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): January 10, 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 1.01 Entry into a Material Definitive Agreement.

Distribution Agreement

On January 10, 2024, AVITA Medical Americas LLC ("AVITA Americas"), a wholly-owned subsidiary of AVITA Medical, Inc., (the "Company") entered into an exclusive multi-year distribution agreement ("Agreement") with Stedical Scientific, Inc. ("Stedical Scientific") to commercialize PermeaDerm® Biosynthetic Wound Matrix in the United States. PermeaDerm is cleared by the Food and Drug Administration as a transparent matrix for use in the treatment of a variety of wound types until healing is achieved.

Under the terms of the agreement, AVITA Americas will hold the exclusive rights to market, sell, and distribute PermeaDerm products, including any future enhancements or modifications, within the United States. The initial term is for five years, with the option to automatically renew for an additional term of five years, contingent upon meeting certain minimums. AVITA Americas also agrees to purchase and maintain minimum quantities of the product to meet the needs of customers and provide monthly and quarterly reporting to Stedical Scientific regarding sales. Purchases of the product from Stedical Scientific do not have the right of return, and AVITA Americas holds title and risk of loss. In accordance with the Agreement, AVITA Americas' gross margin from the sale of PermeaDerm will be 50% of the average sales price.

Minimum Purchase Requirements

AVITA Americas' purchases from Stedical Scientific are subject to minimum requirements. Stedical Scientific may terminate the Agreement upon one year notice if AVITA Americas (1) fails to reach its minimum purchase obligation for two consecutive years and (2) also fails to cure such shortfall with a cash payment or sufficient purchase of products.

Right of First Negotiation

If at any time during the term of the Agreement, Stedical Scientific receives a written offer from a third-party to acquire more than 50% of Stedical Scientific's equity or a sale of substantially all of its assets that are the subject of this Agreement (together, a "Change of Control"), or Stedical Scientific intends to explore a Change of Control, AVITA Americas has the option to deliver a binding letter of intent to Stedical Scientific within thirty days to engage in a Change of Control transaction with Stedical Scientific. Stedical Scientific is restricted from accepting any third-party offers during the 30-day notice period, however, Stedical Scientific is under no obligation to accept AVITA Americas' letter of intent and may enter into a Change of Control transaction with a third-party after the 30-day notice period.

Relocation of Manufacturing

If Stedical Scientific desires to relocate its manufacturing facilities outside the State of California, Stedical Scientific shall offer to assign its manufacturing contract at its existing location to AVITA Americas for a one-time fee payable to Stedical Scientific by AVITA Americas along with a sales-based royalty. Following assignment, other payments to Stedical Scientific will cease and the royalty will be the only recurring payment.

The above description of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending March 31, 2024.

Item 2.02 Results of Operations and Financial Condition.

On January 10, 2024, the Company issued a press release announcing certain preliminary unaudited results for the fourth quarter and full-year ended December 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

The information under this Item 2.02 and Exhibit 99.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933 except as expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD.

On January 10, 2024, the Company issued a press release announcing the entry into the Agreement. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

The information under Item 7.01 and Exhibit 99.2 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933 except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	AVITA Medical Announces Preliminary 2023 Financial Highlights, Provides 2024 Financial Guidance and Business Update
99.2	AVITA Medical Announces Exclusive Distribution Agreement with Stedical Scientific
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: January 10, 2024

By: /s/ Donna Shiroma

Donna Shiroma
General Counsel

AVITA Medical Announces Preliminary 2023 Financial Highlights, Provides 2024 Financial Guidance and Business Update

VALENCIA, Calif., January 10, 2024 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "Company"), a commercial-stage regenerative medicine company focused on first-in-class devices and autologous cellular therapies for skin restoration, today announced preliminary unaudited financial highlights for the fourth quarter and full-year 2023, provided financial guidance for the first quarter and full-year 2024, and announced completion of patient enrollment in its post-market study, TONE.

Preliminary Fourth Quarter and Full-Year 2023 Financial Highlights

- Commercial revenue for the fourth quarter 2023 is expected to be approximately $14.1 million, an increase of approximately 50% compared to same period in 2022
- Commercial revenue for the full-year 2023 is expected to be approximately $49.8 million, an increase of approximately 46% compared to full-year 2022
- Gross margin for the full-year 2023 is expected to be approximately 84.5%
- As of December 31, 2023, approximately $89.1 million in cash, cash equivalents, and marketable securities

"This was a transformative year for AVITA Medical as we focused on accelerating our growth profile," said Jim Corbett, Chief Executive Officer of AVITA Medical. "We have made tremendous progress over the last four quarters, with consecutive commercial revenue growth rates of 40%, 42%, 51%, and 50%, respectively, over the same periods in 2022. We remain committed to sustaining growth and building our business in 2024."

2024 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 at the lower bound of approximately 42% and upper bound of 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 at the lower bound of approximately 57% and upper bound of approximately 69% over the full-year 2023

Business Update

In July 2023, the Company initiated TONE, a post-market study treating patients with stable vitiligo. The purpose of TONE is to evaluate repigmentation and to understand the impact of repigmentation on improving quality of life for patients with this disease. Key study endpoints include patient and clinician satisfaction of treatment, burden of disease, and patient mental health status. The Company believes that developing these health-related quality-of-life indicators will help create a basis to understand the impact of vitiligo on the mental health of patients and the associated healthcare costs of treatment.

The Company completed enrollment of TONE with 109 patients at investigational sites across the United States earlier than anticipated. Patients will be followed for a 12-month period, with the primary follow-up period being 6-months after treatment.

About AVITA Medical, Inc.
AVITA Medical® is a commercial-stage regenerative medicine company transforming the standard of care for skin restoration with innovative devices and autologous cellular therapies. 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. RECELL enables improved clinical outcomes. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

In international markets, our products are approved under the RECELL System brand 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.

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. 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 Announces Exclusive Distribution Agreement with Stedical Scientific

VALENCIA, Calif., January 10, 2024 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "Company"), a commercial-stage regenerative medicine company focused on first-in-class devices and autologous cellular therapies for skin restoration, today announced it has entered into an exclusive multi-year distribution agreement with Stedical Scientific, Inc. to commercialize PermeaDerm® Biosynthetic Wound Matrix in the United States. PermeaDerm is cleared by the Food and Drug Administration as a transparent matrix for use in the treatment of a variety of wound types until healing is achieved.

Under the terms of the agreement, AVITA Medical will hold the exclusive rights to market, sell, and distribute PermeaDerm products, including any future enhancements or modifications, within the United States. The initial term is for five years, with the option to renew for an additional five years, contingent upon meeting certain minimums. The Company expects the gross margin from the sale of PermeaDerm to be 50% of the average sales price.

"Our partnership with Stedical Scientific is an important step in expanding our portfolio and addressing the unmet needs of our patients," said Jim Corbett, Chief Executive Officer of AVITA Medical. "AVITA Medical and Stedical Scientific are ideal partners given the complementary nature of our products, the overlap of call points, and the strength of our footprint and sales force. We anticipate these synergies will allow us to effectively leverage our established commercial presence, enhancing the integration of PermeaDerm into our portfolio. This strategic collaboration underscores our commitment to delivering innovative solutions and improving outcomes for those we serve."

PermeaDerm is a biosynthetic matrix that facilitates wound healing while also providing a high level of permeability and biocompatibility. For burn or wound procedures treated with Spray-On Skin™ Cells from the RECELL® System, PermeaDerm can be applied to further aid in healing. PermeaDerm is eligible for reimbursement in the U.S. across inpatient and outpatient settings.

"We are thrilled to mark this important growth milestone with AVITA Medical, who shares our goal of treating millions of patients suffering from a broad spectrum of wounds," said Lin Sun, Chairman of Stedical Scientific. "AVITA Medical has an established presence in the U.S. wound care market, further validating the clinical and commercial value of PermeaDerm. This collaboration will expand our reach to more patients, physicians, and hospitals with a compelling portfolio of solutions that improve care and surgical performance. We look forward to a long and successful partnership."

About AVITA Medical, Inc.
AVITA Medical® is a commercial-stage regenerative medicine company transforming the standard of care for skin restoration with innovative devices and autologous cellular therapies. 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. RECELL enables improved clinical outcomes. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

In international markets, our products are approved under the RECELL System brand 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.

About Stedical Scientific, Inc.
Stedical Scientific, Inc. is an innovative tissue engineering and regenerative medicine company that develops, manufactures and sells cutting-edge products delivered from a proprietary biosynthetic technology platform for the treatment of acute and chronic wounds, burns, as well as for plastic and reconstructive surgery. Stedical Scientific's mission is to expand its portfolios of disruptive innovations and to serve millions of people around the globe. Stedical Scientific has brought extraordinary clinical experience to patients through its signature product, PermeaDerm®, revolutionizing wound care.

Stedical Scientific's growth strategy, in addition to marketing products in the U.S., is to expand extensively in the international market, while committed to substantially improving patient and clinician experiences through breakthrough technologies and changing the course of human health.

To learn more, visit www.stedical.com.

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. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our partnership with Stedical Scientific, and the anticipated benefits and financial impact of the partnership. 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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Phone +1-661-904-9269
investor@avitamedical.com
media@avitamedical.com

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