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): March 13, 2025 (March 12, 2025)

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

Delaware	**001-36747**	**02-0692322**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 2.02 Results of Operations and Financial Condition.

Vivani Medical, Inc. (the "Company") is disclosing selected preliminary financial information for the year ended December 31, 2024 The Company had approximately $18.4 million (unaudited) in cash and cash equivalents, excluding restricted cash, as of December 31, 2024.

The above information is preliminary financial information for the year ended December 31, 2024 and may change, and were prepared by the Company's management, based upon its estimates, a number of assumptions and currently available information, and are subject to revision based upon, among other things, quarter and year-end closing procedures and/or adjustments, the completion of the Company's consolidated financial statements and other operational procedures. This preliminary financial information is the responsibility of management and has been prepared in good faith on a consistent basis with prior periods. However, the Company has not completed its financial closing procedures for the year ended December 31, 2024, and its actual results could be materially different from this preliminary financial information, which preliminary information should not be regarded as a representation by the Company or its management as to its actual results for the year ended December 31, 2024. In addition, BPM, LLP, the Company's independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial information and does not express an opinion or any other form of assurance with respect to this preliminary financial information. During the course of the preparation of the Company's financial statements and related notes as of and for the year ended December 31, 2024, the Company may identify items that would require it to make material adjustments to this preliminary financial information. As a result, prospective investors should exercise caution in relying on this information and should not draw any inferences from this information. This preliminary financial information should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles and reviewed by the Company's auditors.

Item 7.01 Regulation FD Disclosure.

Spin off Announcement

On March 12, 2025, the Company issued a press release titled "*Vivani Medical Announces Intent to Spin Off Cortigent Neurostimulation Business*." A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

LIBERATE-1 Clinical Trial Announcement

On March 13, 2025, the Company issued a press release titled "*Vivani Medical Achieves First Implant and Full Enrollment in the First-in-Human Clinical Trial of GLP-1 Implant NPM-115 in Obese or Overweight Adults*." A copy of the press release in connection with the announcement is being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

The information included in Item 2.02 is incorporated herein by reference.

On March 12, 2025, the Company announced it intends to pursue a spin-off Cortigent, Inc., a Delaware corporation ("Cortigent") and the Company's wholly-owned subsidiary, with such spin-off transaction planned to be completed by mid-2025, subject to the satisfaction of certain conditions. And, on March 13, 2025, the Company announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1™ clinical trial and announced full enrollment in the LIBERATE-1 study, reaffirming previous estimates that top-line results should be available mid-2025.

Spin off Announcement Press Release

The Company 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.

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.

The Company’s board of directors has authorized management to proceed with a plan to spin off its Cortigent neuromodulation business and the Company 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 the Company’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 the Company’s stockholders that would result in a transaction intended to be tax-free for U.S. federal income tax purposes.

ThinkEquity LLC is acting as the exclusive financial advisor to Cortigent, Inc. with respect to the spin-off transaction.

Implant in the LIBERATE-1 Clinical Trial Press Release

The Company has announced a successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1™ clinical trial. This milestone marks a critical step toward addressing one of healthcare’s most pressing challenges: medication adherence in metabolic diseases including chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant and reaffirming previous estimates that top-line results should be available in mid-2025.

The LIBERATE-1 study is exploring the full pharmacokinetic profile of NPM-115, which has demonstrated consistently smooth and minimally fluctuating drug release both *in vitro* and in animal models. Successful translation to humans is expected to ultimately demonstrate greater effectiveness and tolerability in otherwise poorly adherent patients, potentially providing a transformative option for chronic weight management patients. The Company also expects these results to support the potential application of a GLP-1 (exenatide) implant in the treatment of type 2 diabetes and other diseases for which GLP-1 treatment has demonstrated, or will demonstrate, clinical benefit.

Forward-Looking Statements

This Current Report on Form 8-K contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US 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," "future," and other similar expressions that in this press release, including statements regarding the Company'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, the Company's emerging development plans for NPM-115, NPM-139, NPM-119 or the Company'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 the Company'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 the Company'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 the Company's products, including NPM-115, NPM-139 and NPM-119; delays and changes in the development of the Company's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct the Company's development activities; risks related to the initiation, enrollment and conduct of the Company's planned clinical trials and the results therefrom; the Company's history of losses and the Company's ability to access additional capital or otherwise fund the Company'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 the Company in this Current Report on Form 8-K 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Vivani Medical, Inc. onMarch 12, 2025.
99.2	Press release issued by Vivani Medical, Inc. onMarch 13, 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: March 13, 2025

By: /s/ Brigid A. Makes
Name: Brigid A. Makes
Title: Chief Financial Officer

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, completedan 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 forchronic 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 spin- off. 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.

ThinkEquity LLC 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., 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 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 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. Forward- looking 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 forward- looking 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.

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Vivani Medical Achieves First Implant and Full Enrollment in the First-in-Human Clinical Trial of GLP-1 Implant NPM-115 in Obese or Overweight Adults

Miniature, twice-yearly GLP-1 (exenatide) implant under development for chronic weight management

NPM-115 has demonstrated comparable preclinical weight loss to injections of semaglutide, the active ingredient in Ozempic®/Wegovy®

Rapid full study enrollment with all 24 subjects initiating the 8-week run-in period within four weeks; top-line study results expected in mid-2025

Investor conference call today at 8:30 a.m. ET

ALAMEDA, Calif., March 13, 2025 -- (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 the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1™ clinical trial. This milestone marks a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in metabolic diseases including chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant and reaffirming previous estimates that top-line results should be available in mid-2025.

"We are excited to report that the first dose of the NPM-115 implant was successful. The insertion was well tolerated by the subject. Combined with the achievement of full enrollment in the study, this represents important progress in advancing our GLP-1 implant through clinical development," said Vivani Chief Executive Officer Adam Mendelsohn, Ph.D. "With obesity affecting more than one billion people globally, our implants could redefine treatment paradigms by providing a convenient therapeutic alternative with significantly reduced dosing frequency compared to daily orals and weekly injectables.

"We also believe our innovative NanoPortal™ platform technology could improve medication adherence and thereby significantly improve patient outcomes," explained Dr. Mendelsohn. "About half of people regularly miss doses as indicated by real-world medication adherence data. Missed doses not only lead to suboptimal efficacy but can also exacerbate tolerability issues. In fact, manufacturers of marketed, weekly injectable GLP-1 products recommend that a patient consider reinitiating GLP-1 therapy at the initial starting dose if two doses or more are missed, to avoid tolerability issues associated with rapid increases in GLP-1 exposure levels. We believe our miniature, ultra long-acting implants, designed to improve medication adherence, have the potential to improve efficacy and minimize tolerability issues."

The LIBERATE-1 study is exploring the full pharmacokinetic profile of NPM-115, which has demonstrated consistently smooth and minimally fluctuating drug release both *in vitro* and in animal models. Successful translation to humans is expected to ultimately demonstrate greater effectiveness and tolerability in otherwise poorly adherent patients, potentially providing a transformative option for chronic weight management patients. Vivani also expects these results to support the potential application of a GLP-1 (exenatide) implant in the treatment of type 2 diabetes and other diseases for which GLP-1 treatment has demonstrated, or will demonstrate, clinical benefit.

Investor Conference Call and Webcast
Vivani will host an investor conference call and webcast today at 8:30 a.m. ET to discuss today's announcements further. Participants can access the conference call toll-free at 1 (800) 715-9871, conference ID 1177627, or join via webcast at the following link: https://edge.media-server.com/mmc/p/2x6ivwcs. Following the live event, an archived version of the webcast will be available on the Investors page of the Vivani corporate website.

Bydureon BCise® is a registered trademark under license by AstraZeneca.
Ozempic® and Wegovy® are registered trademarks of Novo Nordisk A/S.

About LIBERATE-1

LIBERATE-1 is a Phase 1, first-in-human study of a miniature, ultra long-acting GLP-1 (exenatide) implant to investigate the safety, tolerability, and full pharmacokinetic profile in obese or overweight subjects. The trial will enroll participants who are intended to be titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (NPM-115, n=8), weekly exenatide injections (Bydureon BCise®, n=8), or weekly 1 mg semaglutide injections (Wegovy®, n=8) for a 9-week treatment duration. Changes in weight will be measured. The study is currently on-going at two study centers in Australia and is fully enrolled. Top-line data from the study is anticipated to be available in mid-2025.

Vivani has successfully utilized research and development rebates from the Australian government for relevant 2024 expenses to defray a portion of the costs from this clinical trial and anticipates being able to utilize similar rebates going forward. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines, data generated in Australia generally are acceptable to the U.S. Food and Drug Administration and other regulatory authorities. Vivani anticipates use of relevant clinical data generated in Australia to support regulatory submissions in other geographies including the United States. Additional guidance regarding future regulatory submissions will be provided as new information becomes available.

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 why 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. 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 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 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. 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, 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 intended spin-off from the Company. 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 filed on March 26, 2024, 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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