AVITA Medical Reports Second Quarter 2025 Financial Results, Updates Full-Year Guidance, and Highlights Continued Clinical Innovation

VALENCIA, Calif., August 7, 2025 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a leading therapeutic acute wound care company delivering transformative solutions, today reported financial results for the second quarter ended June 30, 2025.

Financial Results

- **Commercial revenue of $18.4 million:** Representing an increase of approximately 21% compared to the same period in 2024.
- **Net loss improvement:** Net loss for Q2 2025 was $9.9 million, or a loss of $0.38 per basic and diluted share, an improvement from a net loss of $15.4 million, or a loss of $0.60 per basic and diluted share, in Q2 2024.
- **Operating expense reduction:** Total operating expenses decreased to $26.1 million in Q2 2025 from $28.7 million in Q2 2024.

Business Update

- **Significant headwind from a temporary gap in Medicare Administrative Contractor (MAC) payments** to providers for the use of our flagship RECELL® System, which led to a weakening in demand. Multiple MACs initiated payments in July with resolution expected in Q3.
- **AVITA amends credit terms with OrbiMed**: lowers revenue covenants, issues AVITA common stock in lieu of a cash payment.
- **Strengthening Board with proven healthcare leader:** Appointed Michael Tarnoff, MD, FACS, former Chief Physician Executive and CEO of Tufts Medical Center in Boston, and senior executive at Medtronic and Covidien, to its Board of Directors.

Clinical Highlights

- **RECELL** reduces hospital stays by 36% in real-world analysis of the national burn registry over five years.
- The Centers for Medicare and Medicaid Services (CMS) approves **New Technology Add-on Payment (NTAP)** for the **RECELL System** when performed on trauma wounds in the hospital inpatient setting.
- **Cohealyx™** achieves autograft readiness in as little as five days, first clinical results published.
- **PermeaDerm®** featured in 10 U.S. burn conferences, including first multi-center randomized controlled trial**.**

Jim Corbett, Chief Executive Officer of AVITA Medical, commented: “Although the first half of 2025 tested our resilience and slowed our pace, a resolution is now underway and our strategic direction hasn’t changed. The data tells the story: RECELL reduces hospital stays by 36%, Cohealyx achieves graft readiness in as little as five days. We’re also grateful for CMS’s support in expanding access to RECELL for Medicare beneficiaries with inpatient trauma wounds with the NTAP. We’re accelerating time to heal, time to recover, and time to deliver value, to patients and providers alike.”

Business update: Delay in provider payment dampened RECELL demand in the first half of 2025

In November 2024, the Centers for Medicare and Medicaid Services (CMS) announced new Category I CPT codes for the use of RECELL as part of its 2025 rule update. Unlike the standard process, CMS did not assign a national payment rate. Instead, it assigned pricing responsibility to the Medicare Administrative Contractors (MACs) under a process known as contractor pricing, an approach CMS occasionally uses when initiating long-term code changes.

Following the implementation of the new codes, claims for the use of RECELL were submitted starting in January 2025. Under the contractor pricing model, it is the MACs' responsibility to adjudicate claims by either assigning a payment rate and reimbursing the claim, or denying the claim, which would allow the provider to appeal and trigger an adjudication through that process. However, in this instance, MACs neither assigned a price or assigned an inadequate price and failed to adjudicate claims in a timely manner. As a result, claims accumulated from January through June, creating a significant backlog of unpaid claims and inadequately paid claims to providers for RECELL procedures. This lack of resolution created uncertainty among providers regarding payment expectations and timelines, which led to a reduction in RECELL utilization during the first half of the year.

While AVITA continued receiving payment for RECELL, this provider reimbursement issue constrained demand, meaningfully impacting revenue. For example, across AVITA's top ten hospital accounts, RECELL revenue declined by approximately $5 million when comparing the second half of 2024 to the first half of 2025. The Company estimates that overall demand for RECELL declined by approximately 20%, with revenue declining by approximately $10 million during this period.

Encouragingly, multi-jurisdictional efforts by the American Medical Association and industry stakeholders have resulted in meaningful progress. In July, multiple MACs have indicated their intent to adjudicate and pay claims under the new codes and the remaining MACs are expected to follow. In light of this development, AVITA anticipates continued resolution of this issue, with RECELL demand recovering in the second half of 2025 as the MACs adjudicate the claims backlog.

As a result of slower than expected sales in the first half, significantly compounded by the ongoing reimbursement issue, AVITA has adjusted its full-year guidance as follows:

- Full-year 2025 revenue guidance to a range of $76 million to $81 million compared to previous guidance of $100 million to $106 million. This new guidance reflects growth of approximately 19% to 27% over full-year 2024 revenue.
- Cash flow break-even in the second quarter of 2026 and GAAP profitability in the third quarter of 2026, instead of the previously anticipated second half of 2025 and fourth quarter of 2025, respectively.

David O'Toole, Chief Financial Officer of AVITA Medical, commented: "While we've revised our 2025 guidance, our long-term outlook remains intact. We're pleased to have OrbiMed's continued partnership and their willingness to accept equity in lieu of a cash fee reflects strong alignment with our long-term strategy and confidence in the value of the business we're building. Regarding gross margin and gross profit, our gross margin percentage will decline, and gross profit will increase as revenue from PermeaDerm and Cohealyx grows. With our disciplined cost structure, together with stronger revenue expected in the second half of the year, we now anticipate reaching cash flow break-even and GAAP profitability in 2026 as reimbursement pathways stabilize and adoption progresses."

Second Quarter 2025 Financial Results

Commercial revenue was $18.4 million in the three-months ended June 30, 2025, an increase of $3.2 million, or 21%, compared to $15.2 million in the corresponding period in the prior year. The growth in commercial revenue was largely driven by deeper penetration within customer accounts, new accounts for trauma wounds and, to a lesser extent, new product launches.

Gross profit margin was 81.2% compared to 86.1% in the corresponding period in the prior year. The gross margin for only RECELL products was 84.3% for the quarter, which the Company expects to remain in this range for future quarters. The decrease in the overall gross margin percentage from the prior year was primarily caused by product mix, higher inventory reserve, and other adjustments. The Company shares the average sales price for Cohealyx at 50% and for PermeaDerm at 60%. Although these arrangements are highly beneficial, they inevitably result in an overall decrease in the gross margin percentage. Therefore, the product mix is expected to continue to have an impact on the overall gross margin percentage while increasing the gross profit and, given that expenses associated with this revenue do not increase significantly, operating profit on a quarterly basis.

Total operating expenses for the quarter were $26.1 million, compared to $28.7 million in the same period in 2024. The decrease is primarily attributable to a $2.0 million reduction in sales and marketing expenses, which resulted from lower employee-related costs such as salaries, benefits and stock-based compensation due to cost reduction initiatives. Additionally, G&A expenses decreased by $0.8 million, also attributable to lower salaries, benefits and stock-based compensation. These decreases were partially offset by increased R&D costs of $0.2 million, because of an increase in headcount. Due to the recent commercial field transformation and additional operational efficiencies that were implemented, the Company expects to continue to reduce operating expenses by approximately $2.5 million per quarter going forward.

Other income, net increased by $0.9 million, resulting in an income of $2.5 million compared to $1.6 million in the prior period. In the current period, other income, net includes non-cash gains of $1.2 million from the change in fair value of warrants, $0.9 million from the change in fair value of debt, and $0.4 million from our investments. In the prior period, income consisted of a non-cash gain of $2.1 million from the change in fair value of warrant liability and $0.7 million from our investments, which was offset by a non-cash charge of $1.2 million due to the change in fair value of the debt.

Net loss was $9.9 million, or a loss of $0.38 per basic and diluted share, compared to a net loss of $15.4 million, or a loss of $0.60 per basic and diluted share, in the same period in 2024.

On June 30, 2025, AVITA received a waiver for the trailing 12-month net revenue covenant under its credit agreement with OrbiMed related to the second quarter of 2025, which had been set at $78.0 million. On August 7, 2025, the Company entered into its fifth amendment to its credit agreement with OrbiMed, revising the trailing 12-month (“TTM”) revenue covenants for the period spanning July 1, 2025, through June 30, 2026. Under the amended terms, the TTM revenue covenant thresholds are as follows:

Q3 2025: $73 million
Q4 2025: $77 million
Q1 2026: $90 million
Q2 2026: $103 million

Beginning in Q3 2026, the TTM revenue covenant will be $115 million and will remain at that level for all subsequent quarters through the maturity of the debt. In consideration for this fifth amendment to the OrbiMed credit agreement, AVITA agreed to issue 400,000 unrestricted common shares to OrbiMed in lieu of a cash fee.

As of June 30, 2025, the Company had approximately $15.7 million in cash, cash equivalents, and marketable securities.

Webcast and Conference Call Information

AVITA Medical will host a conference call on Thursday, August 7, 2025, at 1:30 p.m. Pacific Time (Friday, August 8, 2025, at 6:30 a.m. Australian Eastern Standard Time) to discuss its second quarter 2025 financial results and recent business and clinical highlights. The live webcast will be available under the Events & Presentations section of the AVITA Medical website at ir.avitamedical.com. To participate by telephone, please register in advance to receive dial-in details and a personal PIN at: https://register-conf.media-server.com/register/BI2760d86b79a7479f830f23dd916bd991 A replay of the webcast will be available shortly after the live event.

About AVITA Medical, Inc.

AVITA Medical® is a leading therapeutic acute wound care company delivering transformative solutions. Our technologies are designed to optimize wound healing, effectively accelerating the time to patient recovery. At the forefront of our platform is the RECELL® System, approved by the FDA for the treatment of thermal burn and trauma wounds. RECELL harnesses the healing properties of a patient's own skin to create Spray-On Skin™ Cells, offering an innovative solution for improved clinical outcomes at the point-of-care. In the U.S., AVITA Medical also holds the exclusive rights to manufacture, market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, and the exclusive rights to market, sell, and distribute Cohealyx™, an AVITA Medical-branded collagen-based dermal matrix.

In international markets, the RECELL System is approved to promote skin healing in a wide range of applications including burns and full-thickness skin defects. The RECELL System, excluding RECELL GO®, 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,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “future,” “goal,” “guidance,” “intend,” “look forward,” “may,” “outlook,” “project,” “target,” “will,” “would,” 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, as well as other 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.

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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, 2025	December 31, 2024
ASSETS		
Cash and cash equivalents	$ 12,216	$ 14,050
Marketable securities	3,474	21,835
Accounts receivable, net	11,343	11,786
Prepaids and other current assets	1,684	2,060
Inventory	7,536	7,269
Total current assets	36,253	57,000
Plant and equipment, net	9,689	10,018
Operating lease right-of-use assets	3,132	3,571
Corporate-owned life insurance ("COLI") asset	2,913	3,006
Intangible assets, net	5,308	5,570
Other long-term assets	839	546
Total assets	$ 58,134	$ 79,711
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable and accrued liabilities	$ 7,267	$ 6,294
Accrued wages and fringe benefits	7,941	10,451
Loan facility	42,216	-
Current non-qualified deferred compensation ("NQDC") liability	339	2,094
Contingent liability	3,000	-
Other current liabilities	1,839	1,319
Total current liabilities	62,602	20,158
Loan facility - long-term	-	42,245
Non-qualified deferred compensation liability	3,800	2,969
Contract liabilities	307	324
Operating lease liabilities, long-term	2,372	2,840
Contingent liability, long-term	-	3,000
Warrant liabilities	1,900	3,432
Total liabilities	70,981	74,968
Non-qualified deferred compensation plan share awards	45	244
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 26,613,678 and 26,354,042, shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2025 and December 31, 2024	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,296)	(1,319)
Additional paid-in capital	374,073	367,568
Accumulated other comprehensive loss	(2,079)	(1,939)
Accumulated deficit	(383,593)	(359,814)
Total stockholders' equity (deficit)	(12,892)	4,499
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity (deficit)	$ 58,134	$ 79,711

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

	Three-Months Ended		Six-Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Sales revenue	$ 18,226	$ 15,183	$ 36,551	$ 26,287
Lease revenue	192	12	381	12
Total revenues	18,418	15,195	36,932	26,299
Cost of sales	(3,469)	(2,111)	(6,303)	(3,624)
Gross profit	14,949	13,084	30,629	22,675
Operating expenses:				
Sales and marketing	(14,314)	(16,302)	(29,147)	(28,942)
General and administrative	(6,666)	(7,519)	(13,057)	(16,481)
Research and development	(5,117)	(4,887)	(11,400)	(10,081)
Total operating expenses	(26,097)	(28,708)	(53,604)	(55,504)
Operating loss	(11,148)	(15,624)	(22,975)	(32,829)
Interest expense	(1,252)	(1,347)	(2,485)	(2,703)
Other income, net	2,484	1,611	1,693	1,544
Loss before income taxes	(9,916)	(15,360)	(23,767)	(33,988)
Income tax expense	(4)	(33)	(12)	(63)
Net loss	$ (9,920)	$ (15,393)	$ (23,779)	$ (34,051)
Net loss per common share:				
Basic and diluted	$ (0.38)	$ (0.60)	$ (0.90)	$ (1.32)
Weighted-average common shares:				
Basic and diluted	26,367,548	25,760,278	26,400,366	25,699,030