November 14, 2023

# Vivani Medical Provides Business Update and Reports Third Quarter Financial Results

*Company announces addition of NPM-115 (high-dose exenatide implant) to its emerging pipeline, a potential alternative to life-long injections or pills for long-term GLP-1 therapy for the treatment of chronic weight management in obese or overweight patients*

*Vivani is actively engaged in discussions with the US FDA to enable the expeditious initiation of LIBERATE-1, proposed FIH study of NPM-119 in patients with type 2 diabetes; in parallel the Company also plans to submit application to support initiation of the FIH study in Australia*

ALAMEDA, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, preclinical-stage biopharmaceutical company developing novel, long-term drug implants, today reported financial results for the third quarter of 2023 and provided a business update.

Vivani™ continues to advance its emerging pipeline of innovative, highly differentiated drug implants leveraging its proprietary NanoPortal™ subdermal implant technology designed to guarantee medication adherence and improve patient outcomes in the treatment of chronic diseases.

"At Vivani, we continue to make progress in the development of our pipeline of miniature, long-term drug implants designed to improve the treatment of chronic diseases including obesity and type 2 diabetes." said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "We are excited to announce the addition of NPM-115 (high-dose exenatide implant) under development for the treatment of chronic weight management in obese or overweight patients to our emerging portfolio. Although the initial focus of our exenatide implant has been for the treatment of type 2 diabetes, the implant was associated with ~16.6% lower weight than a vehicle control implant and the weight loss was substantially maintained throughout the full 16-week treatment period in non-obese Sprague-Dawley rats. This result is consistent with the magnitude of weight loss reported in the literature from a separate study that administered semaglutide, the drug substance in blockbuster products Ozempic®, Wegovy®, and Rybelsus®, in the same animal model. We believe that NanoPortal has the potential to both address the medication adherence challenges associated with the currently marketed exenatide products and provide higher, more efficacious dosing, thereby enabling patients to receive exenatide's maximum potential benefits in both clinical and real-world settings. Given the extraordinary adoption of GLP-1 products for the treatment of obesity, Vivani intends to emphasize NPM-115 and advance the program towards human testing."

Dr. Mendelsohn continued: “Regarding NPM-119 (6-month exenatide implant) under development for the treatment of type 2 diabetes, Vivani remains actively engaged in discussions with the FDA as part of our efforts to lift the clinical hold, which is exclusively related to outstanding CMC information requests, and enable the expeditious initiation of LIBERATE-1, our First-In-Human (“FIH”) study in patients with type 2 diabetes. In addition, we are announcing parallel plans to pursue the initiation of the FIH study in Australia. Lastly, we continue to make steady progress with NPM-139, another promising treatment for obesity with the added potential for a once-yearly treatment duration.”

**Third Quarter Business Highlights**

Vivani is announcing the addition of NPM-115 (high-dose exenatide implant) under development for chronic weight management in obese or overweight patients to its emerging pipeline. Preliminary evidence suggests NPM-115, if successful, may provide another competitive GLP-1 monotherapy treatment option with potential advantages associated with improved medication adherence and tolerability. In addition, NPM-115 may provide an attractive alternative to life-long injections or pills for long-term maintenance of GLP-1 therapy for chronic weight management.

On July 14, 2023, the Company submitted an Investigational New Drug application to the U.S. Food and Drug Administration (FDA) for the proposed NPM-119 FIH study LIBERATE-1 in patients with type 2 diabetes.

On August 18, 2023, the FDA provided written notification that the LIBERATE-1 study was on full clinical hold exclusively because of insufficient Chemistry, Manufacturing, and Controls (“CMC”) information to assess the risk to human subjects. Vivani remains actively engaged in discussions with the FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1.

In parallel, Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of the Company’s FIH study in that country. If available, Vivani intends to utilize research and development incentives and rebates from the Australian government in order to defray a portion of the costs from the trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines and data generated in Australia are acceptable to the FDA and other regulatory authorities, Vivani plans to use relevant clinical data generated in Australia to support regulatory submissions in other geographies including the US. Additional guidance will be provided as new information becomes available.

LIBERATE-1 is a randomized, 12-week investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119 (GLP-1) implant in patients with type 2 diabetes. LIBERATE-1 will enroll patients who have been on a GLP-1 therapy, which will be discontinued prior to receiving either NPM-119 or the active comparator Bydureon BCise® (exenatide extended-release injectable suspension 2mg).

On July 6, 2023, Vivani changed its state of incorporation from the State of California to the State of Delaware by means of a plan of conversion, effective July 5, 2023. The reincorporation, including the principal terms of the plan of conversion, was submitted to a vote of, and approved by Vivani’s stockholders at its 2023 Annual Meeting of Stockholders held on June 15, 2023.

Moving forward, Vivani will focus on the further development of NPM-119, NPM-115 and its emerging pipeline of innovative, miniature, long-term drug implants to treat patients with chronic diseases. Vivani has grown to 36 full-time employees, which does not include the 14 Cortigent employees of whom some have been furloughed, and Vivani's new headquarters are in Alameda, California.

**Third Quarter ended September 30, 2023, Financial Results**

*Cash Balance:* As of September 30, 2023, Vivani had cash, cash equivalents and restricted cash totaling $26.2 million compared to $46.4 million as of December 31, 2022. The decrease of $20.2 million is attributed to the $19.6 million operating loss plus a net increase in net operating assets of $3.0 million, offset partially by $2.4 million of non-cash charges. The Company believes its cash and cash equivalents as of September 30, 2023, are estimated to be sufficient to fund operations into early 2025.

*Research and development expense.* Research and development expense increased by $0.5 million, or 15%, to $4.4 million in the third quarter of 2023 from $3.9 million in the third quarter of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the quarter by $0.3 million. The remainder of the increase was primarily due to drug implant development costs.

*General and administrative expense.* General and administrative expense increased $1.1 million, or 71%, to $2.7 million in the third quarter of 2023 from $1.6 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $0.6 million in the third quarter of 2023 versus the partial quarter of 2022 which only included one month from the merger date, higher costs associated with being a public company for D&O insurance and professional fees, and higher payroll related expenses.

*Other income (expense).* Other income was impacted by the merger acquisition of cash which increased our interest income to $0.4 million for the three months ended September 30, 2023. The quarter ended September 30, 2022 was impacted by the gain on bargain purchase of $6.9 million recorded on the purchase of Second Sight at the time of the merger.

*Net Loss:* The net loss was $6.8 million as compared to net income of $1.4 million for the three-months ended September 30, 2023, and 2022, respectively. The $8.2 million change in net loss/income was primarily attributable to the bargain purchase gain of $6.9 million recorded on the purchase of Second Sight and by a $1.0 million increase from the inclusion of Cortigent expenses which were not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

**Year to Date September 30, 2023, Financial Results**

*Research and development expense.* Research and development expense increased by $2.6 million, or 26%, to $12.3 million in the first nine months of 2023 from $9.7 million in the same period of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the period by $1.4 million. The remainder of the increase was

primarily due to drug implants development costs and increased payroll related costs.

*General and administrative expense.* General and administrative expense increased $4.8 million, or 129%, to $8.5 million in the first nine months of 2023 from $3.7 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $2.7 million in the first nine months of 2023 versus the partial inclusion of one month in 2022 after the merger date, higher public company costs and higher payroll related expenses.

*Other income (expense).* Other income was impacted by the merger acquisition of cash which increased our interest income to $1.1 million for the nine months ended September 30, 2023. The income for the nine months ended September 30, 2022 included $6.9 million for the gain on bargain purchase from the acquisition of Second Sight.

*Net Loss:* The net loss was $19.6 million as compared to $6.6 million for the nine-months ended September 30, 2023, and 2022, respectively. The $13.0 million increase in net loss was primarily attributable to the bargain purchase gain of $6.9 million recorded on the purchase of Second Sight and a $4.3 million increase from the inclusion of Cortigent expenses, which were not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

**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 tolerance to their medication. Vivani's lead programs, NPM-119 and NPM-115, are miniature, six-month, GLP-1 implants in development for the treatment of type 2 diabetes and chronic weight management in obese or overweight patients, respectively. Both NPM-119 and NPM-115 are exenatide based products with a higher-dose associated with NPM-115 for the treatment of chronic weight management in obese or overweight patients. 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.

Vivani's wholly owned subsidiary Cortigent is developing targeted neurostimulation systems intended to help patients recover critical body functions. Investigational devices include Orion®, designed to provide artificial vision to people who are profoundly blind, and a new system intended to accelerate the recovery of arm and hand function in patients who are partially paralyzed due to stroke. The company has developed, manufactured, and marketed an implantable visual prosthetic device, Argus II®, that delivered meaningful visual perception to blind individuals. Vivani continues to assess strategic options for advancing Cortigent's pioneering technology.

**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 our business, products in development, including the therapeutic potential thereof, the planned development therefor, plans to address any requests from the FDA related to the agency’s current clinical hold on NPM-119, the initiation of the LIBERATE-1 trial and reporting of trial results, our emerging development plans for NPM-115, NPM-139, or our plans with respect to Cortigent and its proposed initial public offering, 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 our 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 our 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 our products, including NPM-119 and NPM-115; delays and changes in the development of our products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct our development activities, including our ability to address any requests from the FDA related to LIBERATE-1 and to commence clinical development of NPM-119; risks related to the initiation, enrollment and conduct of our planned clinical trials and the results therefrom; our history of losses and our ability to access additional capital or otherwise fund our business; market conditions and the ability of Cortigent to complete its initial public offering. 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, 2023, as updated by our subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by us 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 MEDICAL, INC.**
**AND SUBSIDIARIES**

**Condensed Consolidated Balance Sheets (unaudited)**
(in thousands, except per share data)

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 24,821 | $ 45,076 |
| Prepaid expenses and other current assets | 5,861 | 2,452 |
| Total current assets | 30,682 | 47,528 |
| Property and equipment, net | 1,134 | 1,182 |
| Right-of-use assets | 20,050 | 779 |
| Restricted cash | 1,366 | 1,366 |
| Deposits and other assets | 87 | 275 |
| Total assets | $ 53,319 | $ 51,130 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,891 | $ 1,177 |
| Accrued expenses | 1,815 | 2,358 |
| Litigation accrual | 1,675 | 1,675 |
| Accrued compensation expense | 676 | 657 |
| Current operating lease liabilities | 1,376 | 955 |
| Total current liabilities | 7,433 | 6,822 |
| Long term operating lease liabilities | 19,679 | — |
| Total liabilities | 27,112 | 6,822 |
| | | |
| Stockholders' equity: | | |
| Preferred stock, par value $0.0001 per share, 10,000 shares authorized; none outstanding | — | — |
| Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 51,025 as of September 30, 2023 and 50,736 as of December 31, 2022, respectively | 5 | 5 |
| Additional paid-in capital | 118,568 | 117,054 |
| Accumulated other comprehensive loss | 46 | 35 |
| Accumulated deficit | (92,412) | (72,786) |
| Total stockholders' equity | 26,207 | 44,308 |
| Total liabilities and stockholders' equity | $ 53,319 | $ 51,130 |

**VIVANI MEDICAL, INC.**
**AND SUBSIDIARIES**

**Condensed Consolidated Statements of Operations (unaudited)**
(in thousands, except per share data)

| | For the Three Months ended September 30, | | For the Nine Months ended September 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Operating expenses: | | | | |
| Research and development, net of grants | $ 4,441 | $ 3,859 | $ 12,260 | $ 9,742 |
| General and administrative | 2,703 | 1,585 | 8,488 | 3,709 |
| Total operating expenses | 7,144 | 5,444 | 20,748 | 13,451 |
| | | | | |
| Loss from operations | (7,144) | (5,444) | (20,748) | (13,451) |
| Other income (expense), net | 362 | 6,867 | 1,122 | 6,846 |
| | | | | |
| Net income/(loss) | $ (6,782) | $ 1,423 | $ (19,626) | $ (6,605) |
| | | | | |
| Net income/(loss) per common share – basic | $ (0.13) | $ 0.04 | $ (0.39) | $ (0.18) |
| | | | | |
| Net income/(loss) per common share – diluted | $ (0.13) | $ 0.04 | $ (0.39) | $ (0.18) |
| | | | | |
| Weighted average common shares outstanding – basic | 50,837 | 37,965 | 50,757 | 37,712 |
| Weighted average common shares outstanding – diluted | 50,837 | 38,477 | 50,757 | 37,712 |

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

Investor Relations Contact:
Brigid A. Makes
Chief Financial Officer
investors@vivani.com
(415) 506-8462

Media Contact:
Sean Leous
ICR Westwicke
Sean.Leous@westwicke.com
(646) 866-4012

Source: Vivani Medical, Inc.