AVITA Medical Reports Second Quarter Financial Results

August 8, 2024

VALENCIA, Calif., Aug. 08, 2024 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a commercial-stage regenerative medicine company focused on first-in-class devices for wound care management and skin restoration, today reported financial results for the second quarter ended June 30, 2024.

Financial Results and Recent Business Updates

- Commercial revenue of $15.1 million, an increase of approximately 29% compared to the same period in 2023
- Gross profit margin of 86.2%
- RECELL GO ™ premarket approval (PMA) supplement approved by the FDA on May 29, 2024; first case completed on May 31, 2024
- Submitted PMA supplement for RECELL GO mini ™, designed to address smaller wounds, on June 28, 2024; maintains Breakthrough Device designation ensuring a prioritized 180-day interactive review period
- Entered into an exclusive development and distribution agreement with Regenity Biosciences ("Regenity") providing AVITA Medical with the commercialization rights to a unique collagen-based dermal matrix following 510(k) clearance

“Our second-quarter commercial revenue reached a record $15.1 million, reflecting the effectiveness of our enhanced focus on commercial execution,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “The FDA approval of RECELL GO and our recent submission of RECELL GO mini highlight our progress in expanding treatment capabilities for burn and full-thickness skin defects. Additionally, our agreement with Regenity further enhances our ability to address a full spectrum of clinical needs. We remain committed to establishing RECELL as the standard of care for wound therapy while continuing to transform AVITA Medical into a broad-based wound care company, ultimately improving accessibility and reaching more patients.”

Future Milestones

- Expect Regenity to receive 510(k) clearance for the dermal matrix in the fourth quarter of 2024; following clearance, AVITA Medical will begin to market, sell, and distribute
- Plan to initiate multiple post-market clinical studies to establish the unique synergies between the new dermal matrix and RECELL
- Anticipate FDA approval of RECELL GO mini by December 27, 2024
- Expect to submit both our post-market study (TONE) treating patients with stable vitiligo and separate health care economics study for publication by year-end

Financial Guidance

- Commercial revenue for the third quarter 2024 is expected to be in the range of $19.0 to $20.0 million, reflecting growth of approximately 40% to 48% over the same period in 2023
- Commercial revenue for the full-year 2024 is now expected to be in the range of $68.0 to $70.0 million, reflecting growth of approximately 37% to 41% over the full-year 2023
- Expect to achieve previously given guidance of cashflow break even and GAAP profitability no later than the end of the third quarter of 2025

“We anticipate sequential third-quarter commercial revenue growth between 26% to 32% over the second quarter,” said David O'Toole, Chief Financial Officer of AVITA Medical. “Following our solid second quarter and a strong start in July, we are confident in our commercial team's ability to achieve this goal. However, we have adjusted downward our full-year revenue guidance, which still reflects a growth rate of over 37% year-over-year and our ongoing growth trajectory. With positive new developments, including the launch of RECELL GO and PermeaDerm, as well as the anticipated launch

of our new dermal matrix, we intend to build on our second-quarter momentum and continue delivering strong results."

Second Quarter 2024 Financial Results

Total revenues increased by 29.3%, or $3.4 million, to $15.2 million, compared to $11.8 million in the same period in the prior year. Our commercial revenue was $15.1 million in the three-months ended June 30, 2024, an increase of $3.4 million, or 29.5%, compared to $11.7 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within existing customer accounts and new accounts for full-thickness skin defect**.**

Gross profit margin was 86.2% compared to 81.2%, representing an increase of 500 bps from the corresponding period in the prior year. This was largely driven by increases in revenues and the volume of production.

BARDA income decreased to zero, compared to $0.5 million in the corresponding period in the prior year due to the ending of reimbursable clinical trials. BARDA income in the prior year consisted of funding from the Biomedical Advanced Research and Development Authority, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

Total operating expenses for the quarter were $28.7 million, compared to $21.2 million in the same period in 2023. The increase in operating expenses is primarily attributable to an increase of $6.3 million in sales and marketing expenses due to employee-related costs, including salaries and benefits, commissions, professional fees, and travel expenses, collectively, as a result of the expansion of our commercial organization to support our growing commercial operations in the second quarter of 2023 and again in first quarter of 2024. G&A expenses increased by $1.4 million as a result of higher salaries and benefits, severance benefits, partially offset by lower deferred compensation expenses and lower professional fees. In addition, operating expenses were offset by a decrease of $0.2 million in R&D costs, which was primarily due to a decrease in professional fees and development expenses.

Interest expense increased approximately $1.3 million in comparison to the same period in the prior year due to the interest expense related to the long-term debt incurred as part of the OrbiMed Credit Agreement, for a principal amount owed of $40.0 million.

Other income, net increased by $0.8 million to income of $1.6 million. In the current period other income consists of income of $2.1 million related to the change in fair value of warrant liability, $0.7 million in income related to our investments. Income was offset by a non-cash charge of $1.2 million due to the change in fair value of the debt. The prior period income consisted of $0.7 million related to our investments and $0.1 million in gains.

Net loss was $15.4 million, or a loss of $0.60 per basic and diluted share, compared to a net loss of 10.4 million, or a loss of $0.41 per basic and diluted share, in the same period in 2023.

As of June 30, 2024, the Company had approximately $54.1 million in cash, cash equivalents, and marketable securities.

Webcast and Conference Call Information

AVITA Medical will host a conference call on Thursday, August 8, 2024 at 1:30 p.m. Pacific Time (Friday, August 9, 2024, at 6:30 a.m. Australian Eastern Standard Time) to discuss its financial results and recent business highlights. To participate by telephone, please register in advance to receive dial-in details and a personal PIN at https://register.vevent.com/register/BI460b032551fb410185009f5eac59ddac. The live webcast will be accessible through the Events section of AVITA Medical's Investor Relations website at ir.avitamedical.com. A replay of the webcast will be available shortly after the live event.

About AVITA Medical, Inc.

AVITA Medical® is a commercial-stage regenerative medicine company transforming the standard of care in wound care management and skin restoration with innovative devices. At the forefront of our platform is the RECELL® System, approved by the Food and Drug Administration for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create Spray-On Skin ™ Cells, delivering a transformative solution at the point-of-care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States.

In international markets, the RECELL System is approved to promote skin healing in a wide range of applications including burns, full-thickness skin defects, and vitiligo. The RECELL System is TGA-registered in Australia, has received CE-mark approval in Europe, and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to significant risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements generally may be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," and similar words or expressions, and the use of future dates. Forward-looking statements include, but are not limited to, statements relating to the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the Company's control. These statements are made as of the date of this release, and the Company undertakes no obligation to publicly update or revise any of these statements, except as required by law. For additional information and other important factors that may cause actual results to differ materially from forward-looking statements, please see the "Risk Factors" section of the Company's latest Annual Report on Form 10-K and other publicly available filings for a discussion of these and other risks and uncertainties.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

AVITA MEDICAL, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	As of

	June 30, 2024	December 31, 2023
ASSETS		
Cash and cash equivalents	$ 17,452	$ 22,118
Marketable securities	36,604	66,939
Accounts receivable, net	8,717	7,664
BARDA receivables	94	30
Prepaids and other current assets	3,382	1,659
Inventory	6,709	5,596
Total current assets	72,958	104,006
Plant and equipment, net	7,024	1,877
Operating lease right-of-use assets	3,938	2,440
Corporate-owned life insurance ("COLI") asset	2,888	2,475
Intangible assets, net	545	487
Other long-term assets	473	355
Total assets	$ 87,826	$ 111,640
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	4,155	3,793
Accrued wages and fringe benefits	7,624	7,972
Current non-qualified deferred compensation ("NQDC") liability	753	168
Other current liabilities	1,255	1,266
Total current liabilities	13,787	13,199
Long-term debt	40,989	39,812
Non-qualified deferred compensation liability	3,148	3,663
Contract liabilities	340	357
Operating lease liabilities, long term	3,281	1,702
Warrant liability	1,968	3,158
Total liabilities	63,513	61,891
Non-qualified deferred compensation plan share awards	398	693
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,949,906 and 25,682,078, shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2024 and December 31, 2023	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,022)	(1,130)
Additional paid-in capital	358,510	350,039
Accumulated other comprehensive loss	(1,556)	(1,887)
Accumulated deficit	(332,020)	(297,969)
Total stockholders' equity	23,915	49,056
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 87,826	$ 111,640

AVITA MEDICAL, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three-Months Ended		Six-Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Sales revenue	$ 15,183	$ 11,753	$ 26,287	$ 22,303
Lease revenue	12	-	12	-
Total revenues	15,195	11,753	26,299	22,303
Cost of sales	(2,111)	(2,204)	(3,624)	(3,871)
Gross profit	13,084	9,549	22,675	18,432
BARDA income	-	530	-	1,157
Operating expenses:				
Sales and marketing	(16,302)	(10,003)	(28,942)	(16,543)
General and administrative	(7,519)	(6,165)	(16,481)	(14,460)
Research and development	(4,887)	(5,076)	(10,081)	(9,662)
Total operating expenses	(28,708)	(21,244)	(55,504)	(40,665)
Operating loss	(15,624)	(11,165)	(32,829)	(21,076)
Interest expense	(1,347)	(7)	(2,703)	(11)
Other income, net	1,611	801	1,544	1,526

Loss before income taxes	(15,360)	(10,371)	(33,988)	(19,561)
Income tax expense	(33)	(13)	(63)	(43)
Net loss	$ (15,393)	$ (10,384)	$ (34,051)	$ (19,604)
Net loss per common share:				
Basic and diluted	$ (0.60)	$ (0.41)	$ (1.32)	$ (0.78)
Weighted-average common shares:				
Basic and diluted	25,760,278	25,239,723	25,699,030	25,221,009

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