

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 10, 2023**

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: **(617) 588-5555**

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 41st Annual J.P. Morgan Healthcare conference, on January 10, 2023, Vericel Corporation (the “Company”) issued a press release and updated its corporate presentation, both of which include estimates of operating and financial results as of and for the year ended December 31, 2022, as well as other updates regarding its business.

Because the Company’s financial statements for the year ended December 31, 2022, have not been finalized or audited, these preliminary statements regarding the Company’s operating and financial results as of and for the year ended December 31, 2022, 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, stockholders should not place undue reliance on this preliminary estimate. A copy of the Company’s January 10, 2023, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this “Report”).

Item 7.01. Regulation FD Disclosure.

The information set forth in Item 2.02 of this Report is incorporated into this Item 7.01 by reference.

The Company will participate in the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California, which is being held on Wednesday, January 11, 2022, at 7:30 a.m. Pacific Time, and has updated the corporate presentation that the Company 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, preliminary and unaudited full-year revenue for fiscal year 2022, its estimated cash and investments balance as of December 31, 2022, and additional financial and business updates.

A copy of the Company’s updated corporate presentation is attached hereto as Exhibit 99.2 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.

Exhibit No.	Description
99.1	Press Release, dated January 10, 2023, titled “Vericel Announces Preliminary Fourth-Quarter and Full-Year 2022 Financial Results and Accelerated Launch Timeline for MACI Arthroscopic Program”
99.2	Vericel Corporation Presentation, dated January 10, 2023
104 *	Cover Page Interactive Data File (embedded within the Inline XBRL)

* Furnished herewith

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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* 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 10, 2023

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



Vericel Corporation
 64 Sidney Street
 Cambridge, MA 021
 T 617 588-5555 F
 www.vcel.com

Vericel Announces Preliminary Fourth-Quarter and Full-Year 2022 Financial Results and Accelerated Launch Timeline for MACI Arthroscopic Program

Full-Year Total Revenue Expected to be Approximately \$164 to \$165 Million

MACI Full-Year Revenue Expected to be at the High End of Guidance Range, with Fourth Quarter Revenue Growth of Approximately 24%

MACI Arthroscopic Commercial Launch Now Planned for 2024

CAMBRIDGE, Mass., January 10, 2023 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced preliminary, unaudited financial results for the fourth quarter and year ended December 31, 2022 and an accelerated launch timeline for MACI[®] arthroscopic delivery, which is now anticipated to be launched in 2024.

Preliminary, Unaudited Fourth-Quarter and Full-Year 2022 Financial Results

- Total net revenue for full-year 2022 expected to be approximately \$164 to \$165 million
- MACI net revenue for full-year 2022 expected to be approximately \$132 million
- Burn Care net revenue for full-year 2022 expected to be approximately \$32.5 million
- Fourth quarter MACI revenue growth expected to be approximately 24% versus prior year
- Expect tenth straight quarter with positive adjusted EBITDA and Operating Cash Flow
- As of December 31, 2022, the Company had approximately \$140 million in cash and investments and no debt

Recent Business Highlights and Updates

- Following a Type C meeting with the FDA, the Company is planning to initiate a human factors validation study to support expanding the MACI label to include arthroscopic administration of MACI for the treatment of cartilage defects of the knee and now anticipates an accelerated potential commercial launch of arthroscopic MACI in 2024
- Announced FDA approval of NexoBrid[®] (*anacaulase-bcdb*) on December 28, 2022 for the removal of eschar in adults with deep partial-thickness and/or full-thickness thermal burns, with U.S. commercial availability expected in the second quarter of 2023
- Expect to hold a pre-IND meeting with the FDA in the first half of 2023 to discuss the MACI development program for the treatment of cartilage defects in the ankle

“We made tremendous progress advancing our pipeline and expanding our business in 2022, highlighted by an accelerated regulatory pathway for the MACI arthroscopic delivery program and the recent approval of NexoBrid,” said Nick Colangelo, President and CEO of Vericel. “We also had very strong MACI performance to close the year and we look forward to building on this momentum in 2023 across both of our franchises, as we expect accelerating total revenue growth this year and further acceleration in 2024 driven by a full year of NexoBrid on the market and the planned launch of arthroscopic MACI.”

Vericel is scheduled to present at the 41st Annual J.P. Morgan Healthcare Conference at 10:30 a.m. ET (7:30 a.m. PT) on Wednesday, January 11, 2023. A webcast of the presentation will be available on the Investor Relations section of the Vericel Corporation website at: <http://investors.vcel.com>.

About Vericel Corporation

Vericel is a leader in advanced therapies for sports medicine and severe burn care. The Company manufactures and markets two cell therapy products in the United States. MACI[®] (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized 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. Epicel[®] (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. Vericel also holds an exclusive license for North American rights to NexoBrid[®] (anacaulase-bbdb), a biological orphan product containing proteolytic enzymes, which is indicated for eschar removal in adults with deep partial-thickness and/or full-thickness burns. For more information, please visit www.vcel.com.

Epicel[®] and MACI[®] are registered trademarks of Vericel Corporation. NexoBrid[®] is a registered trademark of MediWound Ltd. and is used under license to Vericel Corporation. © 2023 Vericel Corporation. All rights reserved.

Preliminary and Unaudited Nature of Reported Results

Our revenue expectations for the fourth quarter and full-year ended 2022, as well as our estimates concerning adjusted EBITDA, operating cash flows, cash and investments are preliminary, unaudited and are subject to change based on the completion of ongoing internal control, review, and audit procedures. As a result, these amounts may differ materially from the amounts that will be reflected in the Company's consolidated financial statements for the year ended December 31, 2022. Accordingly, you should not place undue reliance on this preliminary estimate.

Forward-Looking Statements

Vericel cautions you that all statements other than statements of historical fact included in this press release 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 press release. 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 expected revenue results for the fourth quarter and full-year ended 2022, adjusted EBITDA, operating cash flow, and estimates of our cash and investments as of December 31, 2022. Vericel's revenue expectations for the fourth quarter and full-year ended 2022, as well as its estimates concerning adjusted EBITDA, operating cash flow, and cash and investments are preliminary, unaudited and are subject to change during ongoing internal control, review, and audit procedures. 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, Epicel, and NexoBrid, 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 and likelihood of the FDA's potential approval of the arthroscopic delivery of MACI to the knee or the use of MACI to treat cartilage defects in the ankle, the estimate of the commercial growth potential of our products and product candidates, competitive developments, changes in third-party coverage and reimbursement, the ultimate timing of the commercial launch of NexoBrid in the United States, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.'s ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and the ongoing or future impacts of the COVID-19 pandemic on our business or the economy generally.

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, 2021, filed with the Securities and Exchange Commission (SEC) on February 24, 2022, Vericel's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 9, 2022, and in other filings with the SEC. These forward-looking statements reflect our views as of the date hereof and Vericel does not assume and specifically disclaims any obligation 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.

Investor Contact:

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+1 (734) 418-4411

Media Contact:

Julie Downs
media@vcel.com



Advanced Therapies for the Sports Medicine & Severe Burn Care Markets

41ST ANNUAL J.P. MORGAN
HEALTHCARE CONFERENCE

JANUARY 11, 2023

Safe Harbor

Verice! 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 press release. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “intends,” “estimates,” “plans,” “expects,” “continues,” “believe,” “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 expected revenue results for the fourth quarter and full-year ended 2022, adjusted EBITDA,

operating cash flow, and estimates of our cash and investments as of December 31, 2022. Verice!’s revenue expectations for the fourth quarter and full-year ended 2022, as well as its estimates concerning adjusted EBITDA, operating cash flow, and cash and investments are preliminary, unaudited and are subject to change during ongoing internal control, review, and audit procedures. 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®, Epice!®, and NexoBrid®, 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 and likelihood of the FDA’s potential approval of the arthroscopic delivery of MACI to the knee or the use of MACI to treat cartilage defects in the ankle, the estimate of the commercial growth potential of our products and product candidates, competitive developments, changes in third-party coverage and reimbursement, the ultimate timing of the commercial

launch of NexoBrid in the United States, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.’s ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and the ongoing or future impacts of the COVID-19 pandemic on our business or the economy generally.

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Vericel is a Leader in
Advanced Therapies for
the Sports Medicine and
Severe Burn Care
Markets

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

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

A graphic consisting of several small squares in shades of purple, pink, and yellow, arranged in a roughly rectangular shape.

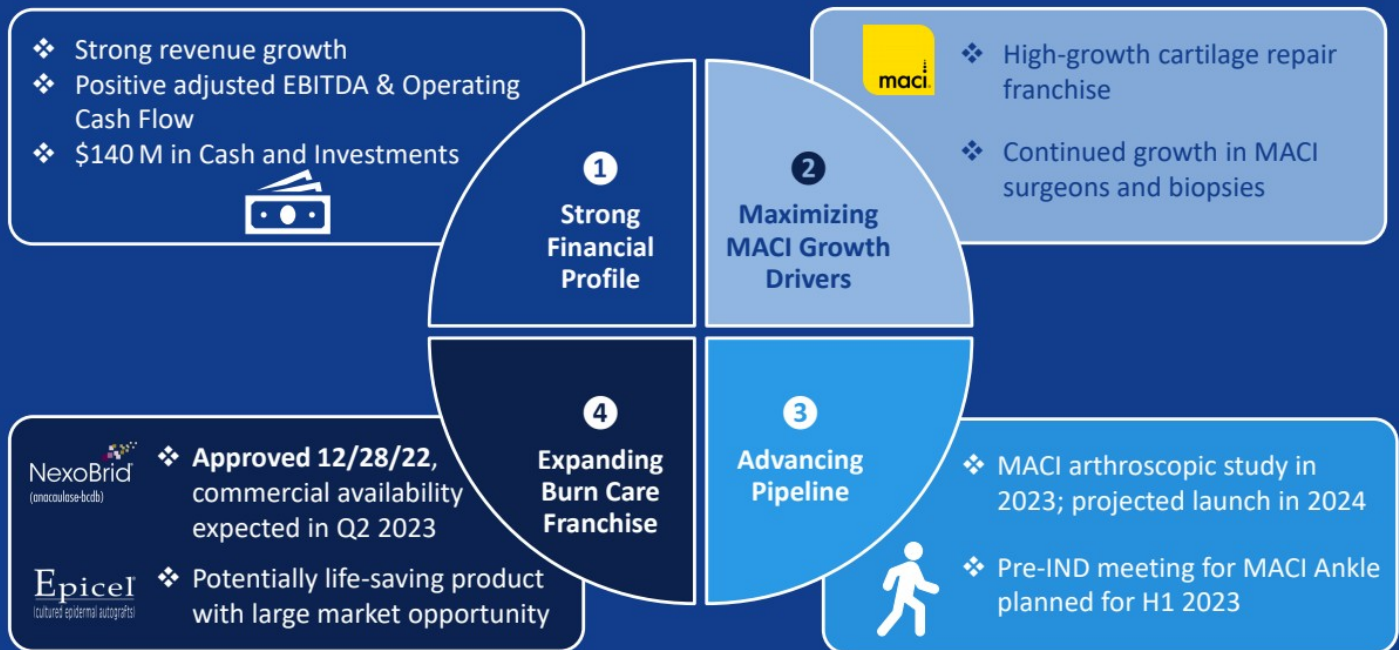
NexoBrid[®]

(anacaulase-bcdeb)

Effective and selective enzymatic
agent that removes eschar while
preserving viable tissue

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

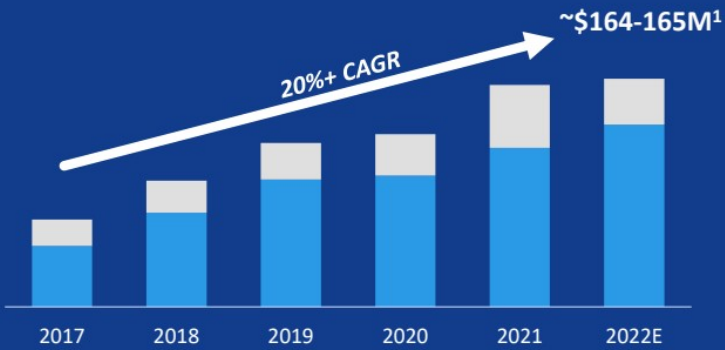
Verice is Well-Positioned to Deliver Sustained Long-Term Growth



Strong Track Record of Financial Results

Top-Tier Revenue Growth

■ Sports Med ■ Burn Care



10 consecutive quarters with positive adjusted EBITDA & Operating Cash Flow¹

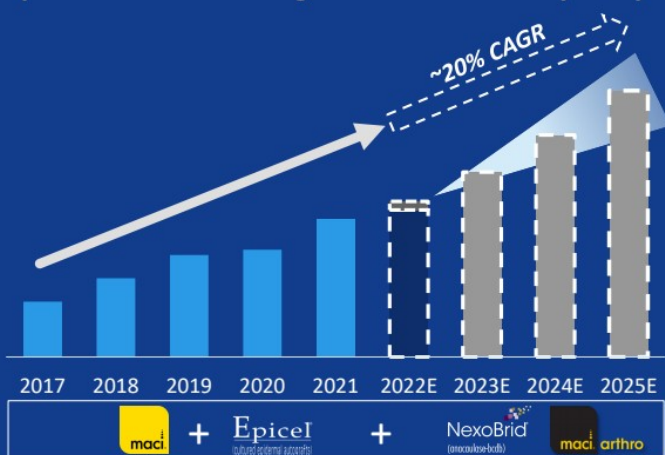


\$140M in cash & investments and no debt as of 12/31/2022¹

¹ Full-year 2022 revenue, adjusted EBITDA and operating cash flow, and cash and investments balances are based on preliminary unaudited 2022 financial results and are subject to change.

Current Portfolio Plus New Product Launches Expected to Drive Strong Revenue and Profit Growth Over the Long Term

Expect to Maintain Strong Revenue Growth Trajectory¹



- ❖ Significantly underpenetrated markets (~\$3B-\$4B)
- ❖ Limited competition with strong barriers to entry
- ❖ Strong reimbursement profiles

Expect Continued Long-Term Margin Expansion¹

GROSS MARGIN **70%+**

ADJUSTED EBITDA **30%+**

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

¹ Based on internal and estimated long-term financial projections.

Knee Cartilage Injuries Represent a Significant Unmet Medical Need

Cartilage defects are found in ~60% of knee arthroscopies¹

- ❖ Damage is caused by acute or repetitive trauma or degenerative conditions

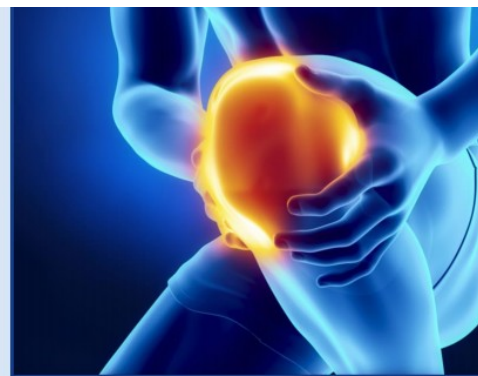
Cartilage has limited capacity for intrinsic healing and repair

- ❖ Untreated cartilage defects may lead to debilitating joint pain, dysfunction, and osteoarthritis
- ❖ Defects can expand and new high-grade lesions can form over time



¹Widuchowski W, et al. Articular cartilage defects: study of 25,124 knee arthroscopies. Knee. Jun 2007.

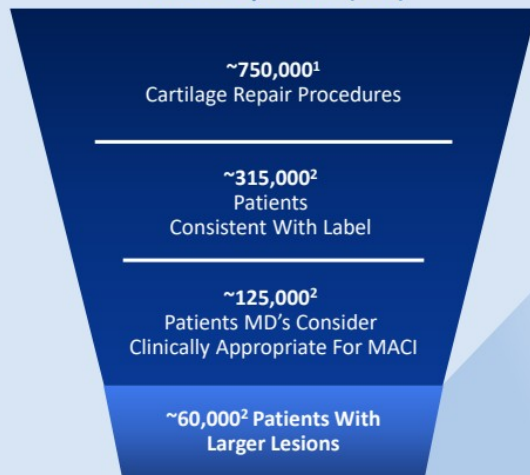
²Data collected from a 2019 Harris Poll survey of 1,002 U.S. adults with knee pain 3 or more days a week that had lasted 2 months or more.



Harris Poll found that 77% of knee pain sufferers can no longer participate in at least one activity they previously enjoyed because of knee pain²

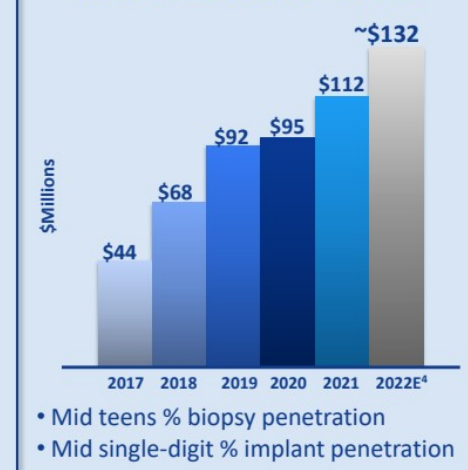
Large Addressable Knee Cartilage Repair Market for MACI

Estimated Annual Addressable Patient Population (U.S.)



\$3 Billion
Addressable Market
in the U.S.³

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).
³ Assumes MACI ASP of ~\$50,000+.
⁴ Full-year 2022 revenue based on preliminary unaudited 2022 financial results and is subject to change.

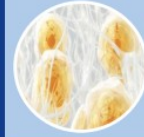
MACI is the Leading Restorative Cartilage Repair Product on the Market



BIOPSY TAKEN



DEFECT DEBRIDED



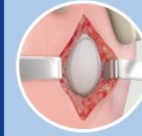
CHONDROCYTES
EXTRACTED,
EXPANDED,
& LOADED



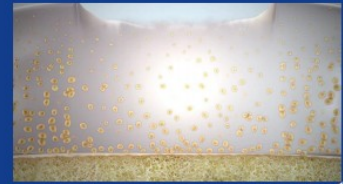
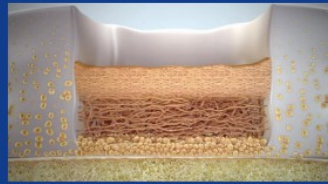
TEMPLATE CREATED



MACI DELIVERED



MACI IMPLANTED



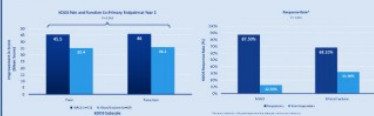
MACI Product Attributes Driving Strong Growth Since Launch

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 membranes)
 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 asymptomatic, 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



MACI demonstrated statistically significantly greater improvement in the (a) primary endpoint of VAS pain and function (VAS) scores compared to microfracture at year 2

The proportion of patients requiring no treatment was statistically significantly greater with MACI compared to microfracture at year 2

Simpler, Less Invasive Procedure



Carticel

- ▷ Technically exacting procedure
- ▷ Required arthrotomy, 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

ACHIEVE ROUTINE

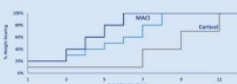
Published MACI patients achieved full weight-bearing in 6-8 weeks compared to 10-12 weeks for published Carticel rehabilitation protocols.

BUILD STRENGTH

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

BE ACTIVE

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



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 Insurance Approval Rates

89% of all MACI surgeries were approved by the insurer on initial submission

- 5% Approved on appeal
- 5% Not appealed
- 1% Denied after appeal

MACI Billing Codes

ACI CPT CODE	ICD-9 CODE
Autologous Chondrocyte Implantation, Knee	27412
HCPCS CODES	ICD-9 CODES
Autologous cultured chondrocytes, implant	J7330



Key MACI Growth Drivers for Continued Long-Term Market Penetration



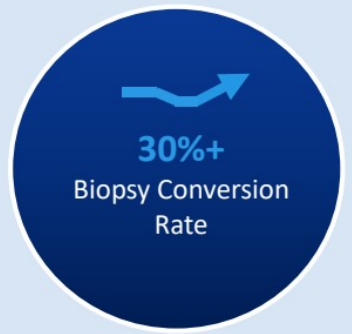
Continued Growth in 2022

Expected to remain a strong
growth driver in 2023



Continued Growth in 2022

Expected to remain a growth
driver, with above-market
growth in 2023 and over time



Stabilized in 2022

Expected to maintain current
levels in 2023 and increase to
historical levels+ over time



Building a Robust and Innovative Pipeline Through Lifecycle Management and Business Development

PRODUCT	INDICATION/STUDY	IN DEVELOPMENT	PHASE I	PHASE II	PHASE III	REGISTRATION	APPROVAL	
 <small>autologous cultured chondrocytes in porous high modulus</small>	Treatment of Symptomatic Cartilage Defects of the Knee in Adults	Commercialized						
	Pediatric (PEAK) Study – Knee	Currently Enrolling						
	Arthroscopic Delivery – Knee				Study Pending ¹			
	Treatment of Cartilage Defects – Ankle				Study Pending ¹			
 <small>cultured epidermal autografts</small>	Treatment of Large Deep Dermal and Full-Thickness Burns	Commercialized						
	Burn Eschar Removal in Adults	Approved						
	Pediatric (CIDS) Study	Enrollment Complete						
	Treatment of Acute Deep Partial and Full Thickness Burn Injuries (NEXT) Study	Expanded Access						

Key Highlights

MACI Arthroscopic Delivery

- ❖ Human factors study planned in 2023, with commercial launch expected in 2024

MACI Ankle Indication

- ❖ Pre-IND meeting with FDA planned for H1 2023

NexoBrid

- ❖ Approved for use in adults December 28, 2022

¹ Study design pending feedback from FDA discussions.

Overview of MACI Arthroscopic Delivery Development Program

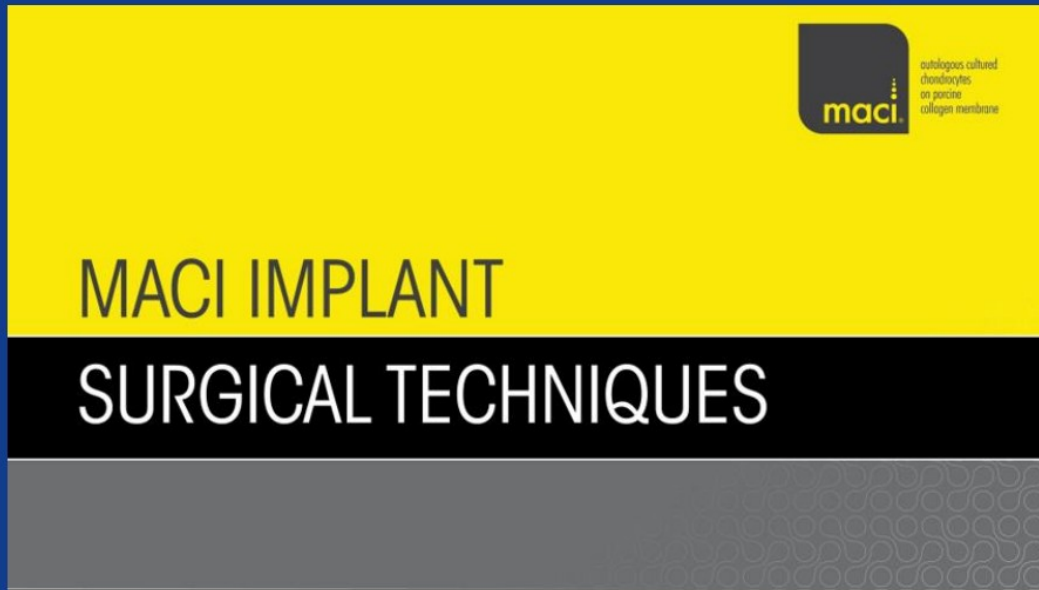
Novel instruments designed and developed to facilitate arthroscopic delivery

Human Factors Validation Study to be initiated in 2023

Planned Launch in 2024



The arthroscopic delivery of MACI is under development and neither such use, nor the sale of the MACI instruments, has been approved in the United States.



[Click here to view an animation of the MACI arthroscopic delivery surgical technique.](#)



Arthroscopic MACI Provides Potential Opportunity for Additional Growth



High Surgeon
Interest in MACI
Arthro

~90% % of target surgeons
expressed **Interest** in
arthro MACI option¹



Potential for
Increased MACI
Volume

~90% % of current MACI users
would expect to
Increase MACI volume¹

Arthroscopic MACI instruments designed to treat the most common defects in the MACI TAM (2-4 cm² defects on the femoral condyles)

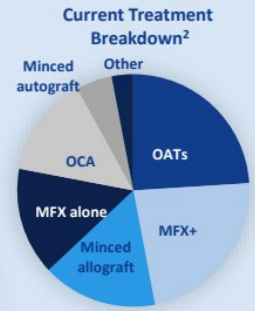


¹Based on Health Advances, LLC MACI market assessment report (2018).

Significant Ankle Cartilage Repair Opportunity



MACI Ankle Annual TAM Estimate (U.S.)



MACI for the treatment of cartilage defects in the ankle represents a \$1 billion³ market opportunity



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 \$50,000+.

The implantation of MACI is currently approved to be performed via an arthrotomy to the knee joint. The use of MACI in the ankle joint is under development and such use has not been approved in the United States.

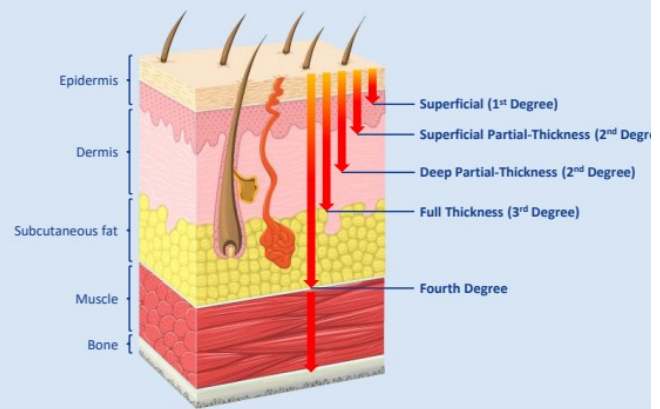
Potential MACI Ankle Indication Would Increase MACI Total Addressable Market to \$4 Billion



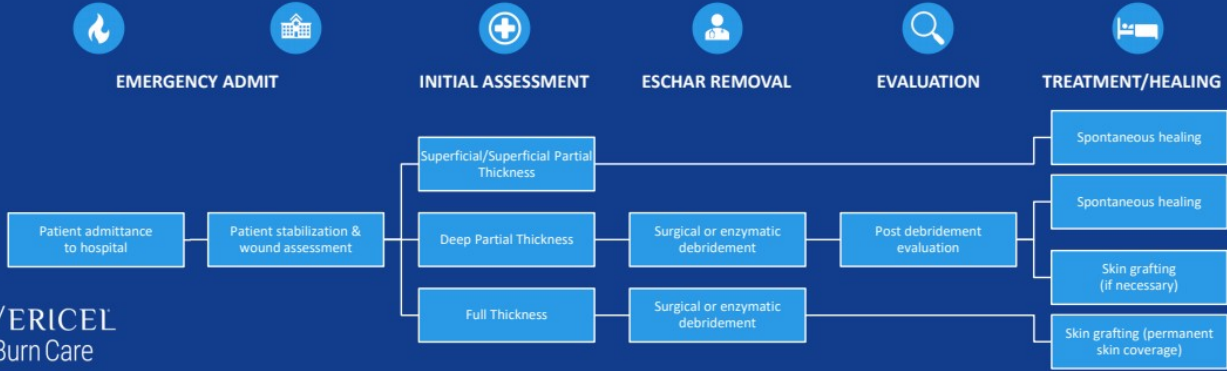
¹ Health Advances LLC MACI market assessment report (2018), Vericel data, LexisNexis, Medtech Insight, NY SASD, SmartTRAK, LSI, PSPS, McCormick, Frank et al. Arthroscopy, (2014) 30(2): 222-6, Montgomery, et al. Knee Surg Sports Traumatol Arthrosc (2014) 22: 2070. ² Health Advances LLC MACI market assessment report (2018) ³ Assumes MACI ASP of \$50,000+ ⁴ SmartTrak Cartilage Repair Procedures; resurfacing includes microfracture, OATS, OCA, etc. and does not include chondroplasty/debridement only. ⁵ Cello Health MACI Ankle quantitative market research survey (2021). The implantation of MACI is currently approved to be performed via an arthrotomy to the knee joint. The use of MACI in the ankle joint is under development and such use has not been approved in the United States.

Burn Injury Size & Depth Determine Treatment Pathway

- ❖ Full thickness burn injuries of any size & partial thickness burn injuries >10% total body surface area (TBSA) are most often transferred to specialized burn centers
- ❖ Full thickness & deep partial-thickness burns **require eschar removal and grafting** to achieve wound closure



TREATMENT PATHWAY



Burn Franchise Addressable Market Opportunity



¹ 2017 National Burn Repository Report Version 13.

² ~90% of hospitalized patients with thermal burns; ~90% of eligible patients require eschar removal (management estimate).

³ Assumes NexoBrid average price of ~\$9,000 per patient.

⁴ Assumes 600 patients x 120 grafts per patient x ~\$4,000+ per graft.

Clear Unmet Need for an Effective and Selective Eschar Removal Agent that Preserves Viable Tissue



❖ Early Eschar Removal and Burn Assessment Are Critical to Patient Healing

- Early eschar removal can reduce inflammation, stop burn progression, and reduce infections and sepsis^{1,2}
- Timely assessment and treatment can support improved healing and reduced scarring, reduced need for surgery and/or grafting, and improved morbidity and mortality^{3,4}



❖ Surgical Eschar Removal Can Cause Loss of Healthy Tissue

- Surgical eschar removal is non-selective and causes considerable pain, blood loss, and unnecessary excision of healthy tissue⁵



❖ Current Non-Surgical Options Lack Efficacy

- Current non-surgical options have limited efficacy, have not shown a statistically significant reduction in the need for surgical eschar removal, and require multiple dressing changes^{6,7}

NexoBrid

Indications and Usage:

Contains proteolytic enzymes and is indicated for eschar removal in adults with deep partial-thickness and/or full-thickness thermal burns

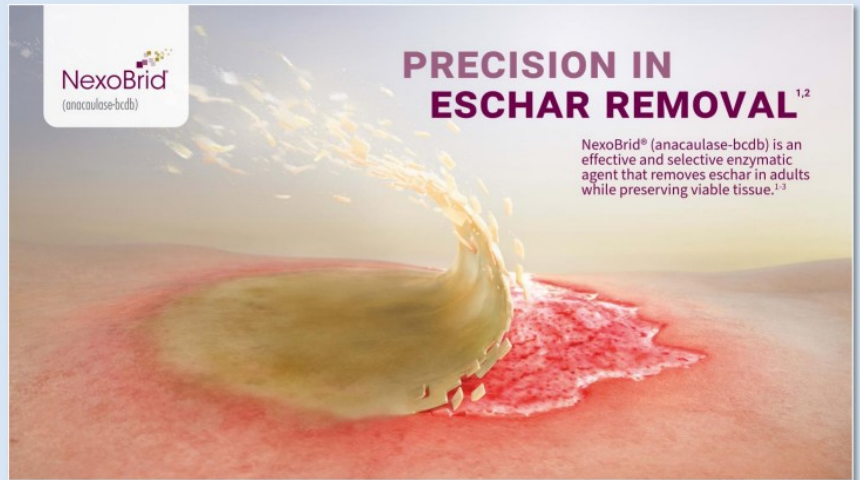
NexoBrid can be applied to up to 20% body surface area in two applications



NexoBrid[®]
(anacaulase-bcdb)

NexoBrid is Now Approved for Use in the United States

- ❖ Concentrated mixture of proteolytic enzymes derived from the stem of the pineapple plant (*Ananas comosus*)
- ❖ Non-surgical topical agent that may be applied at the patient's bedside
- ❖ Selectively degrades eschar in four hours while preserving viable tissue



¹ NexoBrid Label. Cambridge, MA. Verice Corporation; 2022.

² Krieger Y, Bogdanov-Berezovsky A, Gurfinkel R, et al. Efficacy of enzymatic debridement of deeply burned hands. Burns. 2012;38:108-112.

³ Palao R, Aguilera-Saez J, Collado JM, et al. Use of a selective enzymatic debridement agent (NexoBrid) for wound management: Learning curve. World J Dermatol. 2017;6(2):32-41.

NexoBrid Treatment Application

Clean Wound



Antibacterial Pre-Soak



NexoBrid Application



Film Dressing (4 Hours)



Remove Eschar



NexoBrid
(anacaulase-bc**db**)

Images are for illustration and demonstration purposes only; patients will experience individualized results from the use of NexoBrid to treat severe thermal burns.

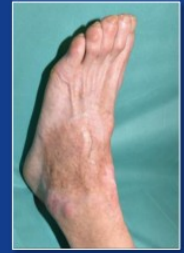
NexoBrid Treatment Results



Before



After



Long-Term



NexoBrid
(anacaulase-bcdeb)

Images are for illustration and demonstration purposes only; patients will experience individualized results from the use of NexoBrid to treat severe thermal burns.

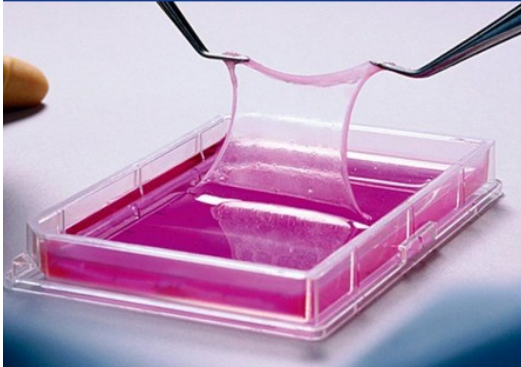
NexoBrid Commercialization

- ❖ NexoBrid is expected to be commercially available in the U.S. in Q2 2023
- ❖ Key commercial activities underway
 - Promotional Materials Rollout
 - P&T Committee Engagement
 - Customer Training
 - Burn Conference Activities
 - Sales Team Deployment & Training



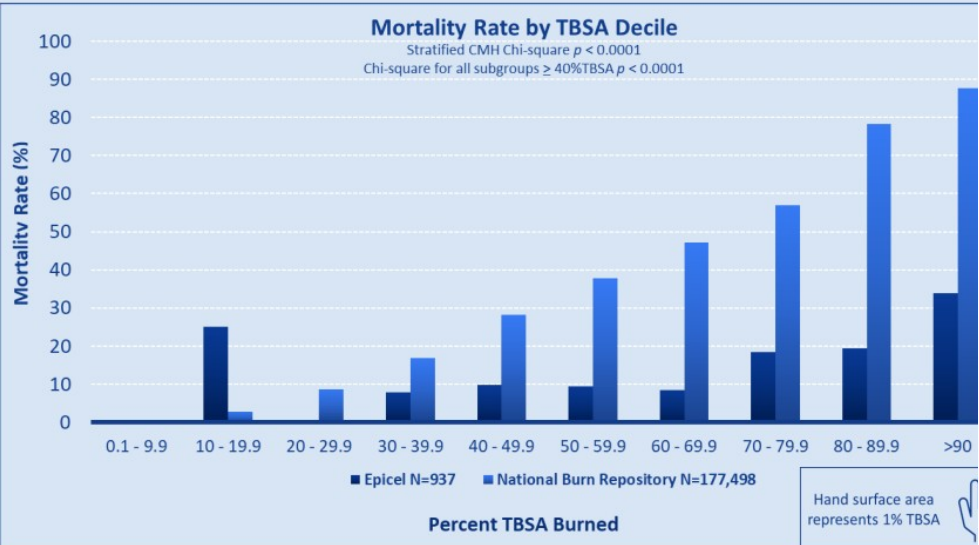
Epicel

- ❖ Only FDA-approved permanent skin replacement for adult and pediatric patients with full-thickness burns $\geq 30\%$ of total body surface area
- ❖ Important treatment option for severe burn patients where little skin is available for autografts



Epicel
(cultured epidermal autografts)

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



Twenty-five Years' Experience and Beyond with Cultured Epidermal Autografts (CEA) for Coverage of Large Burn Wounds in Adult and Pediatric Patients, 1989-2015; Hickerson, Journal of Burn Care & Research, iry061, <https://doi.org/10.1093/jbcr/iry061>.

¹ American Burn Association, National Burn Repository 2016, Version 12.

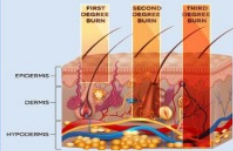
VericeL Remains Focused on Potential Strategic Transactions to Maximize Long-Term Value

ADVANCED CELL THERAPY DEVELOPMENT & MANUFACTURING PLATFORM

Sports Medicine Franchise



Severe Burn Care Franchise



EpiceL
(cultured epidermal autografts)

NexoBrid
(anacaulase-bcclb)

New Advanced Cell Therapy Vertical(s)



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

Growth Strategy Leverages Near-Term & Long-Term Opportunities



Strong Financial Profile

- ❖ Continued strong revenue growth
- ❖ Positive adjusted EBITDA & Operating Cash Flow
- ❖ \$140M in cash and investments



Maximizing MACI Key Growth Drivers

- ❖ 20%+ total revenue CAGR since 2017
- ❖ Focused on maximizing key growth drivers
- ❖ Large underpenetrated TAMs



Advancing Pipeline

- ❖ MACI arthroscopic study planned for 2023, launch expected in 2024
- ❖ Pre-IND meeting for MACI Ankle planned for H1 2023



Expanding Burn Care Franchise

- ❖ NexoBrid approved on December 28, 2022
- ❖ Launch activities underway
- ❖ Commercial availability expected in Q2 2023