

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): September 17, 2025

Vivani Medical, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36747
(Commission
File Number)

02-0692322
(IRS Employer
Identification No.)

1350 S. Loop Road
Alameda, California 94502
(Address of principal executive offices, including zip code)

(415) 506-8462
(Telephone number, including area code, of agent for service)
(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	VANI	The Nasdaq Capital Market

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 8.01 Other Events.

Record Date for Cortigent Spin-off

On September 17, 2025, Vivani Medical, Inc. (the “Company”) announced that the record date for the previously announced spin-off of Cortigent, Inc. (“Cortigent”), the Company’s wholly-owned subsidiary, is set for October 8, 2025 (the “Record Date”). Cortigent is developing brain implant devices with neuromodulation technology. The Company’s stockholders holding common stock of the Company as of the Record Date will receive common stock in Cortigent upon completion of the spin-off. The distribution date and share dividend ratio will be announced at a later date. A copy of the press release issued in connection with this announcement is being attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Vivani Medical, Inc. on September 17, 2025.
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 thereunto duly authorized.

VIVANI MEDICAL, INC.

Date: September 17, 2025

By: /s/ Donald Dwyer
Name: Donald Dwyer
Title: Chief Business Officer

Vivani Medical Announces Record Date for Spin-off of Cortigent Neuromodulation Subsidiary to Shareholders

Cortigent is a leading developer of brain implant devices based on precision neurostimulation technology. It is the only company to have obtained FDA approval of a device providing artificial vision for the profoundly blind

Cortigent's new Orion® artificial vision system, developed to treat blindness caused by common conditions, has successfully completed a 6-year Early Feasibility Study

Cortigent is developing a new medical device aimed at improving recovery of arm and hand motion in patients with paralysis due to stroke

Vivani to sharpen focus on development of miniature, ultra long-acting GLP-1 implants for weight loss management and treatment of type 2 diabetes with once or twice-yearly administration

ALAMEDA, Calif., Sep. 17, 2025 (GLOBE NEWSWIRE) – Vivani Medical, Inc. (NASDAQ: VANI) (“Vivani” or the “Company”), a clinical-stage biopharmaceutical company developing miniature, ultra long-acting drug implants, today announced that its board of directors has set the record date for the approved spin-off of Cortigent, Inc. (“Cortigent”), its wholly-owned subsidiary developing brain implant devices with cutting-edge neuromodulation technology.

Vivani shareholders holding common stock as of the record date, October 8, 2025, will receive common stock in Cortigent. Cortigent is expected to trade on the Nasdaq Stock Market under the ticker symbol “CRGT” subject to regulatory approvals and other conditions. The distribution date and share dividend ratio will be announced at a later date.

“The strategic goal of this transaction is to create two companies dedicated to driving value in their respective areas of expertise,” commented Vivani Chief Executive Officer Adam Mendelsohn, PhD. “This transaction will allow Vivani shareholders to fully and directly participate in Cortigent’s future. We are excited about Cortigent’s prospects as an independent, publicly traded company as it continues to advance its precision neurostimulation technology and build upon the promising results recently achieved in the 6-year Orion Early Feasibility Study in profoundly blind patients.”

“The spin-off will position Cortigent among the few public companies focused on neuromodulation and brain-computer interface, or BCI, technologies, a new medical frontier leveraging artificial intelligence and other advanced technologies to address critical unmet patient needs,” added Cortigent Chief Executive Officer Jonathan Adams, MBA. “Upon closing the transaction, we will proceed towards the planned Orion pivotal clinical trial that is designed to seek FDA approval, and the planned Early Feasibility Study of our Stroke Recovery System.”

The expected benefits of the spin-off of Cortigent include enhanced strategic and operational flexibility by the ability of the Vivani and Cortigent management teams to focus on their respective business strategy and operations, and the opportunity for each company to adopt an optimal capital structure. Post spin-off, the board of directors and management team of each company will be better positioned to facilitate growth and explore acquisitions, strategic alliances, and licensing agreements. Management of each company will be properly incentivized with an improved ability to attract and retain exceptional talent.

When Cortigent becomes an independent, publicly traded company, investors will have the opportunity to invest directly into a pioneer developer of brain implant devices and its proprietary precision neurostimulation technology platform. Jonathan Adams, MBA, Cortigent’s Chief Executive Officer since March 2023, will continue as CEO after the spin-off, and Cortigent will continue to be headquartered in the Los Angeles area. Vivani is expected to provide transition services to Cortigent, as needed.

The spin-off is estimated to be complete by late-2025, subject to the satisfaction of certain conditions, including, among others, receipt of a favorable opinion with respect to the tax-free nature of the transaction, and the effectiveness of a registration statement on Form 10 filed with the U.S. Securities and Exchange Commission on August 20, 2025. The spin-off is expected to be accomplished by distributing the requisite number of shares of Cortigent to Vivani stockholders.

ThinkEquity is acting as the exclusive financial advisor to Cortigent, Inc. with respect to the spin-off transaction. For more information, please visit www.think-equity.com

About Cortigent, Inc.

Cortigent, Inc., a wholly-owned subsidiary of Vivani, is developing brain implant devices to help patients recover critical body functions. Our proprietary technology platform leverages neuroscience, proprietary microelectronics, and artificial intelligence to create advanced medical devices called neurostimulation brain-computer interfaces (BCIs). Our predecessor, Second Sight Medical Products, previously marketed Argus® II, the first and only medical device to obtain FDA approval to treat a rare form of blindness. This innovative device has helped hundreds of profoundly blind patients to achieve meaningful visual perception. Cortigent's next generation investigational system, the Orion® Visual Cortical Prosthesis System, has been designed to treat blindness caused by common conditions including glaucoma and diabetic retinopathy. Orion has an FDA Breakthrough Device designation, completed a 6-year Early Feasibility Study in 2025 with promising safety and efficacy results and is covered by an extensive intellectual property estate. Cortigent is also applying its precision neurostimulation technology to improving recovery of arm and hand motion in patients with paralysis due to stroke. For more information and patient videos, please visit: www.cortigent.com.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and improving patient tolerance to their medication. Vivani is developing a portfolio of GLP-1 based implants for metabolic diseases including obesity and type 2 diabetes. These NanoPortal implants are designed to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the numerous challenges associated with the daily or weekly administration of orals and injectables, including tolerability issues and loss of efficacy. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills. For more information, please visit: www.vivani.com.

Forward-Looking Statements

This press release contains certain “forward-looking statements” within the meaning of the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “target,” “believe,” “expect,” “will,” “may,” “anticipate,” “estimate,” “would,” “positioned,” “future,” and other similar expressions that are used in this press release, including statements regarding Vivani’s business, products in development, including the therapeutic potential thereof, the planned development thereof, Vivani’s plans with respect to Cortigent and its technology, strategy, cash position and financial runway. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Vivani’s current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vivani’s control. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks that the spin-off will not be completed in a timely manner or at all; risks of failure to satisfy any conditions to the spin-off; risks of failure of the spin-off to qualify for non-recognition of gain or loss for U.S. federal income tax purposes; uncertainty of whether the anticipated benefits of the spin-off can be achieved; risks of unexpected costs or delays; and risks and uncertainties associated with the development and commercialization of products and product candidates that may impact or alter anticipated business plans, strategies and objectives. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to market conditions and the ability of Cortigent to complete its spin-off, Cortigent’s history of losses and its ability to access additional capital or otherwise fund its business and advance its product candidates and pre-clinical programs. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. There may be additional risks that the Company or Cortigent consider immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 31, 2025, as updated by the Company’s subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by Vivani in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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