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

January 10, 2023

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., Jan. 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-bcdb), 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.

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,” “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. 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.

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