Vericel Reports Third Quarter 2024 Financial Results

November 7, 2024 at 7:55 AM EST

Total Revenue Growth of 27% to $57.9 Million

Gross Margin of 72% and Adjusted EBITDA Growth of 84%

Full-Year Profitability Guidance Raised

FDA Approval and Commercial Launch of MACI Arthro in Third Quarter

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., Nov. 07, 2024 (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, 2024.

Third Quarter 2024 Financial Highlights

- Total net revenue of $57.9 million
- MACI® net revenue growth of 19% to $44.7 million
- Burn Care net revenue growth of 66% to $13.2 million, consisting of $12.2 million of Epicel® revenue and $1.1 million of NexoBrid® revenue
- Gross margin of 72%, an increase of 480 basis points versus the prior year
- Net loss of $0.9 million, or $0.02 per diluted share
- Non-GAAP adjusted EBITDA increased 84% to $10.0 million, representing adjusted EBITDA margin of 17%, an increase of 540 basis points versus the prior year
- Operating cash flow of $10.2 million
- As of September 30, 2024, the Company had approximately $151 million in cash, restricted cash and investments, and no debt

Year to Date 2024 Financial Highlights

- Total net revenue increased 22% to $161.8 million
- MACI net revenue growth of 19% to $129.0 million
- Burn Care net revenue growth of 35% to $32.9 million
- Gross margin of 70%, an increase of 450 basis points versus the prior year
- Net loss of $9.4 million, or $0.19 per diluted share
- Non-GAAP adjusted EBITDA increased 103% to $23.6 million, representing adjusted EBITDA margin of 15%, an increase of 580 basis points versus the prior year
- Operating cash flow of $36 million

Business Highlights and Updates

- Record third quarter total revenue and MACI revenue, and the highest quarterly Epicel revenue to date
- Record third quarter highs for MACI biopsies and the number of surgeons taking biopsies
- More than 70 NexoBrid Pharmacy and Therapeutics (P&T) committee submissions, with approximately 50 burn centers obtaining P&T committee approval and placing initial orders
- Announced FDA approval of MACI Arthro™ to repair symptomatic single or multiple full-thickness cartilage defects of the knee up to 4 cm^2 using Vericel's custom-designed arthroscopic delivery instruments
- On track to submit MACI Ankle™ IND in the first half of 2025 and expect to initiate clinical study in second half of 2025
- Announced FDA approval of a pediatric indication for NexoBrid for eschar removal in pediatric patients with deep partial-thickness and/or full-thickness thermal burns

"The Company had another excellent quarter as we generated strong revenue and profitability growth and achieved two important regulatory milestones with the FDA approval of MACI Arthro and a NexoBrid pediatric indication," said Nick Colangelo, President and CEO of Vericel. "We believe that the Company is very well-positioned to deliver a strong close to the year and to deliver a unique combination of sustained high revenue and profit growth in 2025 and beyond based on the strength of our core portfolio, the recent launch of MACI Arthro and the continued progress on other long-term growth initiatives."

2024 Financial Guidance

- Maintained total net revenue guidance of $238 to $242 million, or 20% to 23% growth

- Profitability guidance raised to 72% gross margin and 22% adjusted EBITDA margin, compared to the previous guidance of 71% and 21%, respectively

Third Quarter 2024 Results
Total net revenue for the quarter ended September 30, 2024 increased 27% to $57.9 million, compared to $45.6 million in the third quarter of 2023. Total net product revenue for the quarter included $44.7 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue, $12.2 million of Epicel (cultured epidermal autografts) net revenue, and $1.1 million of NexoBrid (anacaulase-bcdb) net revenue, compared to $37.6 million of MACI net revenue, $7.4 million of Epicel net revenue, and $0.6 million of NexoBrid net revenue, respectively, in the third quarter of 2023.

Gross profit for the quarter ended September 30, 2024 was $41.7 million, or 72% of net revenue, compared to $30.6 million, or 67% of net revenue, for the third quarter of 2023.

Total operating expenses for the quarter ended September 30, 2024 were $44.1 million, compared to $35.7 million for the same period in 2023. The increase in operating expenses was primarily due to development and commercial launch activities for MACI Arthro and increased headcount and related employee expenses.

Net loss for the quarter ended September 30, 2024 was $0.9 million, or $0.02 per diluted share, compared to $3.7 million, or $0.08 per diluted share, for the third quarter of 2023.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2024 was $10.0 million, or 17% of net revenue, compared to $5.4 million, or 12% of net revenue, for the third quarter of 2023. A table reconciling non-GAAP measures is included in this press release for reference.

As of September 30, 2024, the Company had approximately $151 million in cash, restricted cash and investments, and no debt.

Conference Call Information
Today's conference call will be available live at 8:30 a.m. 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 7, 2025.

About Vericel Corporation

Vericel is a leading provider of advanced therapies for the sports medicine and severe burn care markets. The Company combines innovations in biology with medical technologies, resulting in a highly differentiated portfolio of innovative cell therapies and specialty biologics that repair injuries and restore lives. Vericel markets three 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 and pediatric patients 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. 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 this 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, MACI Arthro, 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 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, surgeon adoption of MACI Arthro, physician and burn center adoption of NexoBrid, labor strikes, changes in surgeon and hospital treatment prioritizations caused by the temporary shortage of essential medical supplies, supply chain disruptions or other events or factors that might affect our ability to manufacture MACI or Epicel or affect MediWound's ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, including but not limited to, damage or disruption caused by natural disasters and the ongoing military conflicts in the Middle East region involving Israel, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East conflicts, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and the potential future impacts on our business or the economy generally stemming from a 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, 2023, filed with the Securities and Exchange Commission (SEC) on February 29, 2024, Vericel's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 7, 2024, 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,	
	2024	2023	2024	2023
Product sales, net	$ 57,905	$ 45,581	$ 161,848	$ 132,520
Total revenue	57,905	45,581	161,848	132,520
Cost of product sales	16,252	14,973	48,240	45,451
Gross profit	41,653	30,608	113,608	87,069
Research and development	6,093	5,676	19,874	16,141
Selling, general and administrative	38,025	29,989	107,694	90,123
Total operating expenses	44,118	35,665	127,568	106,264
Loss from operations	(2,465)	(5,057)	(13,960)	(19,195)
Other income (expense):				
Interest income	1,578	1,262	4,850	3,196
Interest expense	(154)	(150)	(460)	(444)
Other income (expense)	140	(1)	125	(18)
Total other income	1,564	1,111	4,515	2,734
Loss before income taxes	(901)	(3,946)	(9,445)	(16,461)
Income tax benefit	—	(286)	—	(286)
Net loss	$ (901)	$ (3,660)	$ (9,445)	$ (16,175)
Net loss per common share:				
Basic and diluted	$ (0.02)	$ (0.08)	$ (0.19)	$ (0.34)
Weighted-average common shares outstanding:				
Basic and diluted	49,085	47,649	48,639	47,537

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,	
	2024	2023	2024	2023
Net loss	$ (901)	$ (3,660)	$ (9,445)	$ (16,175)
Stock-based compensation expense	9,224	7,924	28,578	25,416
Depreciation and amortization	1,326	1,154	4,027	3,483
Net interest income	(1,424)	(1,112)	(4,390)	(2,752)

Income tax benefit	—	(286)	—	(286)
Pre-occupancy lease expense	1,815	1,424	4,801	1,899
Adjusted EBITDA (Non-GAAP)	$ 10,040	$ 5,444	$ 23,571	$ 11,585

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,681	$ 69,088
Restricted cash	16,669	17,778
Short-term investments	48,053	40,469
Accounts receivable (net of allowance for doubtful accounts of $12 and $43, respectively)	48,479	58,356
Inventory	15,756	13,087
Other current assets	7,882	6,853
Total current assets	190,520	205,631
Property and equipment, net	88,413	41,635
Intangible assets, net	6,406	6,875
Right-of-use assets	71,561	73,462
Long-term investments	32,895	25,283
Other long-term assets	610	771
Total assets	$ 390,405	$ 353,657
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 20,884	$ 22,347
Accrued expenses	14,343	17,215
Current portion of operating lease liabilities	6,119	6,187
Total current liabilities	41,346	45,749
Operating lease liabilities	91,344	81,856
Other long-term liabilities	243	100
Total liabilities	132,933	127,705
Total shareholders' equity	257,472	225,952
Total liabilities and shareholders' equity	$ 390,405	$ 353,657