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): July 31, 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 July 31, 2024, AVITA Medical, Inc. (the "Company") entered into an exclusive five-year development and distribution agreement (the "Agreement") with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity"). Through this Agreement, following 510(k) clearance by the U.S. Food and Drug Administration (the "FDA"), the Company will hold the exclusive marketing, sales, and distribution rights to a unique collagen-based dermal matrix (the "Product"), which will be manufactured by Regenity.

As part of the Agreement, Regenity expects to secure a 510(k) clearance for a collagen-based dermal matrix developed in collaboration with the Company in the fourth quarter of 2024. Once 510(k) clearance is obtained, Regenity will manufacture and supply the Product to the Company. The Company's exclusive rights will then allow it to market, sell, and distribute the Product, including any future enhancements or modifications to the Product, under the AVITA Medical brand name within the U.S., and potentially in countries in the European Union, as well as in Australia and Japan.

In consideration of the rights to exclusive marketing, sales, and distribution of the Product, the Company will make certain payments totaling up to $5.0 million to Regenity. The first payment of $2.0 million is triggered upon Regenity's receipt of 510(k) clearance by the FDA. The second payment of $3.0 million, which is contingent on positive results of certain clinical studies, is due on or before January 4, 2026. The $3.0 payment is to support the development and manufacturing capacity necessary to meet the Company's distribution needs and will result in an automatic five-year extension to the term of the Agreement.

Revenue-Sharing

The first two years of revenue sharing from sales of the Product is expected to be equal to 50% of the average sales price. In subsequent years, the Company's share of revenue will increase to 60% of the Product's average sales price.

Item 7.01. Regulation FD.

On July 31, 2024, the Company issued a press release announcing its execution of the Agreement. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information under Item 1.01 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	AVITA Medical Expands Portfolio with Unique Dermal Matrix to Advance Wound Care
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: July 31, 2024

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

AVITA Medical Expands Portfolio with Unique Dermal Matrix to Advance Wound Care

Exclusive development and distribution agreement with Regenity Biosciences provides AVITA Medical with the commercialization rights to a unique collagen-based dermal matrix following 510(k) clearance

VALENCIA, Calif., July 31, 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 announced it has entered into an exclusive multi-year development and distribution agreement with Regenity Biosciences ("Regenity"), a leading regenerative medical product developer and manufacturer of bioresorbable technologies. Through this agreement, following 510(k) by the FDA, AVITA Medical will hold the exclusive marketing, sales and distribution rights to a unique collagen-based dermal matrix, which will be manufactured by Regenity.

"This strategic collaboration significantly strengthens our portfolio and advances our long-term growth objectives," said Jim Corbett, Chief Executive Officer of AVITA Medical. "Regenity's proven expertise in developing and manufacturing bioresorbable materials aligns with our vision. By integrating their innovative collagen-based solutions with our existing RECELL technology, we believe we also have the potential to establish a new standard of care with a one-stage closure, thereby improving patient outcomes."

As part of the exclusive development and distribution agreement, Regenity expects to secure 510(k) clearance for a collagen-based dermal matrix developed in collaboration with AVITA Medical in the fourth quarter of 2024. Once 510(k) clearance is obtained, Regenity will manufacture and supply this product to AVITA Medical. AVITA Medical will then hold its exclusive rights to market, sell, and distribute the product, including any future enhancements or modifications, under the AVITA Medical brand name within the U.S., and potentially in countries in the European Union, as well as in Australia and Japan.

Alongside the use of RECELL for the treatment of thermal burn wounds and full-thickness skin defects, our new product will generate a dermal-like tissue in full-thickness wounds through rapid cell repopulation and revascularization of the dermal collagen matrix. Immediately following 510(k) clearance and commercialization, AVITA Medical plans to initiate multiple clinical studies to establish the unique synergies between the new dermal matrix and RECELL. These studies will include the evaluation of the new dermal matrix and other commercially available dermal matrices in full-thickness wounds, followed by delayed treatment with a split-thickness skin graft plus RECELL in a two-stage procedure (the current standard of care), to demonstrate improved time to grafting and wound closure. Additional clinical studies will evaluate the use of the new dermal matrix in full-thickness wounds with immediate grafting together with RECELL in a single procedure, aiming to establish a new standard of care. AVITA Medical anticipates completing these studies in 2025.

The initial term of the exclusive development and distribution agreement is five years, with an automatic extension of an additional five years, contingent upon meeting certain criteria. Under the terms of the agreement, AVITA Medical will make a $2.0 million payment upon receipt of 510(k) clearance by Regenity. AVITA Medical has a further obligation to make up to an additional $3.0 million payment on or before January 4, 2026, to support manufacturing capacity, contingent on the positive results of the clinical studies related to the new dermal matrix. The first two years of revenue sharing from sales of the product is expected to be equal to 50% of its average sales price. In subsequent years, AVITA Medical's share of revenue will increase to 60% of the product's average sales price.

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 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™ 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.

About Regenity Biosciences
Regenity Biosciences, a Linden Capital Partners ("Linden") portfolio company, is the leading global developer and manufacturer of bioresorbable technologies to repair and regenerate natural tissue and bone for a variety of markets including dental, spine, orthopaedic, neurosurgery, ENT, advanced wound and nerve repair. Founded in 1997, Regenity (formerly Collagen Matrix, Inc.) is headquartered in Paramus, New Jersey, with manufacturing locations in Oakland and Allendale, New Jersey and Groningen, the Netherlands. Regenity's product portfolio includes a variety of collagen-based and synthetic polymer solutions that support the company's platform for tissue and bone regeneration. Regenity develops proprietary products that are sold to OEM customers on either a contract or private label basis and offers partnership opportunities including contract product development and manufacturing services. For more information, please visit www.regenity.com.

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 Company's agreement with Regenity Biosciences, and the

anticipated benefits and financial impact from such agreement. 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.