Vericel Reports Third Quarter 2023 Financial Results and Raises Full-Year 2023 Financial Guidance

November 8, 2023 at 7:55 AM EST

Record Third Quarter Revenue of $45.6 Million, Representing 18% Growth versus Prior Year

MACI Revenue Growth of 21% to $37.6 Million

Full-Year 2023 Revenue Guidance Raised to $192.5-197.5 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today reported financial results and business highlights for the third quarter ended September 30, 2023.

Third Quarter 2023 Financial Highlights

- Total net revenue of $45.6 million
- MACI® net revenue of $37.6 million, Epicel® net revenue of $7.4 million and NexoBrid® net revenue of $0.6 million
- Gross margin of 67%
- Net loss of $3.7 million, or $0.08 per diluted share
- Non-GAAP adjusted EBITDA of $5.4 million
- Operating cash flow of $7.2 million
- As of September 30, 2023, the Company had approximately $149 million in cash, restricted cash and investments, and no debt

Business Highlights and Updates

- Record third quarter total revenue, representing 18% growth versus the prior year
- Year-to-date total revenue increased 19% to $132.5 million
- MACI third-quarter revenue growth of 21%, marking the fifth straight quarter of 20%+ growth
- 13th straight quarter of positive adjusted EBITDA and operating cash flow, with adjusted EBITDA growth of 64% versus the prior year
- Record third-quarter highs for MACI biopsies and the number of surgeons taking biopsies
- Completed human factors validation study for MACI arthroscopic delivery program during the third quarter, with commercial launch anticipated in the first half of 2024
- Announced U.S. commercial availability of NexoBrid, significantly expanding the total addressable market for Vericel Burn Care
- Announced publication of positive results from NexoBrid Phase 3 DETECT study in the *Journal of Burn Care & Research*, demonstrating that treatment with NexoBrid resulted in early complete eschar removal in more than 90% of treated burn patients and reduced the need for surgical excision compared to Gel Vehicle and standard of care

“The Company continued to execute well in the third quarter, delivering strong financial results and achieving significant milestones, and as a result we are once again raising our full-year 2023 revenue guidance,” said Nick Colangelo, President and CEO of Vericel. “We believe that we are very well-positioned for a strong close to the year and to generate even stronger financial results in 2024 as we expect higher revenue growth next year driven by continued strength in our core business and contributions from NexoBrid and arthroscopic MACI, as well as significant margin expansion driven by sustained strong revenue growth.”

2023 Financial Guidance

- Total net revenue for 2023 now expected to be in the range of $192.5 to $197.5 million, compared to the previous guidance of $190 to $197 million
- Maintaining profitability guidance of gross margin in the high-60% range and adjusted EBITDA margin in the mid-teens % range

Third Quarter 2023 Results

Total net revenue for the quarter ended September 30, 2023 increased 18% to $45.6 million, compared to $38.6 million in the third quarter of 2022. Total net product revenue for the quarter included $37.6 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue, $7.4 million of Epicel (cultured epidermal autografts) net revenue, and $0.6 million of NexoBrid (anacaulase-bcdb) net revenue compared to $31.0 million of MACI net revenue, $7.3 million of Epicel net revenue, and $0.2 million of NexoBrid net revenue, respectively, in the third quarter of 2022.

Gross profit for the quarter ended September 30, 2023 was $30.6 million, or 67% of net revenue, compared to $25.2 million, or 65% of net revenue, for the third quarter of 2022.

Total operating expenses for the quarter ended September 30, 2023 were $35.7 million, compared to $32.0 million for the same period in 2022. The increase in operating expenses was primarily due to higher sales and marketing expenses and research and development program costs.

Net loss for the quarter ended September 30, 2023 was $3.7 million, or $0.08 per diluted share, compared to $6.6 million, or $0.14 per diluted share, for the third quarter of 2022.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2023 was $5.4 million, or 12% of net revenue, compared to $3.3 million, or 9% of net revenue, for the third quarter of 2022. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2023, the Company had approximately $149 million in cash, restricted cash and investments, and no debt.

Conference Call Information
Today's conference call will be available live at 8:30am Eastern Time and can be accessed through the Investor Relations section of the Vericel website at http://investors.vcel.com/events-presentations. A slide presentation with highlights from today's conference call will be available on the webcast and in the Investor Relations section of the Vericel website. Please access the site at least 15 minutes prior to the scheduled start time in order to download the required audio software, if necessary. To participate by telephone, please register here to receive dial-in details and your personal passcode. A replay of the webcast will be available on the Vericel website until November 8, 2024.

About Vericel Corporation
Vericel is a leader in advanced therapies for the sports medicine and severe burn care markets. The Company markets two cell therapy products and one specialty biologic product 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. The Company also holds an exclusive license for North American rights to NexoBrid® (anacaulase-bcdb), a biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adults with deep partial-thickness and/or full-thickness burns. For more information, please visit www.vcel.com.

GAAP v. Non-GAAP Measures
Vericel's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission (SEC). Vericel has provided in this release certain financial information that has not been prepared in accordance with GAAP. Vericel's management believes that the non-GAAP adjusted EBITDA described in the release, 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 Vericel's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in Vericel's industry. However, the non-GAAP financial measures that Vericel 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.

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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 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 continue to scale our manufacturing operations to meet the demand for our cell therapy products, including the timely completion of a new headquarters and manufacturing facility in Burlington, Massachusetts, 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, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.'s ability to manufacture and supply NexoBrid to meet customer demand, including but not limited to the ongoing Israel-Hamas war, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine and the Israel-Hamas war, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and potential future impacts on our business or the economy generally stemming from a resurgence of COVID-19 or another similar public health emergency.

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, 2022, filed with the Securities and Exchange Commission (SEC) on February 23, 2023, Vericel's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 8, 2023, 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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VERICEL CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts - unaudited)

	Three Months Ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Product sales, net	$ 45,581	$ 38,326	$ 132,520	$ 111,004
Other revenue	—	225	—	667
Total revenue	45,581	38,551	132,520	111,671
Cost of product sales	14,973	13,318	45,451	40,132
Gross profit	30,608	25,233	87,069	71,539
Research and development	5,676	5,046	16,141	14,698
Selling, general and administrative	29,989	26,975	90,123	79,984
Total operating expenses	35,665	32,021	106,264	94,682
Loss from operations	(5,057)	(6,788)	(19,195)	(23,143)
Other income (expense):				
Interest income	1,262	342	3,196	578
Interest expense	(150)	(105)	(444)	(143)
Other (expense) income	(1)	(5)	(18)	98
Total other income	1,111	232	2,734	533
Loss before income taxes	(3,946)	(6,556)	(16,461)	(22,610)
Income tax (benefit) expense	(286)	21	(286)	21
Net loss	$ (3,660)	$ (6,577)	$ (16,175)	$ (22,631)
Net loss per common share:				
Basic and diluted	$ (0.08)	$ (0.14)	$ (0.34)	$ (0.48)
Weighted-average common shares outstanding:				
Basic and diluted	47,649	47,182	47,537	47,096

VERICEL CORPORATION
RECONCILIATION OF REPORTED NET LOSS (GAAP)
TO ADJUSTED EBITDA (NON-GAAP MEASURE)
(in thousands - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (3,660)	$ (6,577)	$ (16,175)	$ (22,631)
Stock-based compensation expense	7,924	9,104	25,416	29,443
Depreciation and amortization	1,154	1,014	3,483	2,942
Net interest income	(1,112)	(237)	(2,752)	(435)
Income tax (benefit) expense	(286)	21	(286)	21
Pre-occupancy lease expense	1,424	—	1,899	—
Adjusted EBITDA (Non-GAAP)	$ 5,444	$ 3,325	$ 11,585	$ 9,340

VERICEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands - unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,473	$ 51,067
Restricted cash	23,088	—
Short-term investments	44,870	68,471

Accounts receivable (net of allowance for doubtful accounts of $44 and $47, respectively)	39,729	46,539
Inventory	12,621	15,986
Other current assets	5,430	4,803
Total current assets	186,211	186,866
Property and equipment, net	30,216	15,837
Intangible assets, net	7,031	7,500
Right-of-use assets	73,294	41,535
Long-term investments	20,231	19,962
Other long-term assets	1,142	1,303
Total assets	$ 318,125	$ 273,003
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,051	$ 16,930
Accrued expenses	13,628	16,190
Current portion of operating lease liabilities	7,267	4,302
Other current liabilities	—	41
Total current liabilities	35,946	37,463
Operating lease liabilities	77,734	43,268
Other long-term liabilities	65	—
Total liabilities	$ 113,745	$ 80,731
Total shareholders' equity	204,380	192,272
Total liabilities and shareholders' equity	$ 318,125	$ 273,003