noted that approximately 1,000 orthopedic surgeon's 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. 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 operating 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.

Drive Epicel Penetration: Many of the same business and process improvements strategies being implemented for Carticel are also being put into place for Epicel. For example, Vericel has increased the number of Epicel sales reps promoting the product. Epicel sales in the third quarter totaled $1.8 million. Sanofi has one sales rep promoting the product before Vericel took over. That's right – one! How does a global pharmaceutical company the size of Sanofi have only one rep selling a product? It's baffling. Nevertheless, 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. This is not a huge market. Vericel does not need dozens of reps pounding the street to promote Epicel. 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%.



The strategy here is not rocket science. Vericel will increase the promotional effort by hiring new sales representatives, and similarly to Carticel, start with targeting the physicians that have shown the most interest in using the product in the past. This will be followed up by peer-to-peer training programs and establishing partner networks on an institution by institution basis based on past Epicel use. Vericel also plans to revise the sales incentive compensation plan around Epicel to increase utilization and drive penetration above the current 6% level.

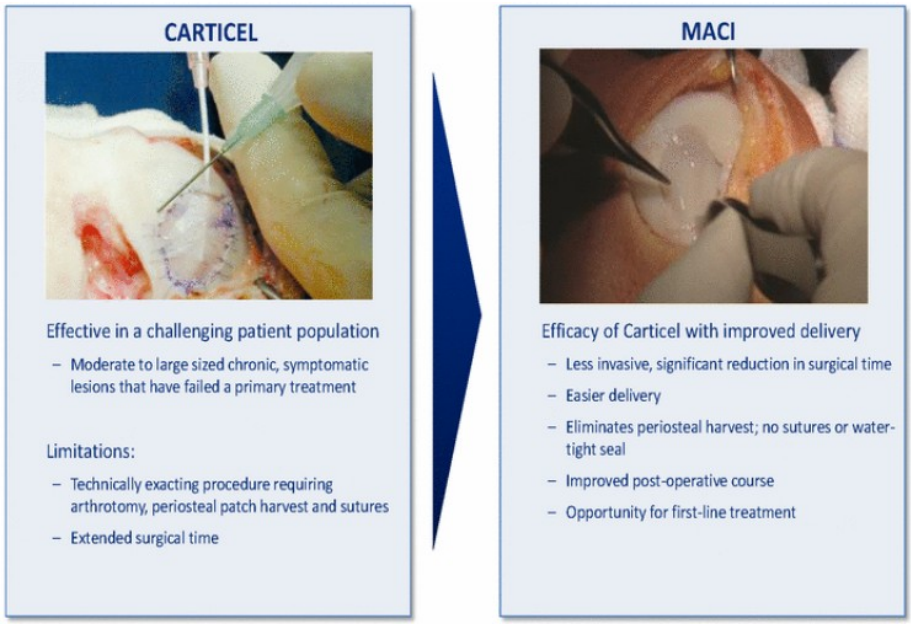
Raise the Epicel Price: Epicel is a product marketed under a Humanitarian Device Exemption (HDE). Previously, the U.S. FDA placed profit restrictions on products under a Humanitarian Use Device (HUD). That is not the case anymore. Vericel only needs to collect and package existing data on the use of Epicel in a pediatric population and present the application to the FDA for review. We suspect this will take place in the second quarter 2015, with an FDA response in the third quarter 2015. Once the agency approves the Epicel label for pediatric use, then Vericel can begin to charge its fully-burdened cost under HUD. This includes allocating infrastructure and employee costs at the Cambridge facility, where Carticel is also made. As a result, charging more money for Epicel improves the overall profitability of the CTRM business.

Closing the Denmark Facility: This is something management spoke about on their third quarter call. As of early 2015, the Denmark facility has been shut down. 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. This equates to roughly positive $0.06 in EPS, or around $0.75 in positive stock valuation using a 12.5x P/E multiple.

All of the above initiatives, from driving volume and price expansion to reducing unnecessary cost, are designed to increase the positive cash flow of CTRM. With positive cash flow comes financial flexibility, new opportunity, and valuation expansion.

MACI & Ixmyelocel-T Offers Enormous Upside

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.

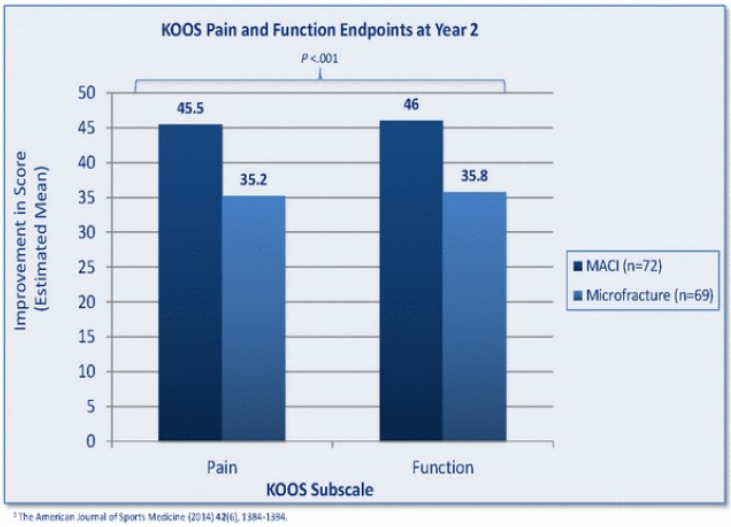


Management's goal is to bring MACI to the market in the U.S., as well as reintroduce the product in Europe. To us, MACI™ looks like represents a potential replacement product for Carticel® as well as an opportunity to expand the market for autologous cartilage repair products. Currently, Vericel has 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 here in the first 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, 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). 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.

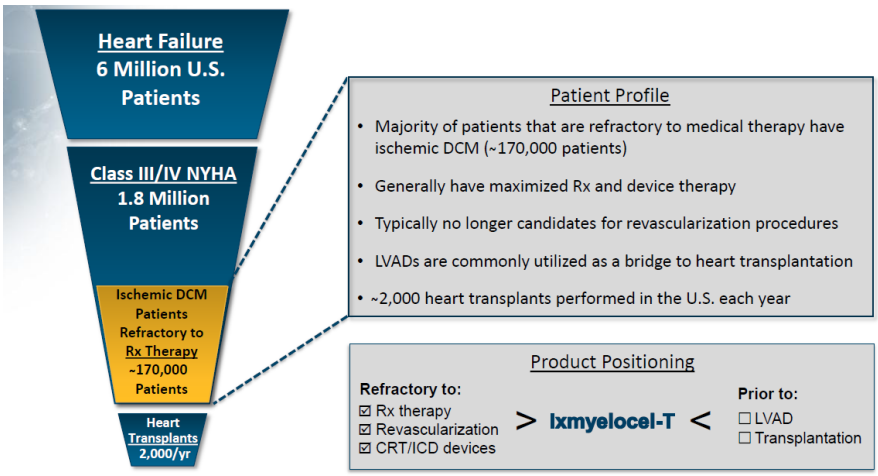
SUMMIT (Demonstrate the Superiority of MACI Implant to Microfracture Treatment) Study



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

With ixmyelocel-T, the Phase 2b ixCELL-DCM program continues on plan. 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 very soon. 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. We expect the company to press release the final patient surgery in the next few weeks.

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, regardless of success of failure, Vericel should be done spending significant R&D dollars are ixmyelocel-T in 2016. Obviously shareholders would like to see a big check and someone else taking over for the Phase 3 trial.

Why We Think Vericel Shares Will Double In 2015

In the third quarter 2014, Vericel reported that CTRM provided $1.0 million in positive cash contribution. This number would have been $1.4 million without the Denmark facility. For all intents and purposes, Denmark is now shut down. We also 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 $6 to 8 million in positive EBITDA in 2015 on revenues of nearly $50 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 $6 to 8 million in positive EBITDA in 2015 is worth between $80 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.

Even taking the low-end of this range at $80 million is more than the company's current market capitalization at around $70 million. Adding in $35 million for ixmyelocel-T and $34 million in cash (estimate as of December 31, 2014) we arrive at a target valuation of $149 million, or ~$6.50 per share. That represents +125% 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	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Dec-15	Dec-16	Dec-17
	2013 A	Q1 A	Q2 A	Q3 A	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**	**$7.5**	**$8.7**	**$19.6**	**$36.0**	**$39.0**	**$42.0**
YOY Growth	*0.0%*	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Epicel	*$7.1*	*$2.5*	**$0.9**	**$1.8**	**$2.3**	**$5.0**	**$12.5**	**$16.0**	**$22.0**
YOY Growth	-					-	-	-	-
MACI	*$1.6*	*$0.1*	**$0.0**	**$0.2**	**$0.0**	**$0.2**	**$0.0**	**$2.0**	**$5.0**
YOY Growth	-					-	-	-	-
Marrow Donation, LLC	**$0**	**$0**	**$0.1**	**$0.2**	**$0.2**	**$0.5**	**$0.6**	**$0.8**	**$1.0**
YOY Growth									
Ixmyelocel-T	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-	-
Total Revenues	**$0**	**$0**	**$4.4**	**$9.7**	**$11.2**	**$25.3**	**$49.1**	**$57.8**	**$70.0**
YOY Growth	-	-	-	-	-	-	*94.1%*	*17.7%*	*21.1%*
Cost of Product Sales & Rentals	$0	$0	$5.0	$5.5	$6.3	$16.8	$22.5	$22.5	$25.0
Product Gross Margin	-	-	*-13.0%*	*42.7%*	*43.8%*	*33.4%*	*54.2%*	*61.1%*	*64.3%*
Research & Development	$15.1	$3.3	$4.4	$7.8	$4.5	$20.0	$20.0	$10.0	$10.0
Selling, General, and Admin	$5.9	$1.4	$3.6	$4.3	$4.6	$13.9	$21.0	$25.0	$27.5
Operating Income	($21.0)	($4.6)	($8.5)	($8.0)	($4.2)	($25.4)	($14.4)	$0.3	$7.5
Operating Margin	-	-	-	-	-	-	-	-	*10.7%*
Other Income (Expenses)	$5.3	($1.4)	$3.9	$1.1	$0.0	$3.6	$2.0	$4.0	$5.0
Pre-Tax Income	($15.6)	($6.0)	($4.6)	($6.9)	($4.2)	($21.8)	($12.4)	$4.3	$12.5
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)	($6.9)	($4.2)	($21.8)	($12.4)	$4.3	$12.5
Net Margin	-	-	-	-	-	-	-	-	*17.9%*
Reported EPS	**($5.18)**	**($1.02)**	**($0.71)**	**($0.82)**	**($0.18)**	**($1.91)**	**($0.52)**	**$0.15**	**$0.39**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares Out	3.0	5.9	6.5	10.3	22.8	11.4	24.0	28.0	32.0

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

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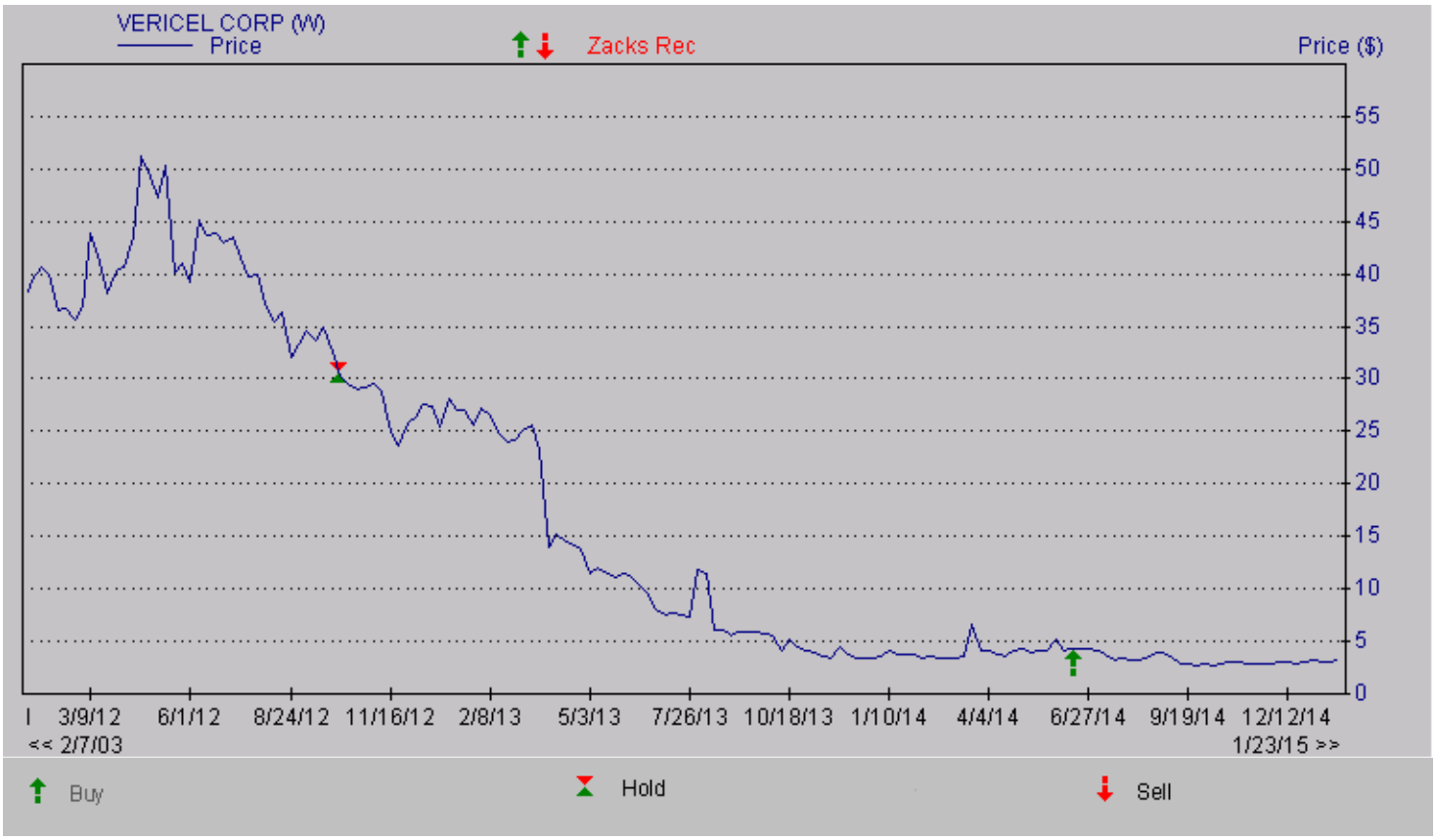
HISTORICAL ZACKS RECOMMENDATIONS



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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.