

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, 2022**

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 Street
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: **(800) 556-0311**

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 (see General Instruction A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	VCEL	NASDAQ

Indicate by a check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§240.12b-2 of this chapter). Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

In connection with its participation in the 40th Annual J.P. Morgan Healthcare conference on January 12, 2022, Vericel Corporation (the "Company") updated its corporate presentation to include disclosure that the Company estimates its full-year revenue growth for fiscal year 2021 to be in the range of 25%-26%, and its total adjusted EBITDA for the year to be approximately \$30 million, based on preliminary unaudited financial results. The corporate presentation also includes disclosure that the Company had approximately \$129 million in cash and investments as of December 31, 2021. The presentation further includes certain updates regarding the Company's life cycle management initiatives.

Because the Company's financial statements for the year ended December 31, 2021 have not been finalized or audited, these preliminary statements regarding the Company's estimated full-year revenue growth rate and total adjusted EBITDA, as well as its approximate cash and investments as of December 31, 2021, are subject to change and the Company's actual results as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01. Regulation FD Disclosure.

The information set forth in Item 2.02 of this Current Report on Form 8-K (this "Report") is incorporated into this Item 7.01 by reference.

The Company will participate in the 40th Annual J.P. Morgan Healthcare Conference in San Francisco, California, which is being held virtually on Wednesday, January 12, 2022 at 7:30 a.m. Eastern Time, and has updated the corporate presentation that it intends to use at the conference. The Company may use this updated corporate presentation in meetings with investors from time to time as well. The Company's updated corporate presentation includes disclosure regarding the Company's estimated full-year revenue growth rate and total adjusted EBITDA for fiscal year 2021, as well as its estimated cash and investments balance as of December 31, 2021.

A copy of the Company's updated corporate presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in Item 2.02 and Item 7.01 of this Report shall not be deemed "filed" for the purposes of Section 18 of the Securities and 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 into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Vericel Corporation Presentation, dated January 12, 2022
104 *	Cover Page Interactive Data File (embedded within the Inline XBRL)

* Furnished herewith

EXHIBIT INDEX

Exhibit No.	Description
99.1 104 *	Vericel Corporation Presentation, dated January 12, 2022 Cover Page Interactive Data File (embedded within the Inline XBRL)

* Furnished herewith.

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

Date: January 12, 2022

By: /s/ Sean C. Flynn
Name: Sean C. Flynn
Title: Vice President, General Counsel and Secretary



Advanced Therapies for the Sports Medicine and Severe Burn Care Markets

CORPORATE PRESENTATION

JANUARY 2022

Safe Harbor

Vericeal has provided in this presentation certain financial information that has not been prepared in accordance with GAAP. Vericeal's management believes that the non-GAAP adjusted EBITDA described in the presentation, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding Vericeal's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in Vericeal's industry. However, the non-GAAP financial measures that Vericeal uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

Additionally, Vericeal cautions you that all statements other than statements of historical fact included in this presentation that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Our actual results may differ materially from those expressed or implied by the forward-looking statements in this presentation. These statements are often, but are not always made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believes," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions.

Among the factors that may result in differences are the inherent uncertainties associated with our expectations concerning our full-year revenue growth rate and total adjusted EBITDA for fiscal year 2021, as well as

the estimate of our cash and investments balance as of December 31, 2021. Vericeal's revenue growth and adjusted EBITDA expectations for the full-year ended 2021, as well as its estimates concerning cash and investments are preliminary, unaudited and are subject to adjustment during our ongoing internal review. Additional factors that could cause actual results to differ materially from those set forth in the forward-looking statements include, but are not limited to, uncertainties associated with our expectations regarding future revenue, growth in revenue, market penetration for MACI® and Epiceal®, growth in profit, gross margins and operating margins, the ability to achieve or sustain profitability, contributions to adjusted EBITDA, the expected target surgeon audience, potential fluctuations in sales and volumes and our results of operations over the course of the year, timing and conduct of clinical trial and product development activities, timing of the resubmission to the Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid® seeking approval for the treatment of severe burns in the United States following MediWound's receipt of a complete response on June 28, 2021, timing or likelihood of approval by the FDA of the NexoBrid BLA resubmission, the estimate of the commercial growth potential of our products and product candidates, availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities, competitive developments, changes in third-party coverage and reimbursement, our ability to supply or meet customer demand for our products, and the wide-ranging impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, the current spread of the COVID-19 "Delta" and "Omicron" variants has adversely affected the United States health system in a variety of ways and, in certain instances and geographies, has resulted in staffing shortages, physician and patient unavailability for treatment and the postponement or cessation of elective surgical procedures. We are currently unable to predict the full impact of the current COVID-19 surge on the performance of elective surgical procedures, the availability of physicians and/or their treatment prioritizations, the level of healthcare facility staffing,

or the willingness or ability of patients to seek treatment, or when future resurgence of COVID-19 infections will cause similar effects. Other disruptions or potential disruptions include restrictions on the ability of Company personnel to travel and access customers for training, promotion and case support, delays in product development efforts, and additional government-imposed quarantines and requirements to "shelter in place" or other incremental mitigation efforts or initiatives that may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products. With respect to NexoBrid, the COVID-19 pandemic may impact the FDA's response time to our future regulatory submissions, its ability to monitor our clinical trials, and its ability to conduct necessary reviews or inspections of manufacturing facilities involved in the production of NexoBrid, any or all of which may result in time being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. The total impact of these disruptions may have a material impact on the Company's financial condition, cash flow and results of operations.

These and other significant factors are discussed in greater detail in Vericeal's Annual Report on Form 10-K for the year ended December 31, 2020, with the Securities and Exchange Commission (SEC) on February 24, 2021; Vericeal's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 2021, and in other filings with the SEC. These forward-looking statements reflect our views as of the date hereof and Vericeal does not assume and specifically disclaims any obligation to update any of these forward-looking statements to reflect a change in views or events or circumstances that occur after the date of this presentation, except as required by law.

Portfolio of Innovative Cell Therapies and Specialty Biologics with Significant Barriers to Entry

Delivering Sustained High Revenue Growth with a Strong Profitability and Operating Cash Flow Profile

SPORTS MEDICINE



autologous cultured chondrocytes on porcine collagen membrane

The leading restorative cartilage repair product in the sports medicine market

SEVERE BURNS

Epicel[®]
(cultured epidermal autografts)

The leading permanent skin replacement in the severe burn care field

The logo for NexoBrid, featuring the word "NexoBrid" in a bold, sans-serif font. The letters "N", "e", "x", and "o" are purple, while "B", "r", "i", and "d" are red. To the right of the text is a graphic of several small squares in various colors (purple, red, yellow, green) arranged in a cluster.

NexoBrid

North American commercial rights to the next generation eschar removal product

Focused on changing the standard of care for patients with cartilage damage and severe burns

Strong Track Record of Revenue and Profit Growth

Top-Tier Revenue Growth

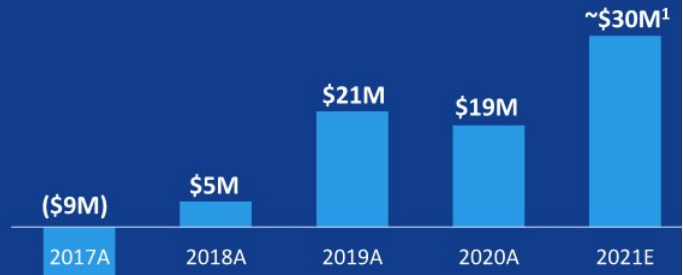
■ Sports Med ■ Burn Care



- > Multiple years of top-tier revenue growth
- > Diversified across two franchises
- > More than 12,000 patients treated with Vericel products

Robust Profitability Profile

■ Adjusted EBITDA

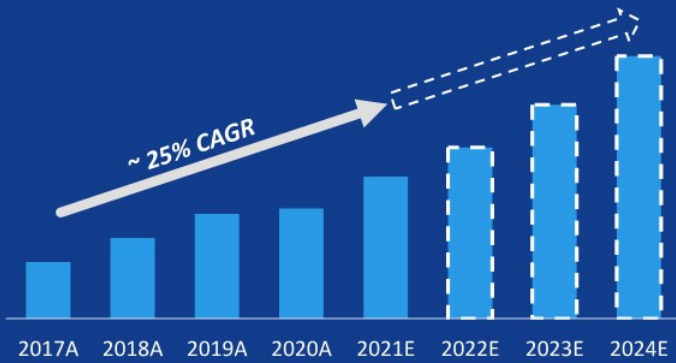


- > Converting strong revenue growth into cash flow generation
- > ~\$129 million in cash and investments as of 12/31/21¹
- > ~1% Free Cash Flow yield

¹ Full-year 2021 revenue growth, adjusted EBITDA (non-GAAP) and cash and investments balances are based on preliminary unaudited 2021 financial results and are subject to change.

Well-Positioned to Sustain High Revenue and Profit Growth Over the Long Term

Expect to Maintain High Revenue Growth Rate¹



- ▷ Significantly underpenetrated markets (~\$2B-3B)
- ▷ Limited competition with strong barriers to entry
- ▷ Strong reimbursement profile

Expect Continued Long-Term Margin Expansion¹

GROSS MARGIN	70%+
ADJUSTED EBITDA	30%+

- ▷ Substantial operating leverage across business
- ▷ Increasing margins and operating cash flow
- ▷ Premium-value products with concentrated call points

¹ Based on internal estimated long-term financial projections.

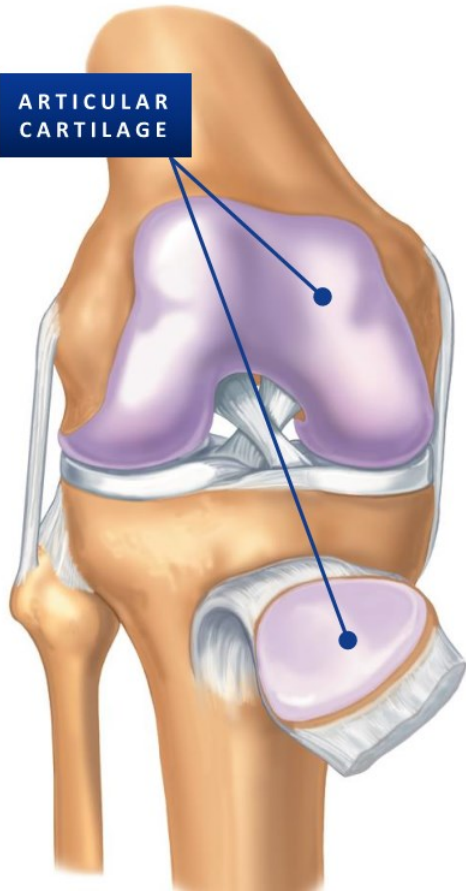
Articular Cartilage Structure and Function

ARTICULAR CARTILAGE IS A HIGHLY SPECIALIZED CONNECTIVE TISSUE OF SYNOVIAL JOINTS

Articular cartilage function

- ▷ Provide a smooth, lubricated surface allowing for nearly frictionless movement
- ▷ Facilitate transmission of loads to underlying subchondral bone
- ▷ Protect joints from compressive, tensile and shearing forces

Chondrocytes are the resident cells responsible for the production, maintenance and repair of articular cartilage





Knee Cartilage Defects and Treatment Options

Knee cartilage injuries are a significant cause of musculoskeletal morbidity

Cartilage defects are found in ~60% of knee arthroscopies

- ▷ Damage is caused by acute and repetitive trauma and degenerative conditions
- ▷ Limited capacity for intrinsic healing and repair
- ▷ Untreated lesions may lead to debilitating joint pain, dysfunction, and osteoarthritis

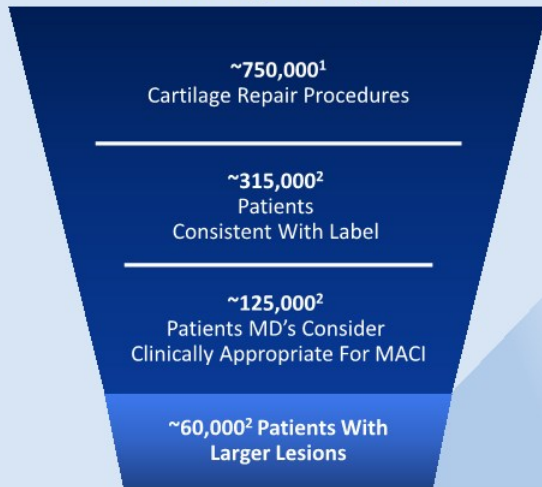
TREATMENT GOALS

- ▷ Reduce symptoms
- ▷ Improve function
- ▷ Prevent degeneration

PALLIATIVE	REPARATIVE	RESTORATIVE
Techniques intended to relieve or prevent pain with little repair of underlying defect	Marrow-stimulation techniques that result in formation of fibrocartilage	Techniques designed to recreate hyaline-like cartilage at the site of the defect
<ul style="list-style-type: none"> ▷ Lavage and debridement ▷ Thermal chondroplasty 	<ul style="list-style-type: none"> ▷ Microfracture/microdrilling ▷ Augmented microfracture 	<ul style="list-style-type: none"> ▷ Autologous chondrocyte implantation ▷ Autograft or allograft

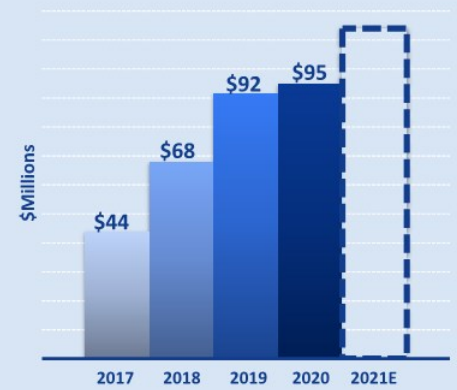
Large Addressable Knee Cartilage Repair Market for MACI

Estimated Annual Addressable Patient Population (U.S.)



\$2+ Billion
Addressable Market in the U.S.

Annual Cartilage Repair Revenue



¹ Health Advances LLC MACI market assessment report (2018), Vericel data, LexisNexis, Medtech Insight, NY SASD, SmartTRAK, LSI, PSPS, McCormick, Frank et al. Arthroscopy, (2014) 30(2): 222-6, Montgomery, et al. Knee Surg Sports Traumatol Arthrosc (2014) 22: 2070.
² Health Advances LLC MACI market assessment report (2018)



MACI Production and Administration



BIOPSY TAKEN



DEFECT DEBRIDED



CHONDROCYTES
EXTRACTED,
EXPANDED,
& LOADED



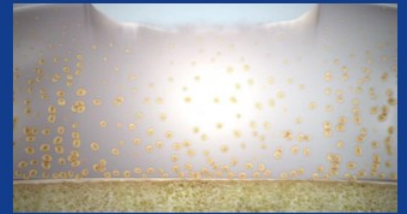
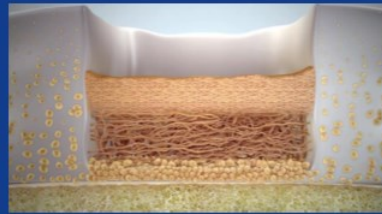
TEMPLATE CREATED



MACI DELIVERED



MACI IMPLANTED



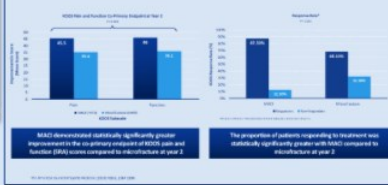
MACI Product Attributes Driving Strong Growth Since Launch

Broad Label with Strong Clinical Data

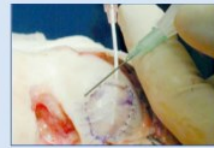
HIGHLIGHTS OF PRESCRIBING INFORMATION
 These highlights do not include all the information needed to use MACI safely and effectively. See full prescribing information for MACI.
 MACI (autologous cultured chondrocytes on porous collagen scaffold)
 Cellular sheet for autologous implantation
 Initial U.S. Approval: 2016

INDICATIONS AND USAGE
 MACI is an autologous cultured scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. (1)
 Limitations of Use

SUMMIT Clinical Study Results – Superiority of MACI Implant Versus Microfracture Treatment

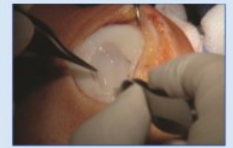


Simpler, Less Invasive Procedure



Carticel

- ▷ Technically exacting procedure
- ▷ Required arthroscopy, periosteal patch harvest and sutures
- ▷ Extended surgical time



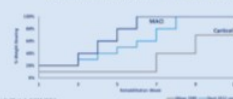
MACI

- ▷ Simpler, less invasive ACI procedure
- ▷ Eliminates periosteal harvest and sutures
- ▷ Significant reduction in surgical time
- ▷ Uniform distribution of cells
- ▷ Improved post-operative course

Shorter Rehab Protocols

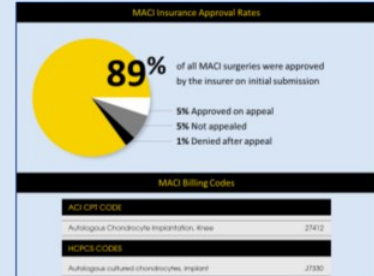


Rehabilitation Timeline for ACL procedures. Time to Weight Bearing



Published MACI rehabilitation protocols achieve full weight-bearing in 6-8 weeks compared to 10-12 weeks for published Carticel rehabilitation protocols

Strong Reimbursement Profile



MACI Product and Procedure Enhancements Driving Broader Surgeon Adoption

1995



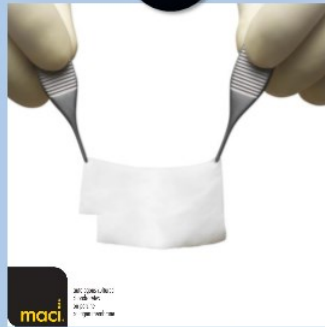
Cells in Suspension

- Highly invasive, technically exacting procedure
- Required periosteal harvest from tibia and suture fixation to confine cells
- Extended surgical time
- High rate of subsequent procedures

ARTHROTOMY



2017

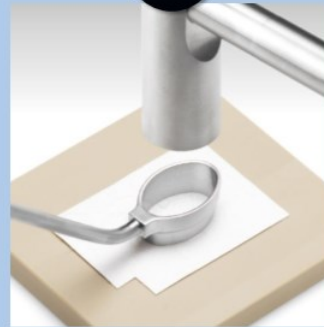


Cells on Collagen Membrane

- Simpler, less invasive ACI procedure
- Eliminates periosteal harvest and sutures
- Significant reduction in surgical time
- Uniform cell distribution
- Improved post-operative course

MINI-ARTHROTOMY

2019

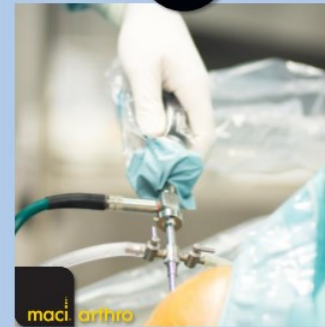


Advanced Instrumentation

- Simplifies templating
- Exact match of implant to defect size
- Reduced implant handling
- Reduced operative time

MINI-ARTHROTOMY

2025+

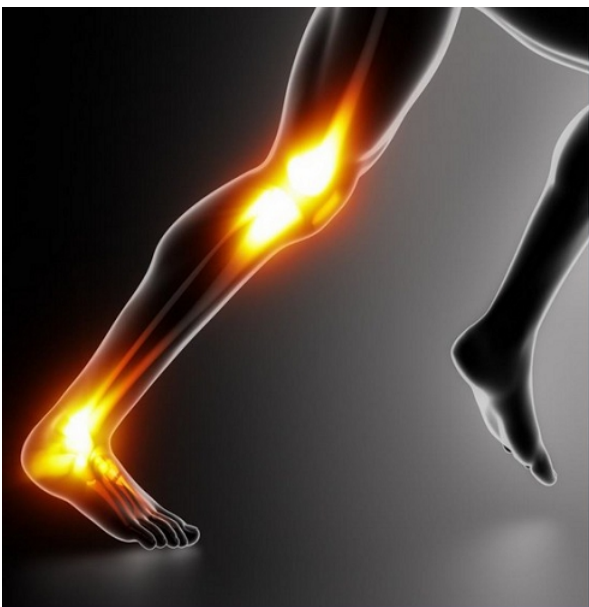


Additional Delivery Option

- Less invasive
- Improved visualization
- Potentially faster patient recovery

ARTHROSCOPY

Significant Ankle Cartilage Repair Opportunity



MACI Ankle Annual TAM Estimate (U.S.)



MACI for the treatment of cartilage defects in the ankle represents a \$700 million³ market opportunity and increases the overall MACI TAM in the U.S. to ~ \$3 billion



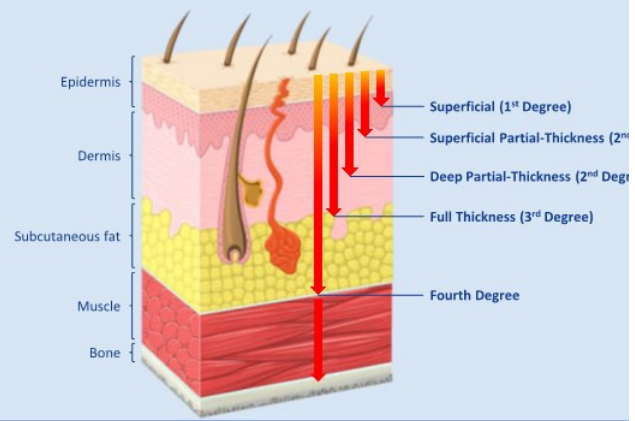
¹ SmartTrak Cartilage Repair Procedures; resurfacing includes microfracture, OATs, OCA, etc. and does not include chondroplasty/debridement only.

² Cello Health MACI Ankle quantitative market research survey (2021).

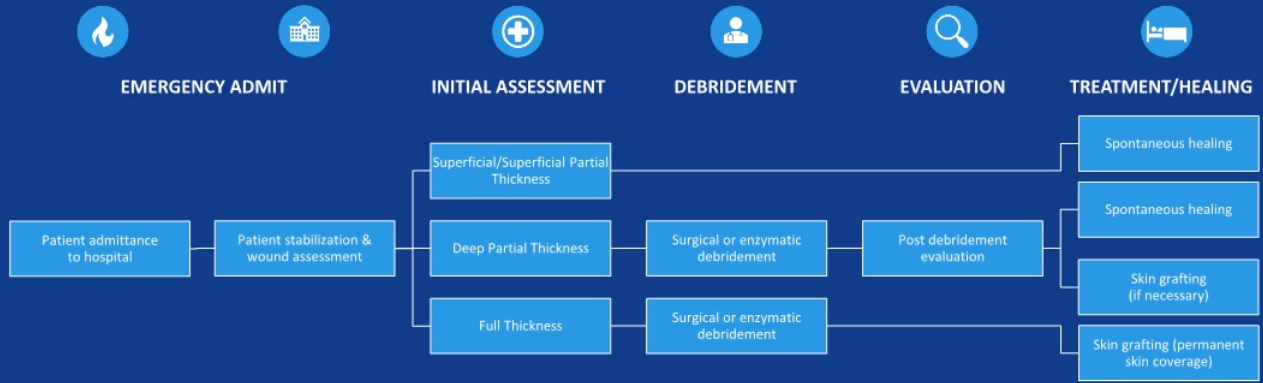
³ Assumes MACI ASP of \$40,000+.

Burn Injury Size and Depth Determine Treatment Pathway

- ▶ Full thickness burn injuries of any size and partial thickness burn injuries >10% TBSA are most often transferred to specialized burn centers
- ▶ Full thickness and deep partial-thickness burns **require eschar removal and grafting** to achieve wound closure

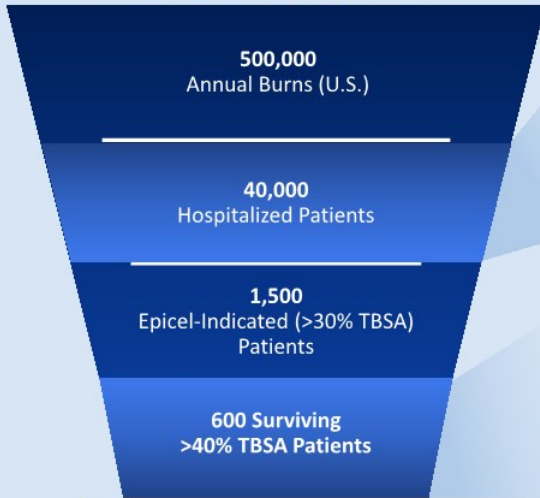


TREATMENT PATHWAY



Burn Franchise Addressable Market Opportunity

Estimated U.S. Burn Patients¹



NexoBrid

\$200+ Million
Addressable
Market in the
U.S.²

Epicel

\$200+ Million
Addressable
Market in the
U.S.³

Upon approval, NexoBrid will significantly expand the total addressable market opportunity for Vericel's burn franchise.

NexoBrid

Epicel
cultured epidermal autografts

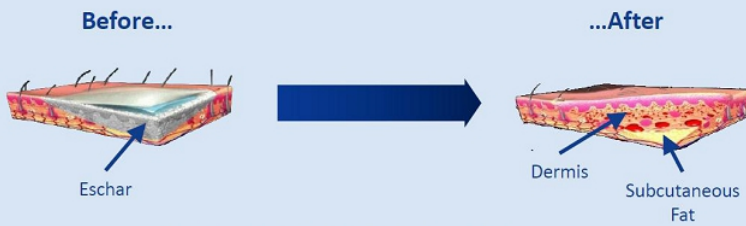
¹ 2017 National Burn Repository Report Version 13.

² ~90% of hospitalized patients with thermal burns; ~90% of eligible patients are debrided (management estimate); ~10% TBSA for average patient with pricing analysis ongoing; ~85% of TAM in burn centers based on 75% of all hospitalized patients admitted into burn centers (<http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>) and burn centers having a higher rate of debridement.

³ Assumes 600 patients x 120 grafts per patient x ~\$3,000+ per graft.

Early Eschar Removal is a Critical 1st Step in Burn Treatment

Eschar Removal



- ▷ Prevents local infection and sepsis
- ▷ Avoids further deterioration and scarring
- ▷ Early eschar removal enables faster initiation of wound healing
- ▷ Allows direct visual assessment of wound bed, enabling an informed treatment plan

Current Standard of Care

Surgical Excision

- ▷ Tangential excision
- ▷ Dermabrasion
- ▷ Hydro-jet surgery



Significant Limitations

- ▷ Traumatic and non-selective
- ▷ Loss of healthy tissue and blood
- ▷ Challenging in delicate areas
- ▷ OR access may delay start of excision

Non-Surgical Approaches

- ▷ Autolysis
- ▷ Topical medications
- ▷ Enzymes, chemicals, biologicals



Significant Limitations

- ▷ Limited efficacy; surgery often needed
- ▷ Protracted; increased morbidities
- ▷ Less useful for deep/extensive burns
- ▷ Multiple dressing changes/wound h

Clear unmet need for selective and effective eschar removal agent for severe burns

NexoBrid



Approved in EU & other OUS markets

Investigational product with orphan biologic designation in the U.S.

Pivotal U.S. Phase 3 clinical study met primary and all secondary endpoints

BLA resubmission activities underway

Orphan and biologic exclusivities upon approval in the U.S.; patent protection until 2029

BARDA funding supports U.S. development, expanded access and medical countermeasure procurement

NexoBrid

Selectively Removes Nonviable Burn Tissue (Eschar) in Patients with Deep Partial- and Full-Thickness Burns

- ▷ Bromelain-based biological product containing a sterile mixture of proteolytic enzymes
- ▷ Easy-to-use, single, non-surgical topical application at the patient's bedside to remove eschar
- ▷ Four-hour treatment enables early visual assessment of the wound, enabling development of an informed treatment plan



NexoBrid is an investigational product in the U.S. and is not approved for commercial use or sale in the U.S. at this time.

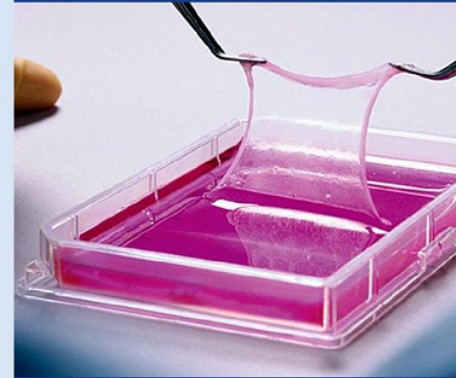
EPICEL OVERVIEW

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

Only FDA-approved permanent skin replacement for adult and pediatric patients with full-thickness burns

Important treatment option for severe burn patients where little skin is available for autografts

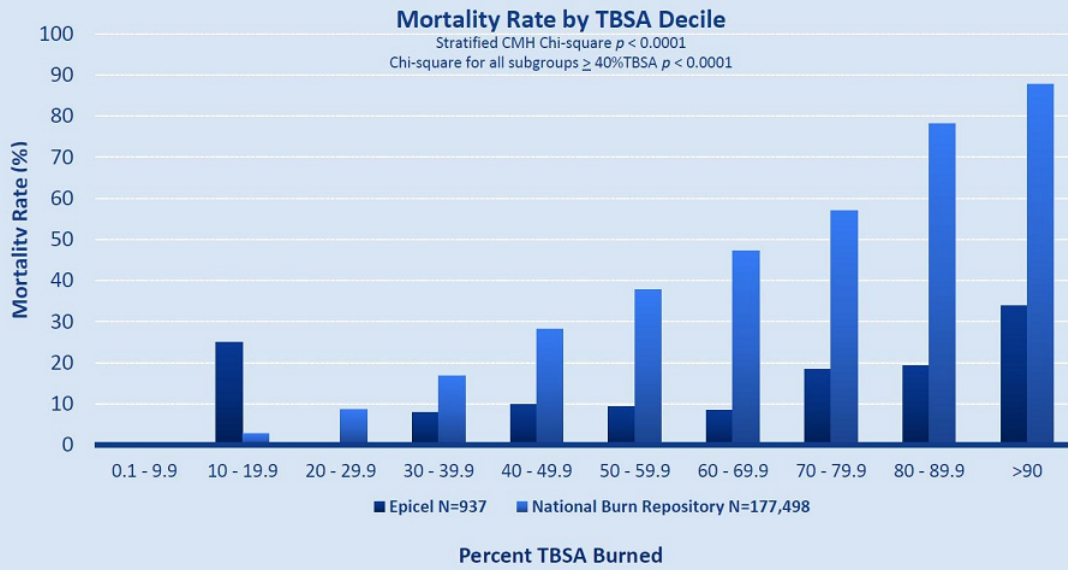
Epicel
[cultured epidermal autografts]





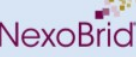
Epicel Production and Administration



Comparison of Epicel Patient Database to National Burn Repository¹ Data Demonstrates Lower Mortality Rate



Building a Pipeline Through Current Portfolio and Business Development

PRODUCT	INDICATION/STUDY	PRECLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	APPROVAL
	Treatment of Symptomatic Cartilage Defects of the Knee in Adults	Commercialized					
	Pediatric (PEAK) Study – Knee	Currently Enrolling					
	Arthroscopic Delivery – Knee	Phase III Ready					
	Treatment of Cartilage Defects – Ankle	Phase III Ready					
	Treatment of Large Deep Dermal and Full-Thickness Burns	Commercialized					
	Burn Eschar Removal in Adults	Pending BLA Resubmission					
	Pediatric (CIDS) Study	Enrollment Complete					

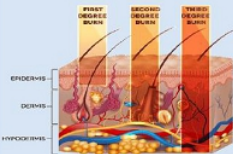
Strategic Transactions to Maximize Long-Term Value

ADVANCED CELL THERAPY DEVELOPMENT AND MANUFACTURING PLATFORM

Sports Medicine Franchise



Severe Burn Care Franchise



New Advanced Cell Therapy Vertical(s)



Business development activities focused on opportunities having a strategic fit with current **franchises** or advanced cell therapy **platform**

Vericel is a leader in advanced therapies for the sports medicine and severe burn care markets

INVESTMENT HIGHLIGHTS



autologous cultured chondrocytes on porcine collagen membrane

Epicel[®]
(cultured epidermal autografts)

NexoBrid[®]

Innovative Portfolio with Significant Barriers to Entry



Sustainable Revenue Growth in Large Addressable Market



Attractive Business Model with Robust Profitability Profile



Strong Balance Sheet and Shareholder Base

Reconciliation of Reported GAAP Net Income (Loss) to Adjusted EBITDA (Non-GAAP Measure) – Unaudited

Twelve Months
Ended December 31,

Annual Adjusted EBITDA	2017	2018	2019	2020
Net Income (loss) (GAAP)	\$(17,286)	(\$8,137)	(\$9,665)	\$2,864
Non-recurring license agreement purchase	-	-	17,500	-
Stock-based compensation expense	2,680	7,223	13,179	13,843
Depreciation and amortization	1,612	1,426	1,744	2,383
Net interest expense (income)	1,093	835	(1,606)	(685)
Change in fair value of warrants	257	2,524	-	-
Loss on extinguishment of debt	860	838	-	-
Revenue reserve related to a dispute between pharmacy provider and payer	1,418	-	-	-
Income tax expense	-	-	-	180
Adjusted EBITDA (Non-GAAP)	\$(9,366)	\$4,709	\$21,152	\$18,585

Vericel has not provided a reconciliation of full-year 2021 adjusted EBITDA estimates to an estimated net income (loss) outlook because net income (loss) and certain items such as stock-based compensation expense, depreciation and amortization, net interest income and income tax expense that are a component of net income (loss) cannot be reasonably estimated due to Vericel's year-end financial closing process. Net income (loss) and these components of net income (loss) could significantly impact Vericel's actual net income (loss).