Vericel Reports Second Quarter 2022 Financial Results

August 3, 2022

Second Quarter Total Net Revenue of $37.0 Million

MACI Net Revenue of $28.6 Million

Conference Call Today at 8:30am Eastern Time

CAMBRIDGE, Mass., Aug. 03, 2022 (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 second quarter ended June 30, 2022.

Second Quarter 2022 Financial Highlights

- Total net revenue of $37.0 million
- MACI® net revenue of $28.6 million, Epicel® net revenue of $8.2 million, and NexoBrid® revenue of $0.2 million
- Gross margin of 62%
- Net loss of $9.0 million, or $0.19 per share
- Non-GAAP adjusted EBITDA of $2.8 million
- Operating cash flow of $3.1 million
- As of June 30, 2022, approximately $131 million in cash, restricted cash and investments, and no debt

Business Highlights and Updates

- Second-quarter MACI revenue growth of 8% compared to the prior year and 10% sequential growth versus the prior quarter, representing the highest quarterly revenue outside of the seasonally-high fourth quarter since the launch of MACI
- NexoBrid BLA resubmission accepted for review by the FDA, with a Prescription Drug User Fee Act date of January 1, 2023
- Announced publication in the *Journal of Burn Care & Research* of results from a retrospective study conducted by the Burn and Reconstructive Centers of America showing a 90% survival rate for patients with large posterior burns treated with Epicel
- Data from a recently published MACI study featured in *Orthopedics Today*, highlighting the expansion of knee cartilage defects and the formation of new high-grade lesions in patients as time between cartilage biopsy and implantation increases
- Entered into a $150 million revolving credit facility with a syndicate of banks led by J.P. Morgan Chase Bank, N.A.
- Issued Vericel's inaugural Environmental, Social, and Governance report, highlighting the Company's commitment to incorporating these important principles across all of its business activities

"The Company delivered another solid quarter as we generated strong revenue for MACI and achieved our eighth consecutive quarter with positive adjusted EBITDA and operating cash flow," said Nick Colangelo, President and CEO of Vericel. "We expect MACI growth to accelerate through the remainder of the year, with continued strong quarterly revenue progression and significantly higher quarterly growth rates compared to last year. We also are very pleased to announce that the FDA has accepted the NexoBrid BLA resubmission for review and we look forward to the potential approval of this important product, which we believe could set a new standard of care for eschar removal in patients with severe burns in the United States."

Full-Year 2022 Financial Guidance Update

- Total revenue guidance maintained at $178 to $189 million
- MACI revenue guidance maintained at $132 to $141 million
- Gross margin now expected to be approximately 69%, offset by lower operating expenses
- Adjusted EBITDA margin maintained at approximately 21%

Second Quarter 2022 Results

Total net revenue for the quarter ended June 30, 2022 was $37.0 million, compared to $39.5 million in the second quarter of 2021. Total net product revenue for the quarter included $28.6 million of MACI (autologous cultured chondrocytes on porcine collagen membrane) net revenue and $8.2 million of Epicel (cultured epidermal autografts) net revenue, compared to $26.5 million of MACI net revenue and $12.2 million of Epicel net revenue, respectively, in the second quarter of 2021. Total net revenue for the quarter also included $0.2 million of revenue related to the procurement of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) by the U.S. Biomedical Advanced Research and Development Authority (BARDA) for emergency response preparedness, compared to $0.8 million in the second quarter of 2021.

Gross profit for the quarter ended June 30, 2022 was $22.9 million, or 62% of net revenue, compared to $26.9 million, or 68% of net revenue, for the second quarter of 2021.

Total operating expenses for the quarter ended June 30, 2022 were $31.9 million, compared to $30.6 million for the same period in 2021.

Net loss for the quarter ended June 30, 2022 was $9.0 million, or $0.19 per share, compared to a net loss of $3.8 million, or $0.08 per share, for the second quarter of 2021.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2022 was $2.8 million, or 7% of net revenue, compared to $7.8 million, or 20% of net revenue, for the second quarter of 2021. A table reconciling non-GAAP measures is included in this press release for reference.

As of June 30, 2022, the Company had approximately $131 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 August 3, 2023.

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 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, a registration-stage biological orphan product for debridement of severe thermal burns. For more information, please visit the Company's website at 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 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.

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 and Epicel, 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, likelihood of the FDA's potential approval of the NexoBrid BLA resubmission seeking approval for the treatment of severe burns in the United States, 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, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and the ongoing impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to COVID-19, we are currently unable to predict whether a future resurgence of COVID-19 infections will result in future restrictions on the performance of elective surgical procedures or affect the availability of physicians and/or their treatment prioritizations, cause healthcare facility staffing shortages, effect the willingness or ability of patients to seek treatment, or heighten the impact of the pandemic on the overall healthcare infrastructure. 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 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 times to regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections of manufacturing facilities involved in the production of NexoBrid, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. The total impact of these disruptions could have a material impact on the Company's financial condition, cash flows and results of operations.

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 June 30, 2022, filed with the SEC on August 3, 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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VERICEL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands, except per share amounts)

	Three Months Ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Product sales, net	$ 36,826	$ 38,680	$ 72,678	$ 72,307
Other revenue	220	839	442	1,780
Total revenue	37,046	39,519	73,120	74,087
Cost of product sales	14,192	12,609	26,814	24,192
Gross profit	22,854	26,910	46,306	49,895
Research and development	4,792	4,449	9,652	8,079
Selling, general and administrative	27,144	26,190	53,009	48,850
Total operating expenses	31,936	30,639	62,661	56,929
Loss from operations	(9,082)	(3,729)	(16,355)	(7,034)
Other income (expense):				
Interest income	148	43	236	119
Interest expense	(20)	(1)	(38)	(2)
Other income (expense)	(9)	(27)	103	57
Total other income	119	15	301	174
Loss before income taxes	(8,963)	(3,714)	(16,054)	(6,860)
Income tax expense	—	72	—	215
Net loss	$ (8,963)	$ (3,786)	$ (16,054)	$ (7,075)
Net loss per common share:				
Basic	$ (0.19)	$ (0.08)	$ (0.34)	$ (0.15)
Diluted	$ (0.19)	$ (0.08)	$ (0.34)	$ (0.15)
Weighted-average common shares outstanding:				
Basic	47,117	46,403	47,052	46,195
Diluted	47,117	46,403	47,052	46,195

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RECONCILIATION OF REPORTED NET LOSS (GAAP)
TO ADJUSTED EBITDA (NON-GAAP MEASURE)
(Unaudited, amounts in thousands)

	Three Months Ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Net loss	$ (8,963)	$ (3,786)	$ (16,054)	$ (7,075)
Stock-based compensation expense	10,808	10,866	20,339	17,885
Depreciation and amortization	1,055	695	1,928	1,506
Net interest income	(128)	(42)	(198)	(117)
Income tax expense	—	72	—	215
Adjusted EBITDA (Non-GAAP)	$ 2,772	$ 7,805	$ 6,015	$ 12,414

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CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands)

	June 30,	December 31,

	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,054	$ 68,330
Short-term investments	44,638	35,068
Accounts receivable (net of allowance for doubtful accounts of $40 and $40, respectively)	33,664	37,437
Inventory	15,929	13,381
Other current assets	4,809	4,246
Total current assets	155,094	158,462
Property and equipment, net	15,919	13,308
Restricted cash	6,184	211
Right-of-use assets	43,583	45,720
Long-term investments	23,718	25,687
Other long-term assets	317	317
Total assets	$ 244,815	$ 243,705
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,684	$ 9,016
Accrued expenses	12,133	14,045
Current portion of operating lease liabilities	3,156	2,950
Other current liabilities	41	41
Total current liabilities	25,014	26,052
Operating lease liabilities	44,964	47,147
Other long-term liabilities	21	44
Total liabilities	69,999	73,243
Total shareholders' equity	174,816	170,462
Total liabilities and shareholders' equity	$ 244,815	$ 243,705