

May 29, 2025



# Vivani Medical Announces Filing of Form 10 Registration Statement for Planned Spin-Off of Cortigent Neurostimulation Business to Vivani Shareholders

*Transaction is anticipated to be completed in third quarter 2025*

*Planned Cortigent Nasdaq listing intended to drive value for Vivani and Cortigent stockholders*

*Cortigent is developing the Orion<sup>®</sup> Visual Cortical Prosthesis System to provide meaningful visual perception to people who are blind*

*Cortigent is developing the Stroke Recovery System to improve the recovery of arm and hand movement in people who have suffered paralysis due to stroke*

*Spin-off will allow Vivani to focus on its continued development of miniature, ultra long-acting GLP-1 implants for chronic weight management and type 2 diabetes with annual or bi-annual dosing*

ALAMEDA, Calif., May 29, 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 Cortigent, Inc. ("Cortigent"), a wholly owned subsidiary of the Company that develops brain implant devices to help patients recover critical body functions, has filed a Form 10 registration statement with the U.S. Securities and Exchange Commission ("SEC") to spin off Cortigent as an independent, publicly traded Nasdaq company in third quarter 2025. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise.

"Filing the Form 10 registration statement is an important milestone in our journey to establish Cortigent as an independent, publicly traded company dedicated to advancing its pioneering neurostimulation technology," said Vivani Chief Executive Officer Adam Mendelsohn, Ph.D. "Elon Musk's Neuralink Corp. has brought renewed excitement to the brain implant field, having commenced a six-year Early Feasibility Study of its brain computer interface device in paralyzed patients last year, which study is expected to be complete in 2031. The Orion Visual Cortical Prosthesis System has a U.S. Food and Drug Administration ("FDA") Breakthrough Device designation and completed a six-year Early Feasibility Study in March 2025, with promising safety and efficacy results. Cortigent's proven technology platform also achieved the first and only FDA authorization (under a

Humanitarian Device Exemption) for an artificial vision device. This remarkable device, called the Argus II<sup>®</sup>, was marketed for a rare form of blindness and implanted in hundreds of patients. Establishing Cortigent as an independent public company on Nasdaq will allow Vivani to be fully focused on leveraging our proprietary NanoPortal<sup>™</sup> drug implant technology and advance the development of our portfolio of miniature, subdermal GLP-1 implants with annual or bi-annual dosing for chronic weight management, type 2 diabetes, and other chronic diseases.”

“Our plan for Cortigent to trade as an independent public company on Nasdaq will best position Cortigent to accelerate development of the Orion Visual Cortical Prosthesis System and the Stroke Recovery System,” said Cortigent Chief Executive Officer Jonathan Adams, MBA. “After successfully completing an Early Feasibility Study of Orion in 2025, which is our latest brain implant device for artificial vision, Cortigent is preparing for a pivotal trial of this breakthrough technology. We will advance clinical evaluation of Orion for commercialization and study applying our precision neurostimulation technology to a device for the recovery of arm and hand movement after paralysis due to stroke. We are confident that the important proprietary technology that underpins our platform will also allow us to address other critical unmet medical needs.”

Adams has served as Cortigent’s CEO since 2023, and prior to joining Cortigent, he founded and was CEO of BioVie Inc., a Nasdaq-listed biopharmaceutical company. He has 35 years of experience in the biopharmaceutical field and with medical devices including technology commercialization, financial management, operations, marketing and sales, and has assisted in the launch of dozens of new drugs and medical devices. Cortigent will continue to be headquartered in the Los Angeles area.

Vivani previously announced the submission of a Form S-1 registration statement to support an Initial Public Offering of Cortigent and revised its strategy to file a Form 10 registration statement with the SEC, enabling the spin-off of Cortigent into a separate, publicly traded Nasdaq company subject to listing and regulatory requirements. This approach will allow Vivani stockholders to directly participate in Cortigent’s future and enable Vivani to focus exclusively on the development of NanoPortal drug implants.

Vivani believes the spin-off of Cortigent will result in two distinct companies that will:

- focus on and pursue strategic priorities specific to their core commercial therapies and pipeline assets;
- benefit from separate capital structures and capital allocation strategies;
- achieve additional operating efficiencies consistent with their respective long-term strategic objectives; and
- respond more quickly to the rapidly changing developments and global opportunities in their respective patient markets.

The spin-off of Cortigent is expected to provide investors with greater visibility into the financial and operational structures of Vivani and Cortigent and a clearer understanding of their respective strategies and risks. Vivani believes creating two stand-alone companies, with dedicated and talented management teams, will provide the necessary foundation for long term value creation for each business.

Vivani's board of directors has authorized management to proceed with a plan to spin off its Cortigent neuromodulation business. The spin-off is planned to be completed during third quarter 2025 or otherwise in 2025, subject to the satisfaction of certain conditions, including, among others, final approval of Vivani's board of directors, receipt of a favorable opinion that the transaction will qualify for non-recognition of gain or loss, as a result of receipt of Cortigent shares, for U.S. Federal Income Tax purposes, and SEC and Nasdaq approval. 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](http://www.think-equity.com).

### **About Cortigent, Inc.**

Cortigent, Inc., formerly Second Sight Medical Products and a wholly owned subsidiary of Vivani, is developing brain implant devices to help people recover critical body functions. Cortigent is a global leader in precision neurostimulation technology that provides meaningful visual perception ("artificial vision") for blind people. Cortigent previously marketed the Argus II, the first and only artificial vision device approved by the FDA, to treat a rare form of blindness. The Argus II has helped hundreds of profoundly blind people to achieve meaningful visual perception. Cortigent's next generation investigational system, the *Orion Visual Cortical Prosthesis System*, has been designed to treat blindness due to glaucoma, diabetic retinopathy, and other common causes. Orion has an FDA Breakthrough Device designation and completed a six-year Early Feasibility Study in 2025 with encouraging safety and efficacy results. Cortigent's platform technology combines advanced neuroscience with proprietary microelectronics, software, and data processing capabilities to create medical devices for alleviating serious medical conditions that cannot be treated with drugs. It is protected by an extensive intellectual property estate. Cortigent is also applying its core precision neurostimulation technology to the recovery of arm and hand motion in paralysis due to stroke by its Stroke Recovery System. For more information and patient videos, please visit: [www.cortigent.com](http://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 potentially to improve patient tolerance to their medication. Vivani's lead program, NPM-115, is a six-month, subdermal, GLP-1 (exenatide) implant under development for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline includes NPM-139 (semaglutide implant), which is also under development for chronic weight management. The semaglutide implant has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's six-month, subdermal, GLP-1 (exenatide) implant under development for the treatment of 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 challenges associated with the daily or weekly administration of orals and injectables. 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. Medication non-adherence, which contributes to more than \$500 billion in annual avoidable healthcare costs and 125,000 potentially preventable deaths annually in the U.S. alone, is a primary and

daunting reason obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments, face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over 50 new molecular entities under clinical stage development, Vivani is confident that its highly differentiated portfolio of miniature long-acting GLP-1 implants have the potential to provide an attractive therapeutic option for patients, prescribers and payers. For more information, please visit: [www.vivani.com](http://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,” “planned,” “positioned,” “potential,” “future,” “allow,” “intended” and other similar expressions that are in this press release, including statements regarding Vivani’s business, products in development, including the therapeutic potential thereof, the planned development therefor, the completion of the LIBERATE-1<sup>™</sup> trial and reporting of trial results, Vivani’s development plans for Vivani’s products, including NPM-115, NPM-139, NPM-119 or Vivani’s plans with respect to Cortigent and its proposed spin-off, 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. 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. Because forward-looking statements relate to the future, they are subject to additional inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vivani’s control. 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 the development and commercialization of Vivani’s products, including NPM-115, NPM-139, NPM-119; delays and changes in the development of Vivani’s products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct Vivani’s development activities; risks related to the initiation, enrollment and conduct of Vivani’s planned clinical trials and the results therefrom; Vivani’s history of losses and Vivani’s ability to access additional capital or otherwise fund Vivani’s business; market conditions and the ability of Cortigent to complete its spin-off, Cortigent’s history of losses and Cortigent’s ability to access additional capital or otherwise fund Cortigent’s 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 and 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 SEC on March 31, 2025, as updated by the Company's subsequent Quarterly Reports on Form 10-Q and in other reports that the Company has filed with the SEC. Any forward-looking statements made by Vivani or Cortigent in this press release are based only on information currently available to the Company and Cortigent and assumptions that Vivani and Cortigent believe to be reasonable. Any forward-looking statement speaks only as of the date on which it is made. Neither the Company nor Cortigent undertake any 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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Source: Vivani Medical, Inc.