

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **January 12, 2015**

**Vericel Corporation**

(Exact name of registrant as specified in its charter)

**Michigan**

(State or other jurisdiction  
of incorporation)

**001-35280**

(Commission  
File Number)

**94-3096597**

(I.R.S. Employer  
Identification No.)

**64 Sidney St.**

**Cambridge, Massachusetts**

(Address of principal executive offices)

**02139**

(Zip Code)

Registrant's telephone number, including area code: **(734) 418-4400**

**Not Applicable**

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01. Regulation FD Disclosure.**

On January 12, 2015, Vericel Corporation (the "Company") prepared an updated company presentation. A copy of the presentation is furnished herewith as Exhibit 99.1.

The information in Item 7.01 of this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
99.1	Investor presentation dated January 12, 2015.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Vericel Corporation**

By:

/s/ Dominick C. Colangelo

Date: January 12, 2015

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor presentation dated January 12, 2015.



# VERICEL

**Company Presentation**

January 2015

# Safe Harbor

This presentation contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding profitability, growth in revenue and earnings per share, cash payments, the costs and expenses as well as expected benefits and cost savings that we anticipate will result from the strategic restructuring plan described herein, clinical trial plans and progress, objectives and expectations, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “intends,” “estimates,” “plans,” “expects,” “we believe,” “we intend,” and similar words or phrases, or future or conditional verbs such as “would,” “should,” “potential,” “could,” “may,” or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements.

Among the factors that may result in differences are the inherent risks and uncertainties associated with competitive developments, estimating profitability, cash payments, growth in revenues and earnings per share prior to us closing our books and verifying such information, clinical trial and product development activities, regulatory approval requirements, the availability and allocation of resources among different potential uses, estimating the commercial potential of our products and product candidates and growth in revenues, market demand for our products and our ability to supply or meet customer demand for our products, our ability to successfully implement the strategic restructuring plan described herein to reduce expenses and produce cost savings, leverage synergies and optimize our resources, the impact of the strategic restructuring plan described herein on our business, regulatory and product development activities as well as potential adverse effects on revenues and other financial results, or unanticipated charges not currently contemplated that may occur as a result of the strategic restructuring plan described herein. These and other significant factors are discussed in greater detail in Vericel’s Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission (“SEC”) on March 13, 2014, Quarterly Reports on Form 10-Q and other documents filed by the Company with the SEC from time to time.

These forward-looking statements reflect management’s current views and Vericel does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

# Vericel Investment Highlights

Vericel Investment Highlights	
<b>New Management Team</b>	<ul style="list-style-type: none"><li>• Strong track record of developing and commercializing products in the U.S.</li><li>• Deep experience in restructuring and integrating acquired businesses</li></ul>
<b>New Business Focus</b>	<ul style="list-style-type: none"><li>• Restructured Vericel's legacy business in 2013 to focus on orphan disease program</li><li>• Acquired Sanofi's global CTRM business in 2014; revenues of \$44 million in 2013</li></ul>
<b>Established Commercial Business</b>	<ul style="list-style-type: none"><li>• Undertook significant restructuring of business; excluding restructuring charges, acquisition was accretive in Q2 and Q3 2014</li><li>• Significant opportunities for topline growth and improved gross margins</li></ul>
<b>High-Potential Late Stage Pipeline</b>	<ul style="list-style-type: none"><li>• Phase 3 candidate with potential to significantly expand cartilage repair franchise</li><li>• Phase 2b orphan disease program for the treatment of advanced heart failure</li></ul>
<b>Strong Financial Position</b>	<ul style="list-style-type: none"><li>• Closed \$40.25 million financing in September 2014</li><li>• Participation by leading institutional healthcare investors</li></ul>

# New Management Team with Deep Operations and Commercialization Experience

## Management Team

### **Nick Colangelo – President & CEO (March 2013)**

- More than 20 years of executive management and corporate development experience
- Nearly a decade with Eli Lilly, including serving as Director of Strategy and Business Development for Lilly's Diabetes Product Group and founding Managing Director of Lilly Ventures
- Extensive experience in the acquisition, development and commercialization of therapies to treat fibrovascular, metabolic and CV diseases

### **Ross Tubo, Ph.D – Chief Scientific Officer (April 2014)**

- More than 20 years of experience in cell therapy, regenerative medicine, and stem cell biology, most recently as Vice President of Stem Cell and Chemokine Biology for Genzyme Corporation
- Pioneer in the research, development, and commercialization of the first autologous cell therapies (Carticel and Epicel)
- Extensive experience in the underlying cell and molecular mechanism(s) of action of mesenchymal stem cells

### **Daniel Orlando – Chief Operating Officer (August 2012)**

- More than 20 years of sales, marketing, and business development experience, most recently serving as Vice President of business development for North and South America at Takeda
- Extensive commercial experience in cardiovascular, diabetes and metabolic disease areas
- Original brand director for Actos

### **David Recker, M.D. – Chief Medical Officer (April 2014)**

- More than 20 years of drug development experience, most recently as Senior Vice President for Clinical Science at Takeda Global R&D
- Responsible for multiple programs in a variety of therapeutic areas, including cardiovascular, diabetes, and metabolic disease areas
- Numerous successful regulatory filings throughout the world

### **Gerard Michel – Chief Financial Officer and Vice President, Corporate Development (June 2014)**

- More than 20 years in the life science industry including large pharma (Lederle Labs, Wyeth Labs), biotech (NPS Pharmaceuticals, Bidel) and management consulting (Booz Allen) with meaningful experience across all major functional and therapeutic areas
- Raised significant amount of capital via strategic, equity, debt, and royalty deals

# Acquisition of Sanofi's Cell Therapy and Regenerative Medicine Business

- Acquired Sanofi's Cell Therapy and Regenerative Medicine business for \$6.5 million
- Acquired Assets:
  - Worldwide commercial rights to three marketed autologous cell therapy products with revenues of approximately \$44 million in 2013
    - Carticel® (autologous cultured chondrocytes)
    - Epicel® (cultured epidermal autografts)
    - MACI™ (matrix-applied characterized autologous cultured chondrocytes)
  - Manufacturing and production centers in the U.S. and Denmark
  - Commercial organization in the U.S. and Europe
  - \$4.3 million in net working capital in Genzyme Denmark
- Acquisition closed on May 30, 2014

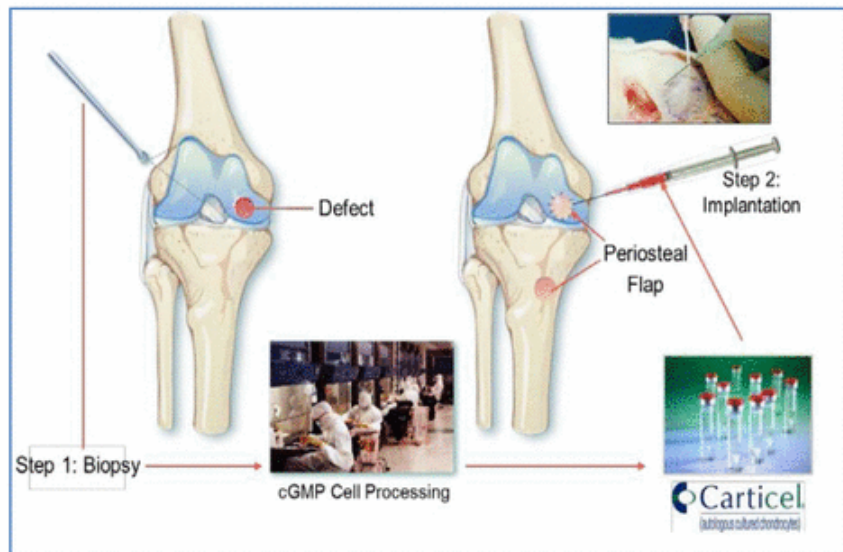
# Robust Product Portfolio





## *Carticel is a 1<sup>st</sup> generation autologous chondrocyte implant (ACI) for the treatment of cartilage defects in the knee*

- First and only FDA-approved autologous cartilage repair product<sup>1</sup>
- Therapeutic advantage: produces natural hyaline cartilage vs. fibrocartilage
- STAR study demonstrated statistically significant and clinically meaningful reductions in pain and improvement in function<sup>2</sup>
- Durability of repair data out to 20 years<sup>3</sup>



<sup>1</sup> Regenerative Med. (2007) 2(1), 95-97.

<sup>2</sup> The American Journal of Sports Medicine (2009) 37(1), 42-55.

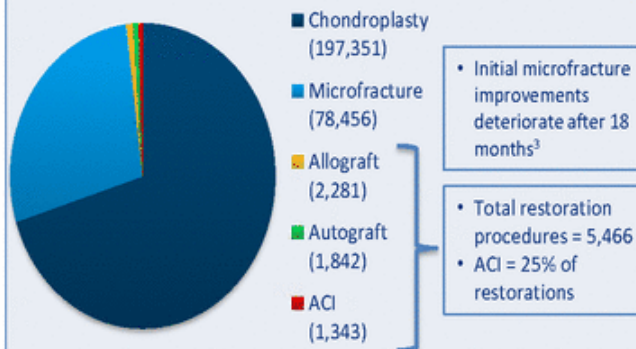
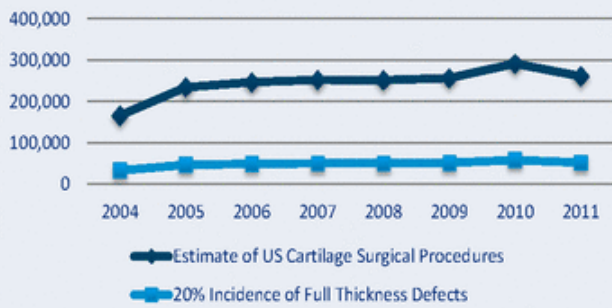
<sup>3</sup> The American Journal of Sports Medicine (2010) 38(6), 1117-112.

# Carticel Commercial Highlights

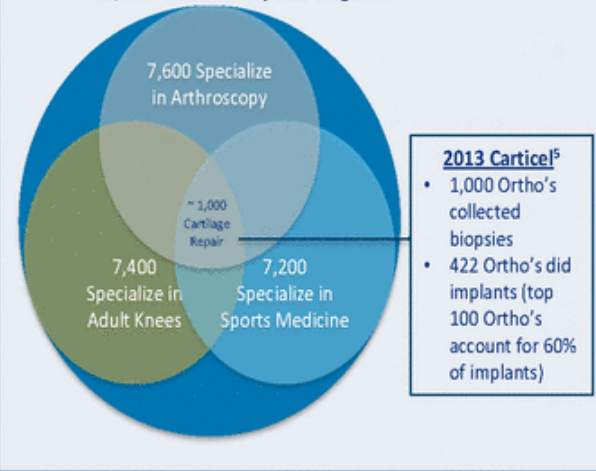
- Net revenues of \$35.2 million in 2013
- Dedicated physician customer base
  - Core physicians drive the majority of implants in the U.S.
- Target patient population is younger and more active patients with larger cartilage defects ( $\geq 3\text{cm}^2$ )
  - Ideal therapy for this patient population; alternative procedures (microfracture, etc.) do not provide durable repair
- Widespread reimbursement coverage
  - 15 largest payers, including the top five national plans, have formal medical policies that allow treatment with Carticel within labeled indications
    - Represents 132 million (98%) of commercial lives in the United States
  - Majority of reimbursement is through private payers
- Limited ACI competition and no generic threat

# Carticel – Stable Market with Growth Potential

**Estimate of US Cartilage Surgical Procedures<sup>1</sup>**  
 (Private Insurance CPT Codes provided in the PearlDiver Database)  
**% with full Chondral Defects<sup>2</sup>**



**20,000 Active Orthopedic Surgeons<sup>4</sup>**



<sup>1</sup> Arthroscopy (2014) 30(2), 222-226.  
<sup>2</sup> Arthroscopy (1997) 13(4), 456-460.  
<sup>3</sup> OsteoArthritis and Cartilage (2006) 14(11), 1119-1125.  
<sup>4</sup> 2010 American College of Surgeons Health Policy Report (ACS/HPR), p85.  
<sup>5</sup> Internal Sales Tracking Report.

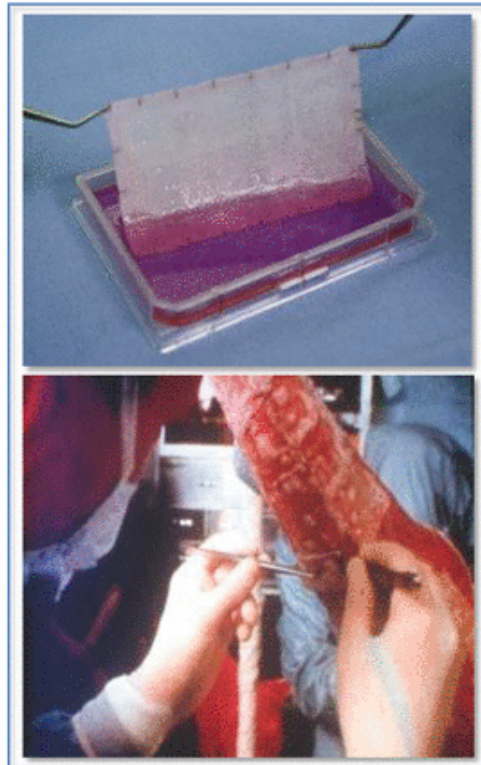
# Carticel 2015 Commercial Priorities

- ✓ Realigned sales territories to optimize Carticel sales potential
- ✓ Revised sales incentive compensation plan to drive improved Carticel profitability (based on volume and efficiency)
  - Assess, Confirm, Treat (ACT) program implemented to reduce biopsy-to-implant ratio
- ✓ Completed military orthopedic facility targeting
- ✓ Reestablished Speakers Bureau
  
- Launch multiple 2015 Peer-to-Peer Programs
- Implement physician segmentation strategy
- Enhance physician and hospital reimbursement support

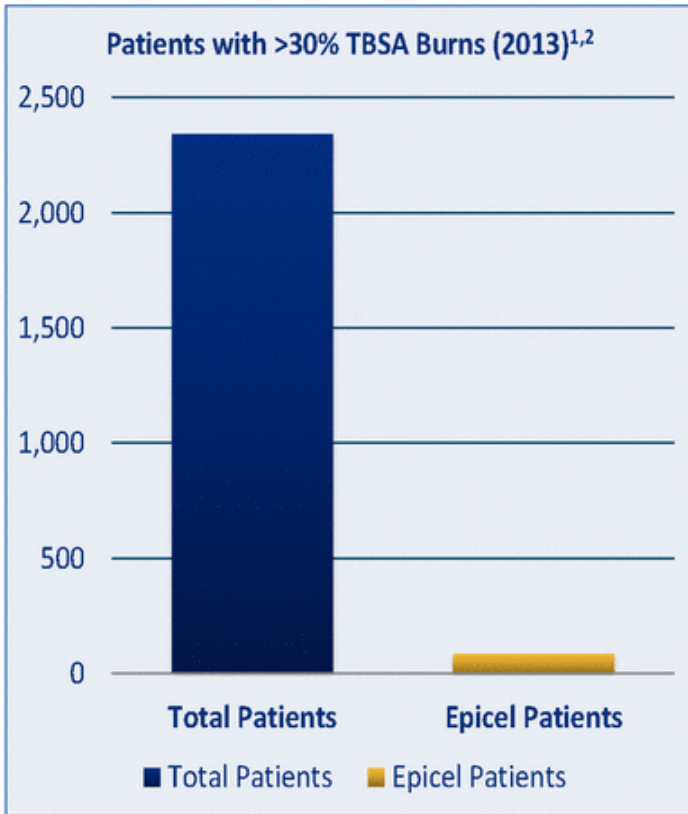
# Epicel Overview

***Epicel is a permanent skin replacement for full thickness burns  $\geq$  30% of total body surface area***

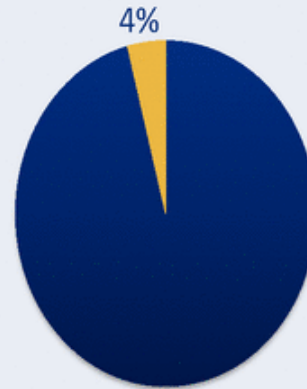
- Only FDA-approved autologous epidermal product available for large total body surface area (TBSA) burns
- Important treatment option for severe burn patients because little skin is available for autografts
- Approved in the United States for use as a Humanitarian Use Device
- Small number of physicians drive the majority of usage of Epicel
- Revenues of \$7.1 million in 2013



# Epichel – Current Market Penetration



**70 of the 1,700 Burn Beds in the U.S. Account for 40%-50% of Epichel Annual Sales<sup>2,3</sup>**



<sup>1</sup> American Burn Association, Burn Incidence Fact Sheet. [http://www.ameriburn.org/resources\\_factsheet.php](http://www.ameriburn.org/resources_factsheet.php)

<sup>2</sup> American Burn Association, National Burn Repository 2014, V10, P10, Table 4.

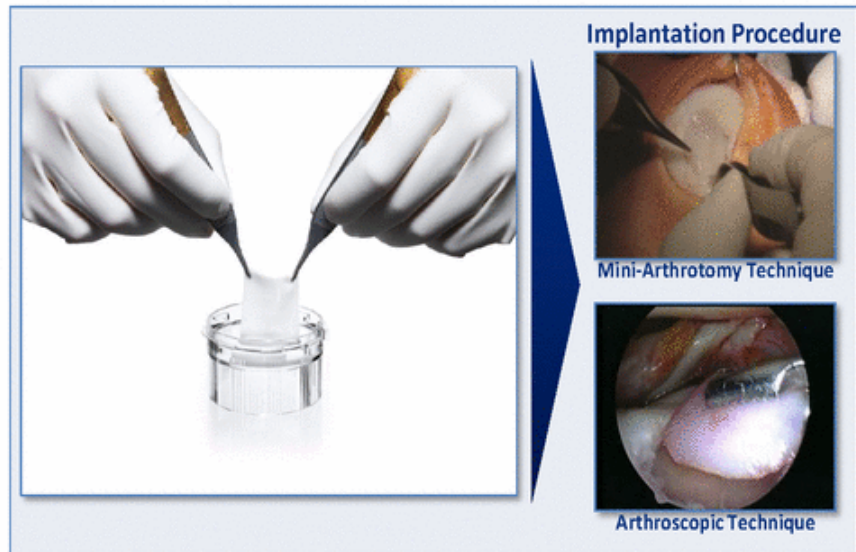
<sup>3</sup> Internal Epichel Sales Data

# Epicef 2015 Commercial Priorities

- ✓ Increased price to reflect costs allowed under the HDE regulations
- ✓ Increased promotional support with additional sales representatives
  
- Revise sales incentive compensation plan to drive expanded Epicef utilization (based on number of treated patients)
- Rebuild the partnership network by targeting institutions that used Epicef prior to the reduction of the Epicef sales force
- Launch Peer-to-Peer training program of best practices
- Pursue pediatric indication to provide greater pricing flexibility under the current HDE regulations

## *MACI is a 3rd generation ACI for the treatment of cartilage defects in the knee*

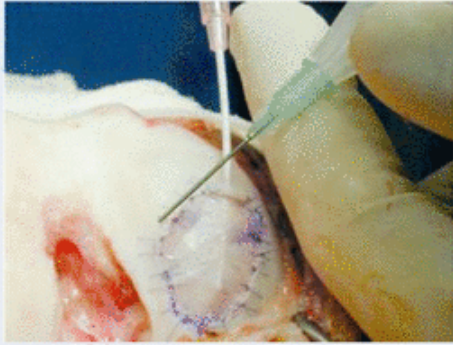
- First tissue-engineered product approved as an Advanced Therapy Medicinal Product by the EC (June 2013)
- Therapeutic advantage: ease of use for the surgeon and reduced morbidity for the patient
- SUMMIT study showed statistically significant improvement in pain and function endpoints compared to microfracture<sup>1</sup>



<sup>1</sup> The American Journal of Sports Medicine (2014) 42(6), 1384-1394.



## CARTICEL



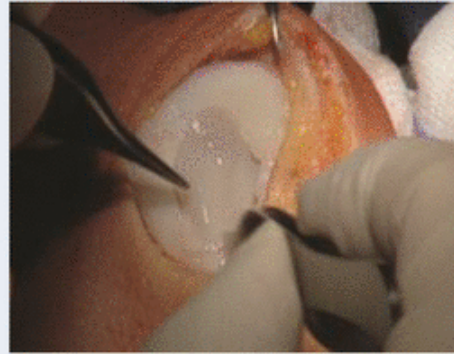
Effective in a challenging patient population

- Moderate to large sized chronic, symptomatic lesions that have failed a primary treatment

### Limitations:

- Technically exacting procedure requiring arthrotomy, periosteal patch harvest and sutures
- Extended surgical time

## MACI

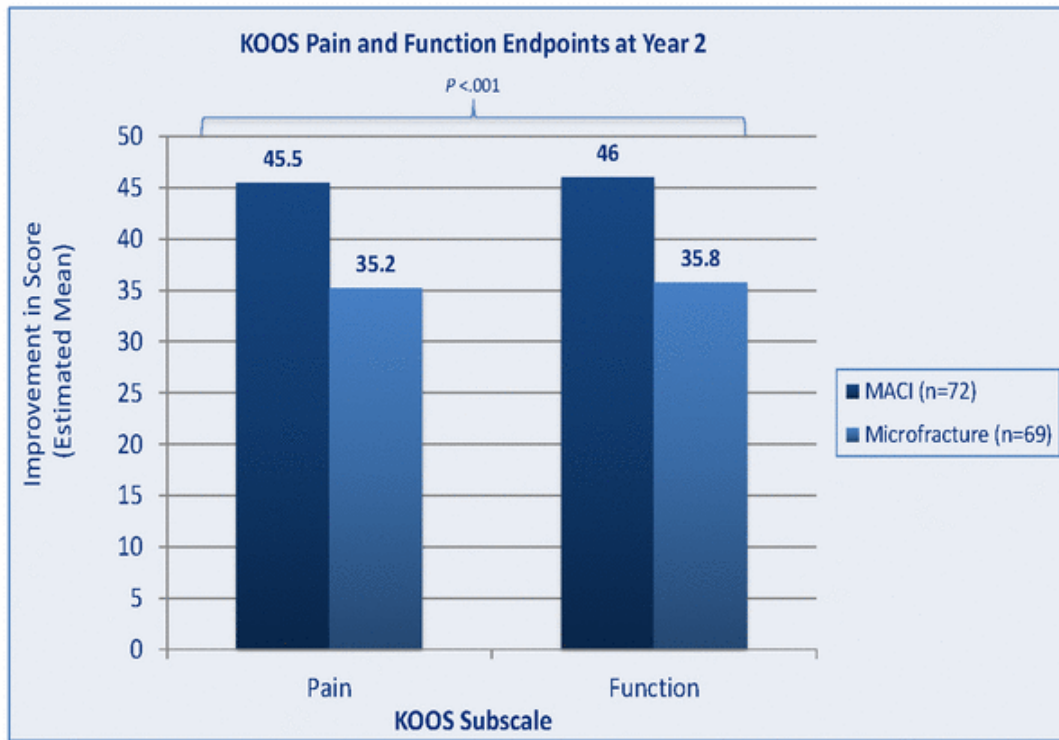


Efficacy of Carticel with improved delivery

- Less invasive, significant reduction in surgical time
- Easier delivery
- Eliminates periosteal harvest; no sutures or water-tight seal
- Improved post-operative course
- Opportunity for first-line treatment

# SUMMIT Study – MACI Significantly Better Than Microfracture at Year 2

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



<sup>1</sup> The American Journal of Sports Medicine (2014) 42(6), 1384-1394.



# Strategic Actions Immediately Initiated to Drive the Acquired Business to Profitability

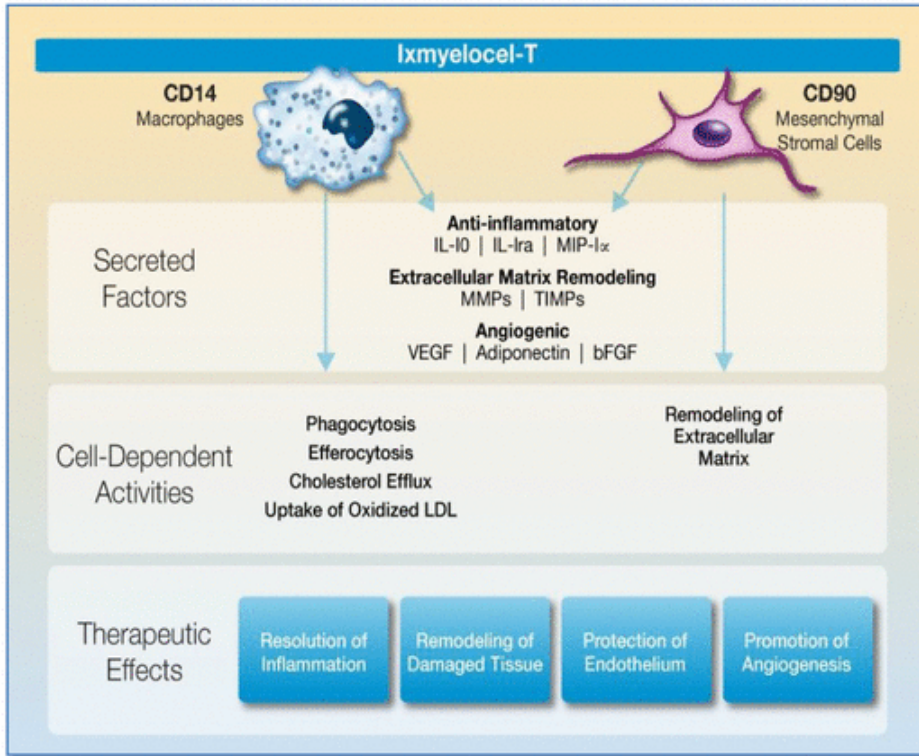
- Temporarily suspended sales of MACI in Europe and discontinued manufacturing in Denmark
  - MACI sales in Europe represented 1% of revenues in 2014
  - Cambridge facility to manufacture MACI for select European countries
  - Reduces annual operating expenses by approximately \$7 million
- Significantly reduced MACI-related R&D expenses as a result of the substantial completion of research activities required to support MACI BLA filing in the U.S.
  - Reduces R&D expenses by approximately \$9 million
- Optimize manufacturing and commercial operations in the U.S.
  - U.S. full-time employee (FTE) reductions decrease annual operating expenses by approximately \$4 million
- Immediate reduction of approximately 80 global FTE positions

***Excluding restructuring charges, the acquired CTRM business was accretive in Q2 and Q3 2014***

# Manufacturing Efficiencies/Cost Reduction Initiatives to Further Improve Gross Margins and Profitability

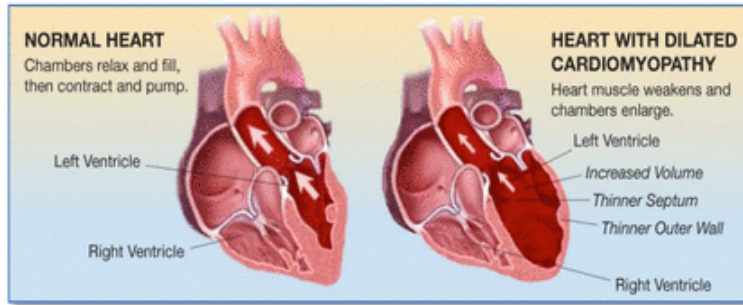
- ✓ Extended Carticel biopsy shelf-life
- ✓ Enhanced Carticel culture media
  
- Multiple Carticel and Epicel process development projects underway designed to
  - Reduce costs
  - Enhance process efficiencies
  - Increase manufacturing capacity and flexibility

# Ixmyelocel-T is a Highly Differentiated Multicellular Therapy



*Expanded populations of M2-like macrophages and MSCs have multiple biological activities that promote tissue repair and regeneration*

# Ixmyelocel-T for the Treatment of Advanced Heart Failure Due to Ischemic DCM



## Patient Profile

- Majority of patients that are refractory to medical therapy have ischemic dilated cardiomyopathy (DCM) (~150,000 patients)
- Generally have maximized Rx and device therapy
- Typically no longer candidates for revascularization procedures
- LVADs are commonly utilized as a bridge to heart transplantation
- ~2,000 heart transplants performed in the U.S. each year

## Product Positioning

### Refractory to:

- Rx therapy
- Revascularization
- CRT/ICD devices



**Ixmyelocel-T**

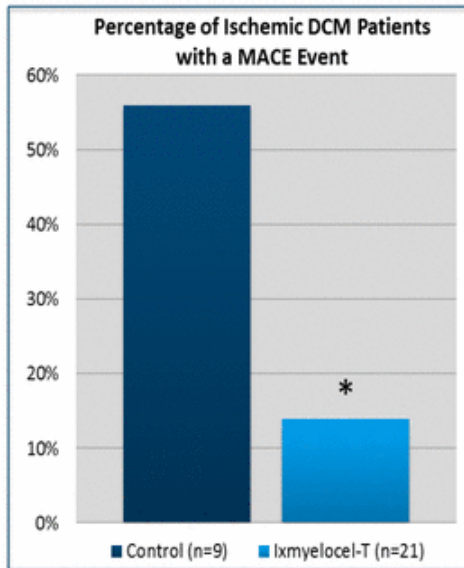


### Prior to:

- LVAD
- Transplantation

***Ixmyelocel-T is the only therapy with an orphan designation for the treatment of DCM***

# Fewer Ischemic DCM Patients Treated with Ixmyelocel-T Experienced a MACE<sup>1</sup>



*75% fewer patients treated with ixmyelocel-T experienced a MACE (\* p < 0.05)*

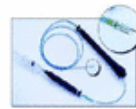
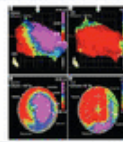
	IMPACT-DCM (6 Months)		Catheter-DCM (1 Year)		Both Studies	
	Control	Ixmyelocel-T	Control	Ixmyelocel-T	Control	Ixmyelocel-T
Number/N (%) of Ischemic DCM Patients with a MACE	3/6 (50)	2/12 (17)	2/3 (67)	1/9 (11)	5/9 (56)	3/21 (14)*

- Statistically significant improvements also were observed in NYHA class and six-minute walk distance

<sup>1</sup> Circulation Research (2014) 10.1161/CIRCRESAHA.115.304554

## Phase 2b ixCELL-DCM Study Design

<b>Objectives</b>	<ul style="list-style-type: none"> <li>To evaluate the efficacy, safety and tolerability of ixmyelocel-T compared to placebo in patients with heart failure due to ischemic DCM</li> </ul>
<b>Patients</b>	<ul style="list-style-type: none"> <li>Males and females, age 30-85</li> <li>Diagnosis of ischemic DCM according to WHO criteria</li> <li>Not a candidate for reasonable revascularization procedures</li> <li>LVEF <math>\leq</math> 35%</li> <li>NYHA class III or IV heart failure</li> </ul>
<b>Design</b>	<ul style="list-style-type: none"> <li>Multicenter, randomized (1:1), double-blind, placebo-controlled phase 2b study</li> <li>108 patients at approximately 35 sites in the US and Canada</li> <li>Administration via catheter injection into the left ventricular endocardium using the NOGA® Myostar™ injection catheter</li> </ul>
<b>Key endpoints</b>	<ul style="list-style-type: none"> <li>Primary: Number of all-cause deaths, cardiac hospitalizations, and emergency department visits for IV treatment of acute worsening heart failure over 12 months</li> <li>Secondary: Additional clinical, functional, structural, symptomatic/QOL, and biomarker measures at 3, 6 and 12 months</li> </ul>
<b>Status</b>	<ul style="list-style-type: none"> <li>Topline study results expected in Q1 2016</li> </ul>





# Strong Financial Position

- Closed \$40.25 million financing in September 2014
  - Participation by leading institutional healthcare investors
  - Use of proceeds
    - Support commercialization of our marketed products
    - Fund the continued development of MACI in the U.S. and the Phase 2b ixCELL-DCM clinical study
    - Working capital and general corporate purposes
    - Potential acquisitions or investments in complementary businesses, technologies, products or assets
- Cash balance at end of Q3 2014 = \$37.6 million
  - No debt other than computer lease (\$115K)

# Q3 2014 Financial Results

	Legacy Business	Acquired Business	Consolidated
<b>Total revenues</b>	\$ 244	\$ 9,414	\$ 9,658
Cost of product sales	222	5,310	5,532
<b>Gross profit (loss)</b>	22	4,104	4,126
Total operating expenses	9,028	3,120	12,148
<b>Income (loss) from Operations</b>	<b>(9,006)</b>	<b>984</b>	<b>(8,022)</b>
Other income (expense)	1,105	—	1,105
Bargain purchase gain	—	—	—
Total other income	1,105	—	1,105
<b>Net Income (loss)</b>	<b>\$ (7,901)</b>	<b>\$ 984</b>	<b>\$ (6,917)</b>

	2014
<b>Contribution from acquired business — Non-GAAP</b>	
Net loss – GAAP – for the three months ended September 30, 2014	\$ (6,917)
Legacy business loss	7,901
Subtotal — Acquired business results	984
Restructure costs	77
Denmark business results	381
Contribution from acquired business — for the three months ended September 30, 2014 - Non-GAAP	<b>\$ 1,442</b>
<b>Adjusted net loss – Non-GAAP</b>	
Net loss - GAAP – for the three months ended September 30, 2014	\$ (6,917)
Impact of accrued expense for the Verigen agreement	3,158
Adjusted Net loss – for the three months ended September 30, 2014 - Non-GAAP	<b>\$ (3,759)</b>

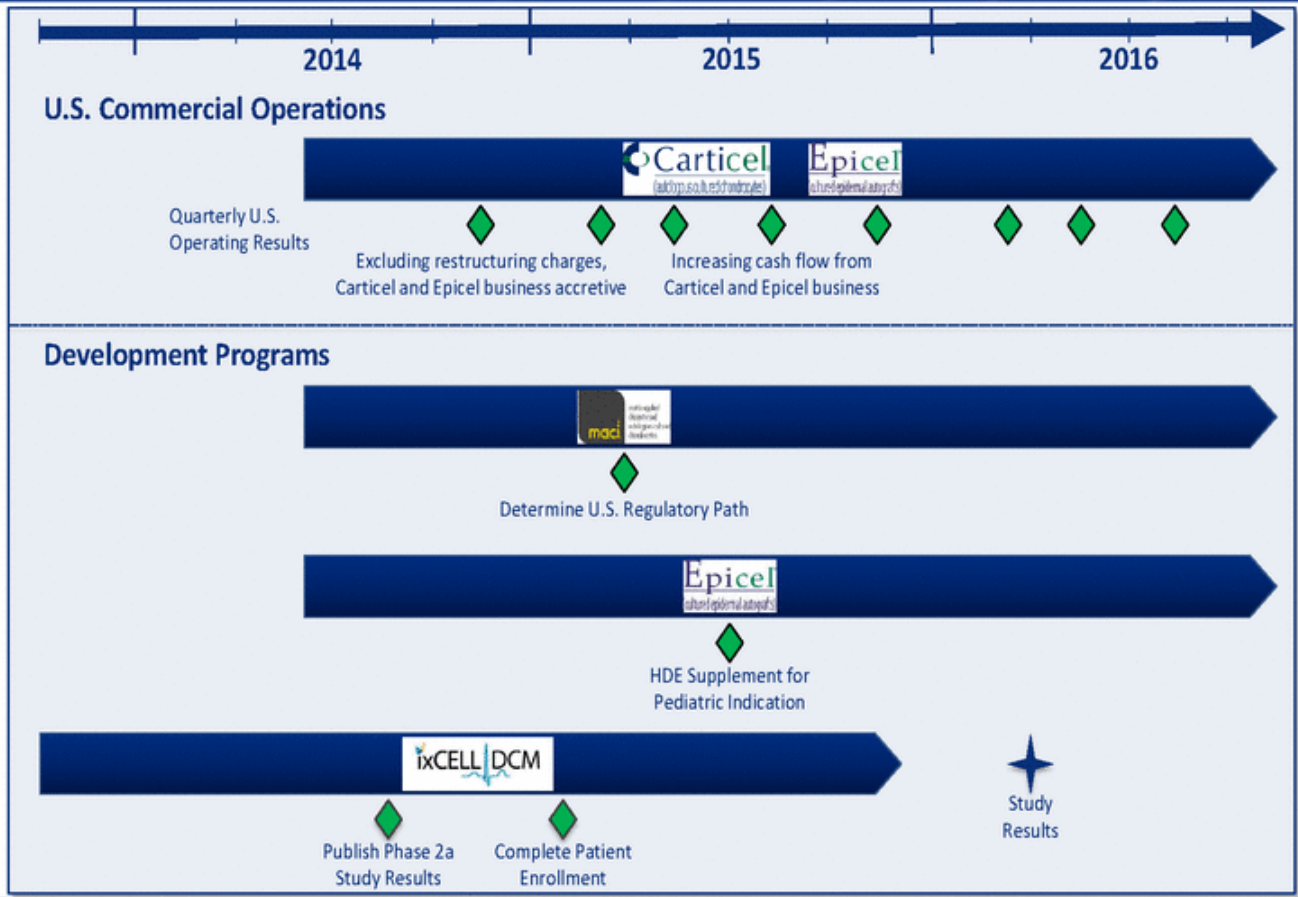
***The acquired business generated a positive contribution of \$1.4 million for the third quarter, excluding restructuring charges and losses from Denmark***

## New Business Attracted Strong Institutional Shareholder Base (> 50% Ownership)

Holder	Position	% Common Stock Outstanding
Consonance Capital Management	2,352,940	9.89%
Great Point Partners	2,170,000	9.12%
Stonepine Capital Management	1,700,000	7.15%
Visium Asset Management	1,422,475	5.98%
Eastern Capital	1,402,889	5.90%
Perceptive Advisors	1,100,000	4.62%
Sabby Management	876,173	3.68%
BlackRock Institutional Trust	558,600	2.35%
The Vanguard Group	397,757	1.67%
Fred Alger Management	392,000	1.65%
Perkins Capital Management	352,000	1.48%
Kennedy Capital Management	300,000	1.26%
Dafna Capital Management	238,900	1.00%
Geode Capital Management	44,366	0.19%
CalPERS	43,900	0.18%

Source: NASDAQOnline (January 9, 2015)

# Several Value-Creating Commercial and Clinical Milestones Over the Coming Quarters



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## Appendix

# Vericel Capitalization Table

Capitalization (as of January 8, 2015)	Shares
Common Stock	23,785,653
Series B Preferred Stock Common Equivalents <sup>1</sup>	615,400
Warrants and Options	<u>3,197,034</u>
Fully Diluted Shares <sup>2</sup>	<u>27,598,087</u>

<sup>1</sup>The preferred stock will accrue 478,492 common share equivalent dividends through 2017 at which point Vericel can force conversion of the preferred stock to common stock. 29

<sup>2</sup>Excludes the 235,077 common share equivalent dividends accrued but not issued.