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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): February 22, 2024

AVITA Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39059**	**85-1021707**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
28159 Avenue Stanford Suite 220 Valencia, California		**91355**
(Address of Principal Executive Offices)		**(Zip Code)**

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

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

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 22, 2024, AVITA Medical, Inc. issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2023. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description of Exhibit**
99.1	Press release titled “AVITA Medical Reports Fourth Quarter and Full Year 2023 Financial Results and Provides 2024 Financial Guidance"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 22, 2024

By: /s/ Donna Shiroma

Donna Shiroma
General Counsel

Exhibit 99.1

AVITA Medical Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides 2024 Financial Guidance

VALENCIA, Calif., February 22, 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 fourth quarter and full-year ended December 31, 2023.

Fourth Quarter 2023 Financial Highlights

- Commercial revenue increased approximately 50% to $14.1 million compared to the same period in 2022
- Gross profit margin of 87.3%

Full-Year 2023 Financial Highlights

- Commercial revenue increased approximately 46% to $49.8 million compared to the same period in 2022
- Gross profit margin of 84.5%
- As of December 31, 2023, approximately $89.1 million in cash, cash equivalents, and marketable securities

“We ended the year with yet another quarter of significant growth, marking a year of extraordinary progress,” said Jim Corbett, AVITA Medical Chief Executive Officer. “In 2023, we successfully executed a series of strategic initiatives to transform our business. These initiatives included expanding our RECELL indications and applications, doubling our commercial field organization ahead of FDA approvals, successfully launching our expanded label for full-thickness skin defects, and establishing an international expansion plan. Looking ahead to 2024, we are eager to capitalize on this momentum, and remain committed to innovation and sustained growth.”

Future Milestones

- Expansion of the field sales organization from 70 to 108 professionals in the first quarter of 2024 to maximize our ability to capitalize on the expanded label of full-thickness skin defects
- Integrating PermeaDerm® Biosynthetic Wound Matrix into our selling portfolio; plan to launch PermeaDerm in March 2024
- Expect U.S. Food and Drug Administration Food (FDA) approval for RECELL GO with plans to commence commercial launch on May 31, 2024
- Renovating and expanding our Ventura warehouse facility; expansion will increase capacity 10-fold, ensuring efficient operations for the next five years at this location; expect final phase to be completed during the third quarter of 2024
- Expect non-U.S. sales following the launch in January 2024 of RECELL within Germany, Austria, and Switzerland
- Plan to submit a PMA supplement for RECELL GO mini, which is being designed to address smaller wounds, and expect to receive FDA approval by year-end
- Expect to submit both our post-market study treating patients with stable vitiligo, TONE, and separate health economics study for publication by year-end

Financial Guidance

- Commercial revenue for the first quarter 2024 is expected to be in the range of $14.8 to $15.6 million, reflecting growth of approximately 42% to approximately 50% over the same period in the prior year
- Commercial revenue for the full-year 2024 is expected to be in the range of $78.5 to $84.5 million, reflecting growth of approximately 57% to approximately 69% over the full-year 2023
- Expect to achieve cashflow break even and GAAP profitability no later than the third quarter of 2025

Fourth Quarter 2023 Financial Results

Our commercial revenue, which excludes Biomedical Advanced Research and Development Authority (BARDA) revenue, increased by 50% to $14.1 million in the three-months ended December 31, 2023, compared to $9.4 million in the same period in 2022. Total revenue, which includes BARDA revenue, increased by 50% to $14.2 million compared to $9.5 million in the same period in 2022.

Gross profit margin was 87.3% compared to 85.8% for the fourth quarter of 2022. The increase was largely driven by higher production of our product associated with our increase in revenue and lower shipping costs.

Total operating expenses for the quarter were $24.7 million, compared to $15.0 million in the same period in 2022. The increase in operating expenses is primarily attributable to an increase of $2.4 million in G&A expenses related to stock-based compensation, consulting expenses, and employee-related costs. In addition, the increase in operating expenses included an increase of $3.4 million in R&D costs, which was primarily due to employee compensation costs, including recruiting costs, costs associated with insourcing RECELL GO to our Ventura facility, and accelerated recruitment and third-party costs associated with the TONE study. Lastly, operating expenses included an increase of $3.9 million in sales and marketing costs primarily due to employee related costs, including commissions, travel, and promotion expense, as a result of the expansion of our commercial organization in the second quarter of 2023.

Net loss was $7.1 million, or a loss of $0.28 per basic and diluted share, compared to a net loss of $5.4 million, or a loss of $0.21 per basic and diluted share, in the same period in 2022.

BARDA income 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.

Other income, net for the quarter was $6.3 million, comprised primarily of $1.1 million in income from our investing activities and a $9.4 million non-cash foreign exchange gain as a result of the foreign entity liquidation for previously deferred unrealized cumulative translation adjustments in equity. This was partially offset by a loss on debt issuance of $1.2 million, debt issuance costs of $0.8 million, the change of fair value for our debt of $1.6 million, and change in fair value of warrants for $0.7 million.

Full-Year 2023 Financial Results

Our commercial revenue, which excludes BARDA revenue, increased by 46% to $49.8 million in the full-year ended December 31, 2023, compared to $34.1 million in the same period in 2022. Total revenue, which includes BARDA revenue, was $50.1 million compared to $34.4 million in the same period in 2022.

Gross profit margin was 84.5% compared to 82.4% in the same period in 2022.

Total operating expenses for the year were $86.4 million compared to $59.1 million in the same period in 2022. The increase in operating expenses is largely attributed to an increase of $15.4 million in sales and marketing costs as a result of the expansion of our commercial organization in the first half of 2023. Alongside this expansion, G&A costs increased by $5.0 million due to the increased headcount and related salaries and benefits, stock-based compensation, and recruiting costs. Lastly, R&D costs increased by $6.9 million, primarily driven by the cost of the TONE study, final work and completion of the PMA Supplement to the FDA in June of 2023 for RECELL GO and employee related costs, including stock-based compensation.

Net loss for the full-year 2023 was $35.4 million, or a loss of $1.40 per basic and diluted share, compared to a net loss of $26.7 million, or a loss of $1.07 per basic and diluted share, in the same period in 2022.

Other income, net for the full-year 2023 was $8.5 million, comprised primarily of $3.1 million in income from our investing activities and a $9.4 million non-cash foreign exchange gain as a result of the foreign entity liquidation for previously deferred unrealized cumulative translation adjustments in equity. This was partially offset by a loss on debt issuance of $1.2 million, debt issuance costs of $0.8 million, the change of fair value for our debt of $1.6 million, and change in fair value of warrants for $0.7 million.

Webcast and Conference Call Information

AVITA Medical will host a conference call to discuss its financial results, business highlights, and 2024 revenue guidance on Thursday, February 22, 2024, at 1:30 p.m. Pacific Time (being Friday, February 23, 2024, at 8:30 a.m. Australian Eastern Daylight Time). To access the live call via telephone, please register in advance using the link here. Upon registering, each participant will receive an email confirmation with dial-in numbers and a unique personal PIN that can be used to join the call. A simultaneous webcast of the call will be available via the Company's website at https://ir.avitamedical.com.

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, 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

Statements in 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. Applicable risks and uncertainties include, among others, 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.

Investor & Media Contact:
Jessica Ekeberg
Phone +1-661-904-9269
investor@avitamedical.com
media@avitamedical.com

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)
(Unaudited)

	As of	
	December 31, 2023	**December 31, 2022**
ASSETS		
Cash and cash equivalents	$ 22,118	$ 18,164
Marketable securities	66,939	61,178
Accounts receivable, net	7,664	3,515
BARDA receivables	30	898
Prepaids and other current assets	1,659	1,578
Inventory	5,596	2,125
Total current assets	104,006	87,458
Marketable securities long-term	-	6,930
Plant and equipment, net	1,877	1,200
Operating lease right-of-use assets	2,440	851
Corporate-owned life insurance ("COLI") asset	2,475	1,238
Intangible assets, net	487	465
Other long-term assets	355	122
Total assets	$ 111,640	$ 98,264
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,793	3,002
Accrued wages and fringe benefits	7,972	6,623
Current non-qualified deferred compensation ("NQDC") liability	168	78
Other current liabilities	1,266	990
Total current liabilities	13,199	10,693
Long-term debt	39,812	-
Non-qualified deferred compensation liability	3,663	1,270
Contract liabilities	357	698
Operating lease liabilities, long term	1,702	306
Warrant liability	3,158	-
Total liabilities	61,891	12,967
Non-qualified deferred compensation plan share awards	693	557
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,682,078 and 25,208,436, shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2023 and December 31, 2022	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,130)	(127)
Additional paid-in capital	350,039	339,825
Accumulated other comprehensive income/(loss)	(1,887)	7,627
Accumulated deficit	(297,969)	(262,588)
Total stockholders' equity	49,056	84,740
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 111,640	$ 98,264

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

	Three-Months Ended		Year-Ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Revenues	$ 14,195	$ 9,455	$ 50,143	$ 34,421
Cost of sales	(1,796)	(1,347)	(7,780)	(6,041)
Gross profit	12,399	8,108	42,363	28,380
BARDA income	59	1,026	1,428	3,215
Operating expenses:				
Sales and marketing	(10,216)	(6,342)	(37,291)	(21,913)
General and administrative	(7,750)	(5,321)	(28,334)	(23,330)
Research and development	(6,765)	(3,379)	(20,821)	(13,857)
Total operating expenses	(24,731)	(15,042)	(86,446)	(59,100)
Operating loss	(12,273)	(5,908)	(42,655)	(27,505)
Interest expense	(1,122)	(6)	(1,143)	(16)
Other income, net	6,342	585	8,483	892
Loss before income taxes	(7,053)	(5,329)	(35,315)	(26,629)
Income tax expense	(12)	(24)	(66)	(36)
Net loss	$ (7,065)	$ (5,353)	$ (35,381)	$ (26,665)
Net loss per common share:				
Basic and Diluted	$ (0.28)	$ (0.21)	$ (1.40)	$ (1.07)
Weighted-average common shares:				
Basic and Diluted	25,477,690	25,082,816	25,331,264	25,000,180