

Vivani Medical Announces Intent to Spin Off Cortigent Neurostimulation Business

Planned Cortigent Nasdaq listing intended to drive value for Vivani and Cortigent shareholders

Cortigent's Orion[®] artificial vision system, which is in development to treat blindness, completed an initial 6-year clinical study in 2024, with encouraging safety and efficacy results

Formerly Second Sight Medical Products, Cortigent achieved the first and only FDA authorization (under a Humanitarian Device Exemption) for an artificial vision device called the Argus[®] II, which was marketed for a rare form of blindness and implanted in hundreds of patients

Cortigent's precision neurostimulation technology is also being developed for the recovery of arm and hand motion in paralysis due to stroke

Spin-off will allow Vivani to focus on developing miniature, ultra long-acting GLP-1 implants for chronic weight management and type 2 diabetes with once or twice-yearly administration

ALAMEDA, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (NASDAQ: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra long-acting drug implants, today announced that it intends to spin off Cortigent, Inc., a division that develops brain implant devices to help people recover critical body functions, as an independent publicly-traded company. 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.

"Since the merger of legacy companies Nano Precision Medical and Second Sight Medical Products in August 2023, and the formation of Cortigent, we have been committed to identifying and pursuing strategic options to advance Cortigent's pioneering technology. We expect that Cortigent will continue to be a leader in discovering, developing, and commercializing innovative therapies for vision, stroke recovery and other critical body functions that can benefit from neurostimulation technology," said Vivani Chief Executive Officer Adam Mendelsohn, Ph.D. "We believe that the best way to realize the full potential of Cortigent is to enable it to operate independently with a management team dedicated to advancing its proprietary neuromodulation technology and developing medical devices that address human conditions where there is significant unmet medical need. Our mission at Vivani remains unchanged as we continue to leverage our proprietary NanoPortal™ implant technology and advance the development of our portfolio of miniature, subdermal GLP-1 implants with once or twice-yearly dosing for chronic weight management, type 2 diabetes,

and other chronic diseases."

"Today's announcement is a major milestone for Cortigent," said Cortigent Chief Executive Officer Jonathan Adams, MBA. "As an independent company, we will intensify our efforts to develop and commercialize life-changing medical devices for people with critical unmet medical needs such as blindness, paralysis due to stroke, and potentially other conditions."

Adams has served as Cortigent's CEO since 2023 and will retain that position after the spinoff. Prior to joining Cortigent, he founded and was CEO of the biopharma company BioVie Inc., which listed on the Nasdaq Global Market in 2020. He has 35 years of experience in biopharma and 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 has now revised its strategy to file a Form 10 registration statement with the U.S. Securities and Exchange Commission ("SEC"), enabling the spin-off of Cortigent into a fully independent, publicly traded company subject to listing and regulatory requirements. This approach will allow Vivani shareholders 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 is expected to provide investors with greater visibility into the financial and operational structures of each company and a clearer understanding of their respective strategies. 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 company.

There is significant interest in neurostimulation technology, driven in part by companies like Elon Musk's Neuralink, with the global neurostimulation market experiencing substantial growth driven by rising prevalence of chronic diseases and advancements in technology increasing regulatory approvals for innovative neurostimulator devices. Vivani believes it is in the best interest of shareholders to spin off Cortigent into an independently operated, publicly traded company to deliver enhanced value to Vivani and Cortigent shareholders.

Cortigent is a global leader in precision neurostimulation technology that seeks to provide meaningful visual perception ("artificial vision") for blind people. This involves implanting a micro-electrode array on the surface of the brain (cortex) to deliver finely tuned electrical pulses to neuron bundles to elicit spots of light called phosphenes. The company proved its U.S. Food and Drug Administration ("FDA") regulatory and CMS reimbursement capabilities

when it commercialized, under a Humanitarian Device Exemption, the Argus II[®] Retinal Prosthesis System, the first and only artificial vision device authorized by the FDA to treat a rare form of blindness called retinitis pigmentosa. The Argus[®] II has helped hundreds of profoundly blind people to achieve meaningful visual perception. Based on Cortigent's next generation platform, which is protected by an extensive intellectual property estate, the Orion[®] Cortical Visual Prothesis System has been designed to treat blindness due to glaucoma, diabetic retinopathy, and other common causes. Orion has an FDA Breakthrough Device designation and in 2024 completed a 6-year Early Feasibility Study with encouraging safety and efficacy results. The company's core precision neurostimulation technology is being leveraged for other indications including the recovery of arm and hand motion in paralysis due to stroke.

Vivani's board of directors has authorized management to proceed with a plan to spin off its Cortigent neuromodulation business and Vivani is expected to provide certain transition services. The spin-off is planned to be completed during or prior to Q3 2025, subject to the satisfaction of certain conditions, including, among others, final approval of Vivani's board of directors, receipt of a favorable opinion with respect to the tax-free nature of the transaction, and regulatory and Nasdaq approval. The spin-off is expected to be accomplished by distribution of the requisite number of shares of the new publicly traded company to Vivani stockholders that would result in a transaction intended to be tax-free for U.S. federal income tax purposes.

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

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, has been designed to treat blindness due to glaucoma, diabetic retinopathy, and other common causes. Orion has an FDA Breakthrough Device designation and in 2024, completed a 6-year Early Feasibility Study 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. 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 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 sixmonth, 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 nonadherence, 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 remains 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.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. Forwardlooking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "planned," "positioned," "future," and other similar expressions that 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 trial and reporting of trial results, Vivani's emerging development plans for 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 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 as a tax-free transaction 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 forwardlooking statements include, among others, risks related to the development and

commercialization of Vivani's products, including NPM-115, NPM-139 and 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. 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 considers 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 ("SEC") filed on March 26, 2024, 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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250311539715/en/

Company Contact: Donald Dwyer Chief Business Officer info@vivani.com (415) 506-8462

Investor Relations Contact: Jami Taylor Investor Relations Advisor investors@vivani.com (415) 506-8462

Media Contact:
Sean Leous
ICR Healthcare
Sean.Leous@icrhealthcare.com
(646) 866-4012

Source: Vivani Medical, Inc.