

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): April 12, 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.

On April 12, 2025, Vivani Medical, Inc. (the “Company”) entered into an amendment to that certain License and Supply Agreement with Okava Pharmaceuticals, Inc. (“Okava”) to expand the Company’s ongoing collaboration with Okava to include dogs in the development of OKV-119, a long-acting GLP-1 therapy for weight management, diabetes and other cardiometabolic conditions (the “Okava Collaboration”). On April 15, 2025, the Company and Okava jointly issued a press release titled “*Vivani Medical and Okava Expand Collaboration to Develop OKV-119 for Dogs, Targeting Metabolic Health and Longevity*” in relation to the Okava Collaboration. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued April 15, 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: April 15, 2025

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

Vivani Medical and Okava Expand Collaboration to Develop OKV-119 for Dogs, Targeting Metabolic Health and Longevity

Over half of all dogs in the United States today are overweight or obese, placing them at increased risk for chronic diseases, metabolic decline and shortened lifespans

ALAMEDA, Calif. and SAN FRANCISCO, Calif. — April 15, 2025 — Vivani Medical, Inc. (NASDAQ: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra long-acting drug implants, and Okava Pharmaceuticals, Inc. ("Okava"), a clinical-stage company focused on diseases of aging in dogs and cats, today announced an expansion of their collaboration to include dogs in the development of OKV-119, a long-acting GLP-1 therapy for weight management, diabetes and other cardiometabolic conditions. Vivani and Okava initiated their collaboration in 2019, with a focus on developing OKV-119 for cardiometabolic conditions in cats.

OKV-119 leverages Vivani's proprietary NanoPortal™ technology, which provides smooth and steady delivery of therapeutic molecules, including GLP-1 receptor agonists, over extended periods from a single implant. According to Okava, dosing every six months or longer supports a "One-and-Done" approach between office visits consistent with the product profile of Vivani's NPM-115, an ultra long-acting GLP-1 implant in clinical stage development to improve medication adherence and tolerability for the treatment of chronic weight management in humans.

"Caloric restriction, or fasting, is one of the most well-established interventions for extending the lifespan and improving metabolic health in dogs," said Okava CEO Michael Klotsman, PhD, MBA. "But it is also one of the hardest to maintain. OKV-119 mimics many of the physiological effects of fasting—improved insulin sensitivity, reduced fat mass and more efficient energy metabolism—without requiring significant changes in feeding routines or disrupting the human-animal bond that often centers around food."

Over half of all dogs in the United States today are overweight or obese, placing them at increased risk for chronic disease, metabolic decline and shortened lifespans. Similar to the changes humans face as they grow older, aging dogs experience declines in metabolic fitness, leading to weight gain, insulin resistance and loss of muscle mass. Research shows that leaner dogs can live more than two years longer than their heavier counterparts. By restoring and maintaining a healthy metabolism through a single, long-acting dose, OKV-119 has the potential to enhance quality of life, promote healthy aging and become the most impactful life-extending therapy available for dogs.

"This collaboration aligns with Vivani's broader mission to develop innovative medicines that will revolutionize the treatment of chronic diseases by leveraging proprietary drug delivery technologies," said Vivani CEO Adam Mendelsohn, PhD. "This expanded partnership with Okava reflects our shared confidence in the potential of NanoPortal technology to serve a broad array of prospective beneficiaries in the management of metabolic disease. The structure of this expanded partnership minimizes costs and risks for Vivani while integrating upside potential for Vivani shareholders through future milestone payments and royalties. Together with Okava, we are broadening the reach of our technology, meeting unmet needs in veterinary medicine while positioning Vivani to capture future value within an industry segment experiencing continued and unprecedented growth."

Financial terms of the expanded agreement were not disclosed.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal platform, Vivani develops therapeutic 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 programs, NPM-139 (semaglutide implant) and NPM-115 (exenatide implant), are miniature, subdermal GLP-1 implants under development for chronic weight management in obese or overweight individuals designed for once or twice-yearly administration. Vivani's emerging pipeline also includes NPM-119, which refers to the Company's six-month, subdermal, GLP-1 (exenatide implant) under development for the treatment of type 2 diabetes. Development of a semaglutide implant for the treatment of type 2 diabetes is also under consideration. These NanoPortal implants are designed to provide patients with the opportunity to experience the full potential benefit of their medication by avoiding the challenges associated with the daily or weekly administration of oral and injectable medications.

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, ultra 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.

About Okava Pharmaceuticals, Inc.

OKAVA is a clinical-stage research and development company that develops new treatment options for dogs and cats suffering from chronic diseases of aging. OKAVA is building a portfolio of products to transform and humanize standards of care in veterinary medicine. By harnessing human technologies for the treatment of common diseases in household pets, the company has the potential of increasing the lifespans of dogs and cats by an average of 1 to 3 years. OKAVA is a private company headquartered in San Francisco, California. For more information, see www.okava.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,” “future,” “believe,” “expect,” “will,” “may,” “anticipate,” “estimate,” “would,” “positioned,” 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 thereof, the completion of the ongoing clinical trial and reporting of trial results, Vivani’s emerging development plans for its products, Vivani’s collaboration agreement with Okava, and Vivani’s 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; 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 SEC filed 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.

Vivani Contacts:

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

Okava Contacts:

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