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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 07, 2024**

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**AVITA Medical, Inc.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39059**  
(Commission File Number)

**85-1021707**  
(IRS Employer  
Identification No.)

**28159 Avenue Stanford  
Suite 220  
Valencia, California**  
(Address of Principal Executive Offices)

**91355**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 661 367-9170**

(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RCEL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 7, 2024, AVITA Medical, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On November 7, 2024, the Company and an affiliate of OrbiMed Advisors, LLC (the "Lender") mutually agreed to amend the credit agreement between the Lender and the Company executed on October 18, 2023, as amended on November 30, 2023 and May 28, 2024. Under the terms of this amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate two additional tranches of available debt in the aggregate amount of \$50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at \$67.5 million. All revenue covenants for subsequent quarters remain in effect.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
99.1	Press release titled " <a href="#">AVITA Medical Reports Third Quarter Financial Results</a> "
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVITA Medical, Inc.

Date: November 7, 2024

By: /s/ David O'Toole  
David O'Toole  
Chief Financial Officer

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## AVITA Medical Reports Third Quarter Financial Results

**VALENCIA, Calif., November 7, 2024** — 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 third quarter ended September 30, 2024.

### Financial Results and Recent Business Updates

- Commercial revenue of \$19.5 million, an increase of approximately 44% compared to the same period in 2023
- Gross profit margin of 83.7%
- On July 31, 2024, entered into a multi-year development and distribution agreement with Regenity Biosciences that provides AVITA Medical with the exclusive rights to market, sell, and distribute Cohealyx™, an AVITA Medical branded collagen-based dermal matrix
- On November 7, 2024, amended the credit agreement with OrbiMed in a mutually beneficial arrangement, forgoing access to an additional \$50 million in funding in exchange for removal of the 12-month trailing revenue covenant for the period ending December 31, 2024

"Third-quarter commercial revenue surpassed our second-quarter record by 29%, underscoring the strength of RECELL GO as a transformative product and the success of adoption," said Jim Corbett, Chief Executive Officer of AVITA Medical. "With over 75% of our revenue base now transitioned to RECELL GO and the anticipated launch of Cohealyx in 2025, we are positioned to address a broad continuum of wound care needs. We remain committed to establishing RECELL as the standard of care and transforming wound care, all while advancing our mission to improve patient outcomes and expand access."

### Future Milestones

- Anticipate FDA approval of RECELL GO mini by December 31, 2024
- Anticipate 510(k) clearance of Cohealyx before year-end; expect to launch in January 2025
- Anticipate initiating post-market clinical study to validate the preclinical work of Cohealyx in Q1 2025

### Financial Guidance

- Commercial revenue for the fourth quarter 2024 is expected to be in the range of \$22.3 to \$24.3 million, reflecting growth of approximately 58% to 72% over the same period in 2023
- Commercial revenue for the full-year 2024 is expected to be within the previously provided revenue guidance of \$68.0 to \$70.0 million, reflecting growth of approximately 37% to 41% over the full-year 2023
- Confirming previously given guidance of achieving cashflow break-even and GAAP profitability no later than the end of Q3 2025

### Third Quarter 2024 Financial Results

Commercial revenue was \$19.5 million in the three-months ended September 30, 2024, an increase of \$5.9 million, or 43.8%, compared to \$13.6 million in the corresponding period in the prior year. The growth in commercial revenue was largely driven by accelerating the transition to RECELL GO, as well as deeper penetration within existing customer accounts and new accounts for full-thickness skin defects.

Gross profit margin was 83.7% compared to 84.5% in the corresponding period in the prior year. The decrease was due to ongoing engineering and validation of the RECELL GO durable and disposable cartridge.

BARDA income decreased to zero, compared to \$0.2 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 \$30.2 million, compared to \$21.1 million in the same period in 2023. The increase in operating expenses is primarily attributable to an increase of \$4.6 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 the Company's commercial organization to support its growing commercial operations. G&A expenses increased by \$3.5 million as a result of higher salaries and benefits, severance benefits, deferred compensation expenses, and professional fees, partially offset by lower other corporate expenses. In addition, the increase in operating expenses included an increase of \$1.0 million in R&D costs, which was primarily due to employee compensation costs related to the Company's expanded team of medical science liaisons.

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 (expense) income, net decreased by \$1.7 million to an expense of \$1.1 million from income of \$0.6 million in the prior period. In the current period, other (expense) income consists of non-cash charges of \$1.0 million and \$0.8 million related to the changes in fair value of the debt and warrant liability, respectively, offset by \$0.6 million in income related to the Company's investments. The prior period income consisted of \$0.7 million related to our investments offset by \$0.1 million in other losses, net.

Net loss was \$16.2 million, or a loss of \$0.62 per basic and diluted share, compared to a net loss of \$8.7 million, or a loss of \$0.34 per basic and diluted share, in the same period in 2023.

As of September 30, 2024, the Company had approximately \$44.4 million in cash, cash equivalents, and marketable securities.

### **Webcast and Conference Call Information**

AVITA Medical will host a conference call on Thursday, November 7, 2024, at 1:30 p.m. Pacific Time (Friday, November 8, 2024, at 8:30 a.m. Australian Eastern Daylight Time) to discuss its third quarter 2024 financial results and recent business highlights. The live webcast will be accessible under the Events & Presentations section of the AVITA Medical website at [ir.avitamedical.com](http://ir.avitamedical.com). To participate by telephone, please register in advance to receive dial-in details and a personal PIN at <https://register.vevent.com/register/BI5bf899d9f4574896abaf08308299cbdf>. A replay of the webcast will be available shortly after the live event.

### **About AVITA Medical, Inc.**

AVITA Medical<sup>®</sup> 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<sup>®</sup> System, approved by the U.S. 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<sup>™</sup> 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. In the United States, AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm<sup>®</sup>, a biosynthetic wound matrix, and Cohealyx<sup>™</sup>, 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, 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](http://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," "would," "may," "will," "believe," "continue," "estimate," "look forward," "forecast," "goal," "target," "project," "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, 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.*

**Investor & Media Contact:**

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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	
	September 30, 2024	December 31, 2023
<b>ASSETS</b>		
Cash and cash equivalents	\$ 18,639	\$ 22,118
Marketable securities	25,766	66,939
Accounts receivable, net	10,288	7,664
BARDA receivables	111	30
Prepays and other current assets	2,892	1,659
Inventory	6,229	5,596
Total current assets	63,925	104,006
Plant and equipment, net	9,151	1,877
Operating lease right-of-use assets	3,780	2,440
Corporate-owned life insurance ("COLI") asset	3,059	2,475
Intangible assets, net	590	487
Other long-term assets	546	355
Total assets	\$ 81,051	\$ 111,640
<b>LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY</b>		
Accounts payable and accrued liabilities	\$ 4,187	\$ 3,793
Accrued wages and fringe benefits	9,776	7,972
Current non-qualified deferred compensation ("NQDC") liability	1,870	168
Other current liabilities	1,308	1,266
Total current liabilities	17,141	13,199
Long-term debt	42,547	39,812
Non-qualified deferred compensation liability	2,742	3,663
Contract liabilities	332	357
Operating lease liabilities, long term	3,079	1,702
Warrant liability	2,759	3,158
Total liabilities	68,600	61,891
Non-qualified deferred compensation plan share awards	224	693
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 26,217,629 and 25,682,078, shares issued and outstanding at September 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 September 30, 2024 and December 31, 2023	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,255)	(1,130)
Additional paid-in capital	363,769	350,039
Accumulated other comprehensive loss	(2,065)	(1,887)
Accumulated deficit	(348,225)	(297,969)
Total stockholders' equity	12,227	49,056
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	\$ 81,051	\$ 111,640

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

	Three-Months Ended		Nine-Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Sales revenue	\$ 19,394	\$ 13,645	\$ 45,681	\$ 35,948
Lease revenue	152	-	164	-
<b>Total revenues</b>	<b>19,546</b>	<b>13,645</b>	<b>45,845</b>	<b>35,948</b>
Cost of sales	(3,190)	(2,113)	(6,814)	(5,984)
<b>Gross profit</b>	<b>16,356</b>	<b>11,532</b>	<b>39,031</b>	<b>29,964</b>
BARDA income	-	212	-	1,369
<b>Operating expenses:</b>				
Sales and marketing	(15,144)	(10,532)	(44,086)	(27,075)
General and administrative	(9,590)	(6,124)	(26,071)	(20,584)
Research and development	(5,428)	(4,394)	(15,510)	(14,056)
<b>Total operating expenses</b>	<b>(30,162)</b>	<b>(21,050)</b>	<b>(85,667)</b>	<b>(61,715)</b>
Operating loss	(13,806)	(9,306)	(46,636)	(30,382)
Interest expense	(1,359)	(10)	(4,063)	(21)
Other (expense) income, net	(1,068)	615	478	2,141
Loss before income taxes	(16,233)	(8,701)	(50,221)	(28,262)
Income tax benefit (expense)	28	(11)	(35)	(54)
<b>Net loss</b>	<b>\$ (16,205)</b>	<b>\$ (8,712)</b>	<b>\$ (50,256)</b>	<b>\$ (28,316)</b>
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.62)	\$ (0.34)	\$ (1.95)	\$ (1.12)
<b>Weighted-average common shares:</b>				
Basic and diluted	25,983,929	25,401,754	25,794,690	25,281,920



