UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ________ to ________

Commission File Number 001-36747

Vivani Medical, Inc.

(*Exact name of registrant as specified in its charter*)

Delaware	**02-0692322**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

1350 S. Loop Road, Alameda, CA 94502
(*Address of principal executive offices, including zip code*)

Registrant's telephone number, including area code: **(415) 506-8462**

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	VANI	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically on its corporate website, if any, every Interactive Data File required to be submitted and pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes☐ No ☒

The aggregate market value of the shares of the registrant's Common Stock held by non-affiliates of the registrant as of June 30, 2024, computed by reference to the closing sales price on the Nasdaq Capital Market on June 30, 2024, was approximately $45.1 million.

As of March 28, 2025, the registrant had 59,242,903 shares of common stock, par value $0.0001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Registrant intends to file a definitive proxy statement pursuant to Regulation 14A with the Securities and Exchange Commission (the "SEC") within 120 days after the end of registrant's fiscal year end of December 31, 2024.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

FORM 10-K

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SUMMARY OF RISK FACTORS

Below is a summary of the principal risk factors related to the Annual Report on Form 10-K (“Form 10-K”) for the fiscal year ended December 31, 2024.

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this Form 10-K. These risks include, but are not limited to, the following:

- We are a clinical stage company with a limited operating history, and have no products approved for commercial sale.
- We are dependent on the successful development, regulatory approval and commercialization of one or more product candidates; there can be no assurance that we may achieve any of these objectives.
- Final marketing approval of NPM-115, NPM-139, NPM-119 or any of our other product candidates by the U.S. Food and Drug Administration (“FDA”) or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.
- We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.
- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing our product candidates, and our clinical development efforts may not yield favorable results.
- The commercial success of our product candidates, if approved, depends upon their market acceptance among physicians, patients, healthcare payors, and the medical community.
- We are subject to a multitude of complex manufacturing challenges and risks, including reliance on third parties, any of which could substantially increase our costs and limit supply of our product candidates.
- We may not be able to adequately protect our proprietary or licensed technology.
- We may infringe the intellectual property rights of others, which may prevent or delay our development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates, if approved.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-K, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the"Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended the ("Exchange Act"). All statements other than statements of historical fact contained in this Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan,", "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- our anticipated operating and financial performance, business plans, and prospects;
- expectations for our products, including anticipated regulatory submissions, study completion, approvals, clinical trial results and other developing data that become available, potential market size, and potential reimbursement pathways;
- the timing and likelihood of, and our ability to obtain and maintain, regulatory clearance of our Investigational New Drug ("IND") applications for and regulatory approval of our product candidates;
- our ability to successfully scale manufacturing operations in a manner that enables us to complete our clinical trials and if our product candidates are approved, to meet commercial demand;
- our ability to create and maintain a pipeline of product candidates;
- our ability to advance any product candidate into, and successfully complete clinical trials;
- our ability to initiate and successfully maintain operations of our subsidiary in Australia, including with respect to studies of our products and product candidates;
- the initiation, timing, design, progress and results of our clinical trials, and our research and development program;
- the success of the business combination on including future capital expenditures, expenses, synergies, economic performance, indebtedness, financial condition, losses, future prospects, business and management strategies for the management, expansion and growth of the combined company's operations and other conditions to the successful synergies of the business combination;
- the lingering impacts from the COVID-19 pandemic and macroeconomic factors that could impact our business, such as supply chain and inflationary pressures, imposition of tariffs, and the effects of military conflicts on the global economy, on our business or operations; and
- the impact of laws and regulations in the United States and foreign countries on various aspects of our operations, including our regulatory and clinical strategy.

Any forward-looking statements in this Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, assumptions and other factors described under the "Risk Factors" section and elsewhere in this Form 10-K, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources**.**

PART I

Item 1. Business

Our Company

Company Overview

Vivani Medical, Inc. (“Vivani,” the “Company,” “we,” “us,” “our” or similar terms) is a clinical stage biopharmaceutical company which develops miniaturized, subdermal drug implants utilizing its proprietary NanoPortal™ technology, which is designed to enable ultra long-acting, near constant-rate delivery of a broad range of medicines to treat chronic diseases. Vivani uses this platform technology to develop and potentially commercialize drug implant candidates, alone or in collaboration with pharmaceutical company partners, to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual’s behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injection) discontinue therapy within the first year of treatment, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, subdermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. In addition, our aim is to minimize fluctuations in patients’ drug levels through the use of our NanoPortal technology, which may improve the tolerability profiles for medicines, including GLP-1 receptor agonists, that produce side effects associated with fluctuating drug levels in the blood.

We believe our emerging portfolio of miniature, ultra long-acting drug implants has the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving patient tolerability to their treatments which has the potential to translate into better health outcomes for patients in the real-world setting. Vivani's lead programs include NPM-115 (high-dose exenatide) and NPM-139 (semaglutide). These miniature, subdermal, GLP-1 implants are under development for chronic weight management in obese and overweight individuals with once or twice-yearly dosing.ent NPM-115, is a miniature, six-month, GLP-1 (high-dose exenatide) implant currently in clinical-stage testing for chronic weight management in obese and overweight individuals. This first-in-human clinical study, also called LIBERATE-1™, is being conducted in Australia and is anticipated to report top-line data in mid-2025. NPM-139, a semaglutide implant, also in development for the treatment of chronic weight management, is currently in preclinical-stage development and has recently generated encouraging preclinical weight loss data. NPM-139 has the added potential benefit of once-yearly dosing.

Other programs include, NPM-119 (exenatide implant) in development for the treatment of type 2 diabetes and OKV-119, another GLP-1 based implant in development for the treatment of cardiometabolic disorders in cats in collaboration with animal health partner Okava Pharmaceuticals, Inc. (“Okava”). Finally, the company is also considering the development of a semaglutide implant for the treatment of type 2 diabetes.

Vivani resulted from the business combination of Second Sight Medical Products, Inc. (“Second Sight”) and Nano Precision Medical, Inc. (“NPM”). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani’s main priority is the further development of its lead programs NPM-115 (exenatide implant) and NPM-139 (semaglutide implant) for chronic weight management in obese or overweight patients with one or more risk factors and further development of the balance of the company’s miniature, ultra long-acting drug implant portfolio. In parallel, Vivani’s management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight aimed at helping patients recover critical body functions.

In December 2022, we contributed our neurostimulation assets from legacy company Second Sight and certain liabilities to Cortigent, Inc. (“Cortigent”), a wholly owned subsidiary of Vivani to advance the Company’s pioneering neurostimulation technology. Cortigent has 5,000,000 shares of common stock outstanding, all owned by Vivani. In March 2023, Vivani announced the filing of a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission (“SEC”) for a proposed initial public offering of Cortigent. In March 2025, Vivani announced a change in strategy to discontinue efforts to pursue a proposed initial public offering and shift focus to file a Form 10 with the SEC to support the spin-off of Cortigent into a fully 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.

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. As part of this change of incorporation the Company established a par value of $0.0001 per share and all periods have been retroactively adjusted to reflect this change. If the spinoff is successful, the loan payable from Cortigent to Vivani would be forgiven.

An Investigational New Drug ("IND") application for NPM-119 (GLP-1 implant) was submitted to the FDA on July 14, 2023, to support the initiation of a first-in-human study of an exenatide implant in patients with type 2 diabetes. On August 18, 2023, FDA provided written notification that the study was on full clinical hold, primarily due to insufficient Chemistry, Manufacturing, and Controls (“CMC”) information to assess the risk to human subjects. After providing additional information to sufficiently address the FDA's requests, the FDA lifted the clinical hold on NPM-119 on June 13, 2024 allowing for the proposed study to proceed. The primary objective of this first-in-human clinical study was to evaluate the safety, tolerability and pharmacokinetics of NPM-119 in type 2 diabetes patients. The initial study design also incorporated Bydureon BCise® (exenatide injection) for comparison purposes.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the “Amendment”) to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the “TFSSA”). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner in which business operations of Cortigent were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, at the discretion of Vivani or after the closing of an initial public offering of Cortigent. If an initial public offering of Cortigent closes, Cortigent has agreed to repay $1,500,000 to Vivani and enter into a five-year promissory note at 5% interest for $2,000,000 in favor of Vivani. Consequently, Vivani will forgive any remaining amounts due by Cortigent. Efforts to support a successful initial public offering of Cortigent ceased in March 2025 and efforts are now focused on a potential spinoff with the filing of a Form 10 registration statement. The TFSSA terminated effective December 31, 2024.

In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia, was established to support studies of our product candidates.

On February 28, 2024, Vivani announced positive preclinical weight loss data with its exenatide implant that was comparable to semaglutide, the active ingredient in Ozempic and Wegovy, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections in the same study. In addition, the Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, another miniature, ultra long-acting, subdermal GLP-1 implant in development for chronic weight management further demonstrating our prioritization on obesity. NPM-139 also has the added potential benefit of once-yearly administration.

On March 1, 2024, the Company entered into a securities purchase agreement (“Securities Purchase Agreement”) with an institutional investor to purchase 3,947,368 shares of common stock, par value $0.0001 per share (the “Common Stock”) and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering (the “Offering”). The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance.

On April 22, 2024, the Company entered into an Open Market Sale Agreement[SM] (the “Sales Agreement”) with Jefferies LLC (“Jefferies”), under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the company's miniature, long-acting GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration.

As stated previously, on June 13, 2024, Vivani announced that the FDA cleared the IND and lifted the clinical hold for NPM-119, the Company's miniature, six-month GLP-1 implant under development for the treatment of patients with type 2 diabetes.

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company redesigned the first-in-human study, LIBERATE-1, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight patients.

On September 4, 2024, Vivani announced positive preclinical liver fat results with its miniature, ultra long-acting GLP-1 implant currently under development for chronic weight management in obese and overweight individuals and type 2 diabetes. The Company's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. These liver fat data are consistent with published results from similar investigations with semaglutide, the active pharmaceutical ingredient in Ozempic and Wegovy.

On September 26, 2024, the Company reported receiving regulatory approval to initiate its first-in-human clinical trial with a miniature, ultra long-acting GLP-1 (exenatide) implant in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1™ , is part of the NPM-115 program and will investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant. The trial also represents the first clinical application of the Company's proprietary NanoPortal drug implant technology. LIBERATE-1™ was redesigned to enroll participants who will 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 (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

On December 19, 2024, Vivani announced that screening and enrollment of LIBERATE-1™, the first-in-human clinical trial with its NPM-115 program GLP-1 implant in obese and overweight patients, was initiated at two study centers in Australia. Study results are anticipated to be reported in mid-2025. On March 13, 2025, Vivani announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1 clinical trial. 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 miniature, six-month, subdermal GLP-1 implant and reaffirming previous estimates that top-line LIBERATE-1 results should be available in mid-2025.

On March 26, 2025, the Company entered into a private sale transaction with an entity affiliated with one of its independent directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in one or more closings as provided in the purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on the Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $8.25 million.

Our Proprietary NanoPortal Implant Technology

Vivani's implant technology, which we refer to as NanoPortal, utilizes a space-efficient design that allows a miniaturized implant to provide many months of therapeutic delivery of potent molecules. The technology has no moving parts, which is intended to minimize fluctuating drug delivery over the duration of the implant and is also tunable. Vivani has primarily been developing implant candidates around peptide therapeutics, but the technology has potential application across a wide range of molecular types. The key innovative component of the technology is a biocompatible titanium-oxide nano-porous membrane which consists of millions of precisely sized nanotubes whose inner diameters represent the only path for drug molecules to exit the reservoir once the implant is fully assembled.

We believe the key to the technology's ability to achieve near constant release of drug without moving parts is the ability to precisely tune the inner diameter of the nanotubes to the same size range as individual drug molecules. If the inner diameter of the nanotubes is smaller than the size of a given drug molecule, there would be no release at all. If the inner diameter of the nanotubes is much larger than the size of a given drug molecule, the rate at which the drug leaves the reservoir would follow traditional physics and would decrease over time as the drug concentration decreases. However, when the opening is close enough in size to the drug molecules, the drug release is constrained and can result in a variety of desirable delivery profiles, including near constant release. Vivani's NanoPortal technology has demonstrated near constant release in an animal model for six months.

For drug molecules with adequate potency and stability, NanoPortal can allow minimization of the implant size while extending implant duration. A custom delivery profile can also be achieved by adjusting the number of accessible nanotubes, engineering changes to the implant, and/or changes in formulation parameters. With the design flexibility afforded by the NanoPortal technology, Vivani plans to develop a portfolio of drug implant candidates aimed at addressing chronic diseases with high unmet medical need.

Vivani's NanoPortal technology has demonstrated near constant *in vitro* release for two dose configurations (see left portion of the chart below). *In vitro* testing was performed at 37°C on implant devices stored in a buffer solution adjusted to a physiological pH of 7.4. For a high-dose configuration, the observed near-constant release was demonstrated over the 12-week measurement period, after which the drug began to be depleted. For a low-dose configuration, the observed near-constant release lasted for 24 weeks. In addition, the near-constant *in vitro* release observed has been shown to translate into sustained exposure levels *in vivo* over a 6-month duration in an animal model (depicted in the chart below entitled "6-month NPM-119 Prototype (N=6)"). Finally, NanoPortal has demonstrated minimal *in vitro* fluctuations during 2.5-hour interval sampling periods which demonstrates a very smooth release profile (see right portion of the chart below entitled "Near-Constant and Minimally-Fluctuating Release" for individual device release rates). For clarity, the Day 98-100 period was selected to ensure the 2.5 hour variability results were representative of steady-state conditions.

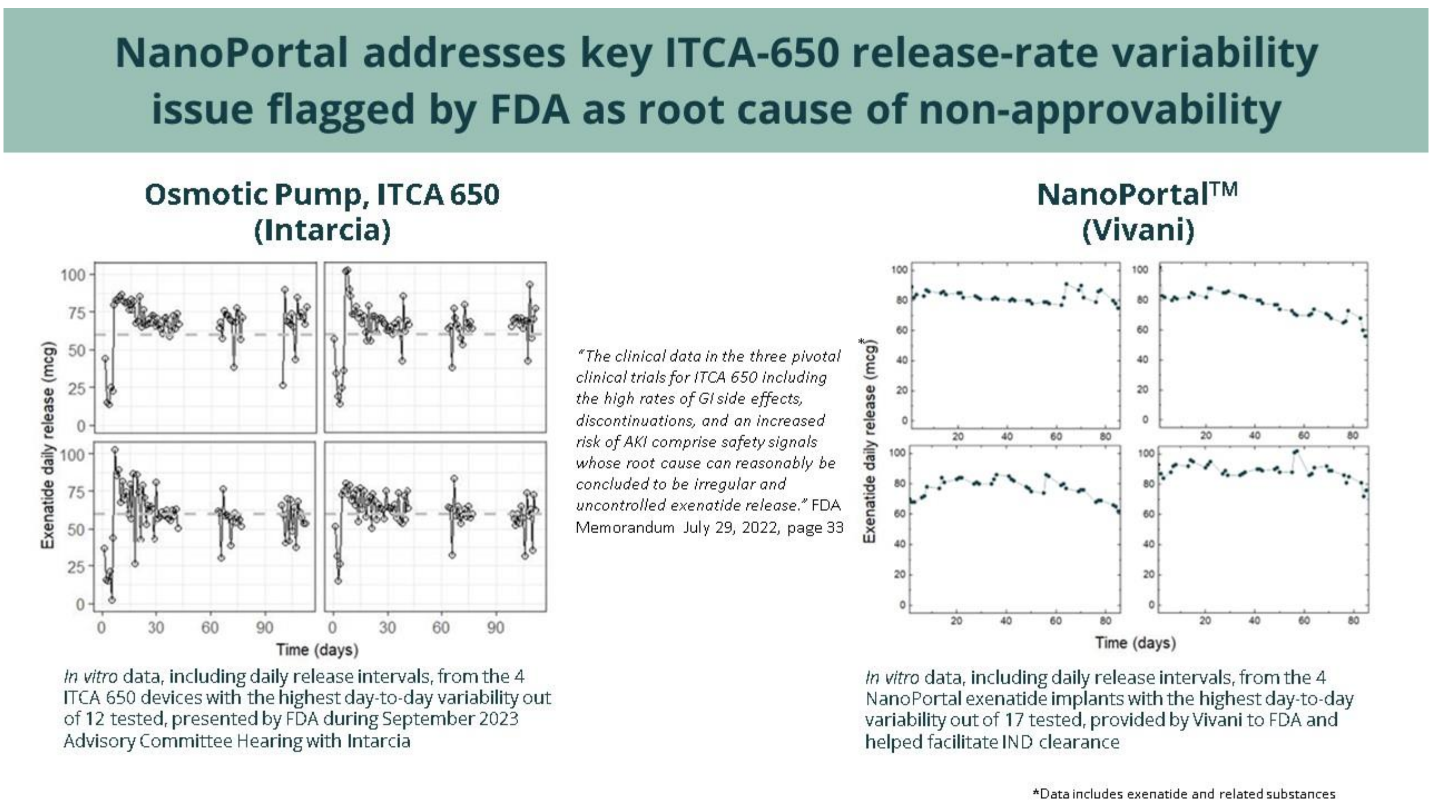
Vivani believes its proprietary NanoPortal implant technology has potential to revolutionize the treatment of chronic diseases by addressing two important limitations of oral and injectable therapies, namely, poor real-world medication adherence, and, in the case of GLP-1 therapy, the potential to improve gastrointestinal tolerability. We believe Vivani's NanoPortal technology, which is specifically designed and tested to deliver regular and controlled exenatide release, may overcome these challenges. Our NanoPortal implant technology has no moving parts that could otherwise contribute to variations in drug release rates. NanoPortal has demonstrated the ability to release exenatide with minimal fluctuations *in vitro* as evidenced by the 2.5-hour release rates shown in the NanoPortal Implant Technology section above. Since the half-life of exenatide in humans is 2.4-4 hours, steady release from one 2.5-hour interval to the next is expected to be associated with minimal device-related exposure fluctuations, potentially minimizing the opportunity for gastrointestinal events.

To address medication adherence, the Company's NanoPortal implants are designed to provide steady dosing from a single miniature, subdermal device for six months or longer. Current GLP-1 products are associated with only 50-60% real-world medication adherence. Non-adherent patients do not receive the full potential benefits of existing treatments. For example, medication non-adherence for patients with type 2 diabetes is associated with approximately $5,500 per non-adherent patient in avoidable healthcare costs associated with unnecessary acute care and hospitalization visits. The NanoPortal technology can enable ultra long-acting dosing, up to 6 months or longer, which can directly address the medication adherence challenge.

A well-documented side effect of the GLP-1 class is poor gastrointestinal ("GI") tolerability. GI intolerance can present as nausea, vomiting, and/or diarrhea which can lead to volume loss, acute kidney injury ("AKI") and potentially major cardiovascular adverse events. GI-related issues are the most commonly reported side effect for all drugs in the GLP-1 class. In responding to a marketing application filed for Intarcia's ITCA 650 exenatide implant candidate, with a proposed indication for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus ("T2DM"), the FDA stated in a July 29, 2022 letter that they believe marked increases in the dose of a GLP-1 are responsible for increased risk of GI intolerance and combined with the daily *in vitro* variability exhibited by ITCA 650 resulted in the FDA summarizing their findings as follows: "the clinical data in the three pivotal clinical trials for ITCA 650–including the high rates of nausea, vomiting, and diarrhea, the high rates of discontinuations due to these adverse gastrointestinal reactions, and most notably, the increased risk of AKI comprise safety signals whose root cause can reasonably be concluded to be irregular and uncontrolled exenatide release" and "The data provided to validate the limits of the in vitro dose delivery specifications did not support the safe and effective use of the device constituent of ITCA 650."

We believe Vivani's NanoPortal technology, which is specifically designed and tested to deliver regular and controlled exenatide release, may overcome these challenges. Our NanoPortal implant technology has no moving parts that could otherwise contribute to variations in drug release rates. NanoPortal has demonstrated the ability to release exenatide with minimal fluctuations *in vitro* as evidenced by the 2.5-hour release rates shown in the NanoPortal Implant Technology section above. Since the half-life of exenatide in humans is 2.4-4 hours, steady release from one 2.5-hour interval to the next is expected to be associated with minimal device-related exposure fluctuations, potentially minimizing the opportunity for gastrointestinal events.

Evidence to support non-fluctuating drug release afforded by Vivani's NanoPortal technology compared to the drug release profile of the ITCA 650 osmotic pump technology is provided in the schematic below. Although head-to-head testing was not conducted, the left panel shows, the *in vitro* daily release profiles for the 4 ITCA 650 devices with the highest day-to-day variability of the 12 total devices tested. The ITCA 650 device data was presented by FDA at the September 28, 2023. FDA Open Public Hearing to review the approvability of Intarcia Therapeutic's ITCA 650 (exenatide implant). The right panel shows the *in vitro* daily release profiles for the 4 NanoPortal devices with the highest day-to-day variability of the 17 total devices tested by Vivani.

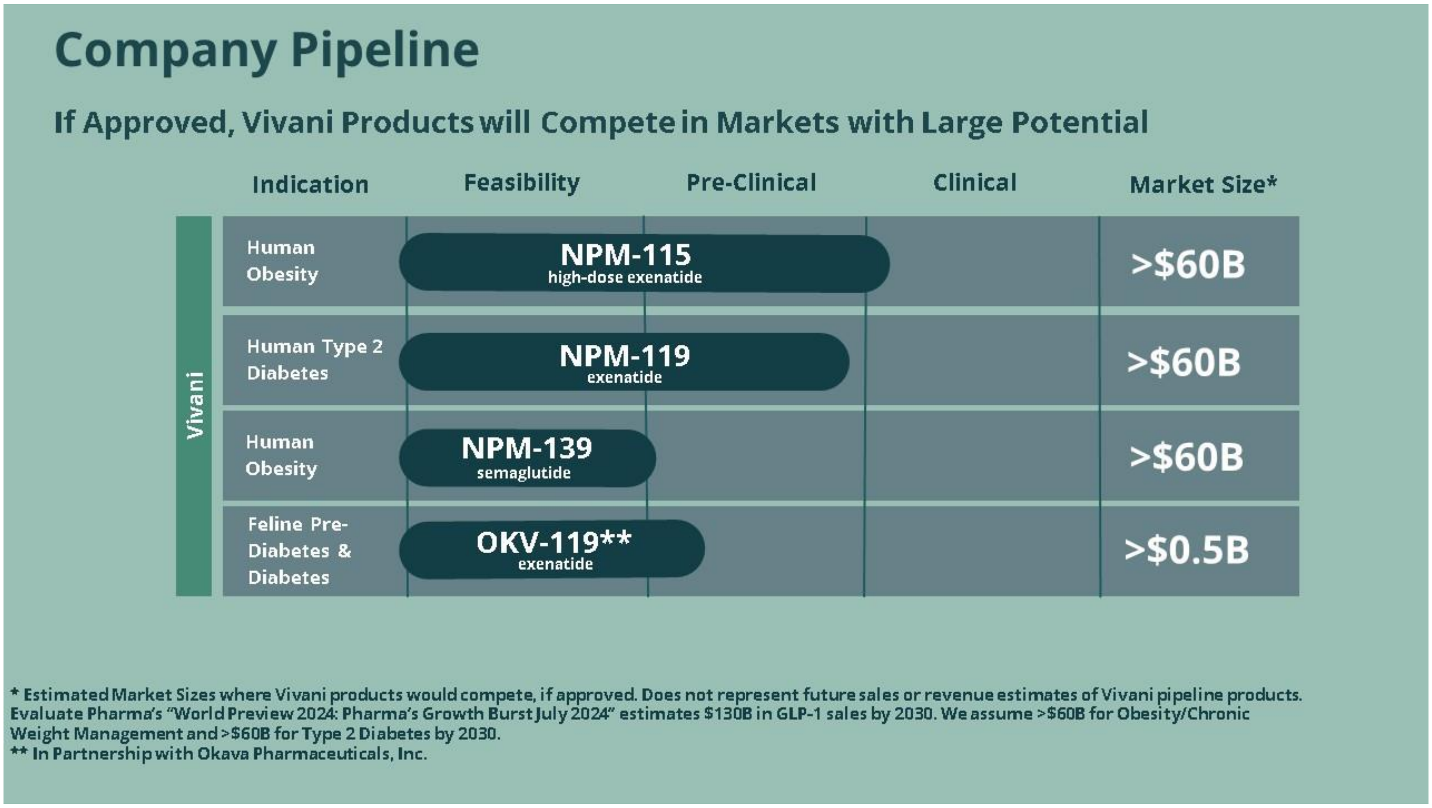


Preliminary market research regarding the potential adoption and market penetration of Vivani's emerging drug implant candidates has been encouraging. For example, during FDA's Open Public Hearing on September 28, 2023 to reviewIntarcia's ITCA 650 (exenatide implant), the independent firm dQ&A Market Research reported results from a patient preference study testing a product profile reflective of both ITCA 650 and NPM-119 (e.g. miniature, six-month, subdermal, GLP-1 implant). Of the 324 patients currently on GLP-1 therapy, 56% indicated either "Definitely" or "Likely" when asked about the likelihood of getting and using a GLP-1 implant if it was approved by FDA, recommended by their healthcare provider, and covered by insurance.

For example, results from a small, third-party market research study funded byVivani indicate that the majority of physicians would be highly likely to recommend a product with the NPM-119 target product profile to their type 2 diabetes patients. In this market research study, primary care physicians (n=10) provided an average rating of 8.3 out of 10 in terms of likelihood of recommending a product with NPM-119's target product profile. Although additional market research will be conducted as Vivani's drug implant candidates progress in development, these early signals regarding product adoption indicate significant market opportunity and a highly differentiated, convenient, alternative GLP-1 treatment option for patients, healthcare providers, and payers.

Our Emerging Portfolio

Although Vivani's proprietary NanoPortal implant technology may potentially be broadly applied across a wide range of therapeutic molecules and disease areas, our initial focus is on peptide therapeutics for the treatment of patients with metabolic disease. The pipeline table below depicts our current portfolio of four distinct pre-clinical stage programs targeting type 2 diabetes (in humans and companion cats), and obesity/chronic weight management



Below is a summary description of each pipeline program:

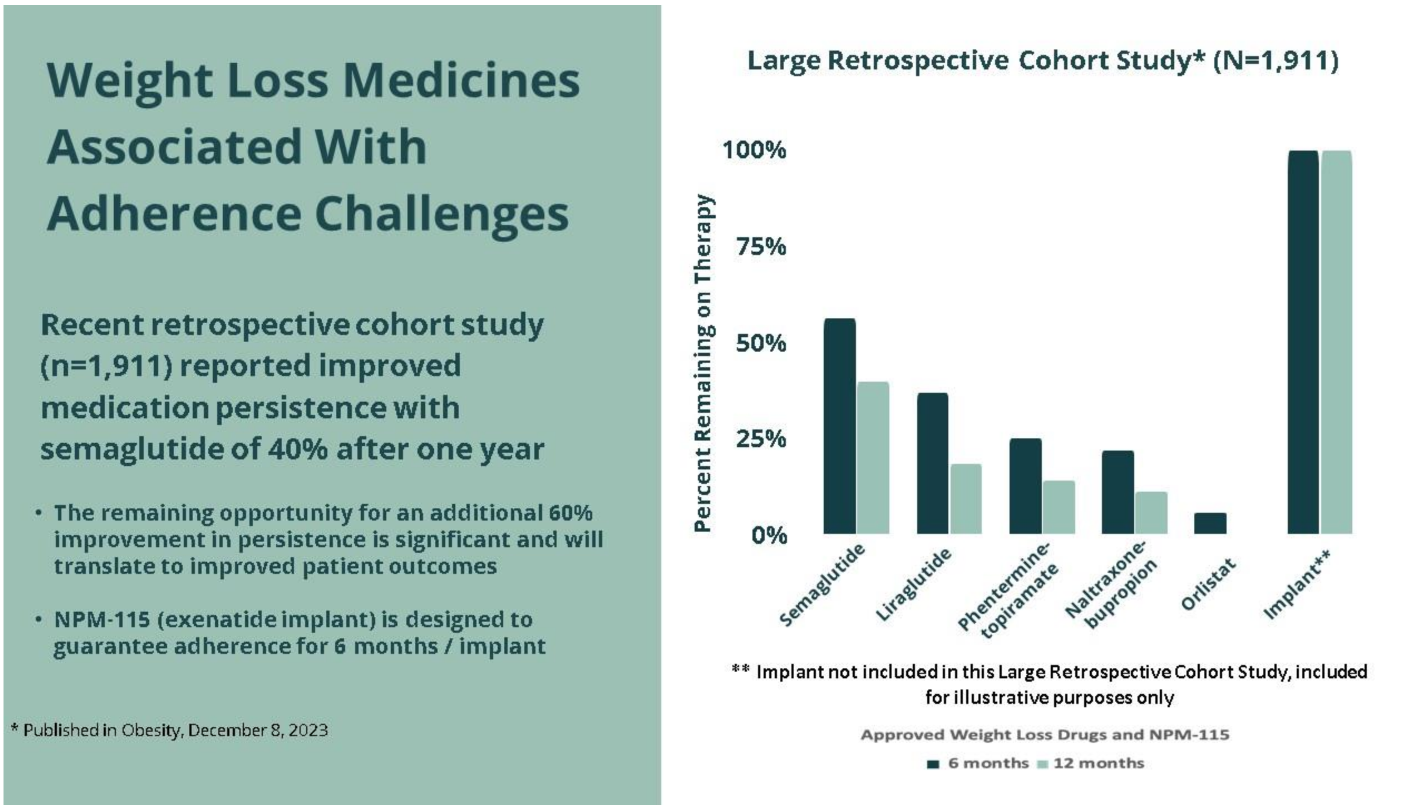
NPM-115: This high-dose exenatide implant candidate is in clinical stage development for the treatment of chronic weight management in patients with obesity or overweight. Obesity is a global epidemic with over 1 billion adults and children currently living with obesity globally. The global prevalence of obesity has more than tripled since 1975. Today, less than 5% of these people are medically treated. Obesity affects both the individual and society at large. Obesity is associated with over 200 health complications and is associated with an increasing proportion of healthcare costs.

Leveraging the ultra long-acting six-month dosing regimen, the Company will also be exploring the potential for NPM-115 to provide maintenance therapy for patients who have previously lost weight on other injectable or oral GLP-1 therapies, including dual or triple incretin products. This differentiated treatment approach could provide patients, caregivers and healthcare professionals the convenience of a miniature, twice-yearly, subdermal GLP-1 implant that is administered during a routine office visit.

Vivani received regulatory approval and has subsequently initiated its first-in-human clinical trial for the NPM-115 program in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1™, will investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant leveraging the Company's proprietary NanoPortal drug implant technology. LIBERATE-1 is designed to enroll participants who will 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 (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Although not the primary objective of LIBERATE-1, changes in weight will also be measured. The trial was initiated at the end of 2024 with data projected to be available in mid-2025.

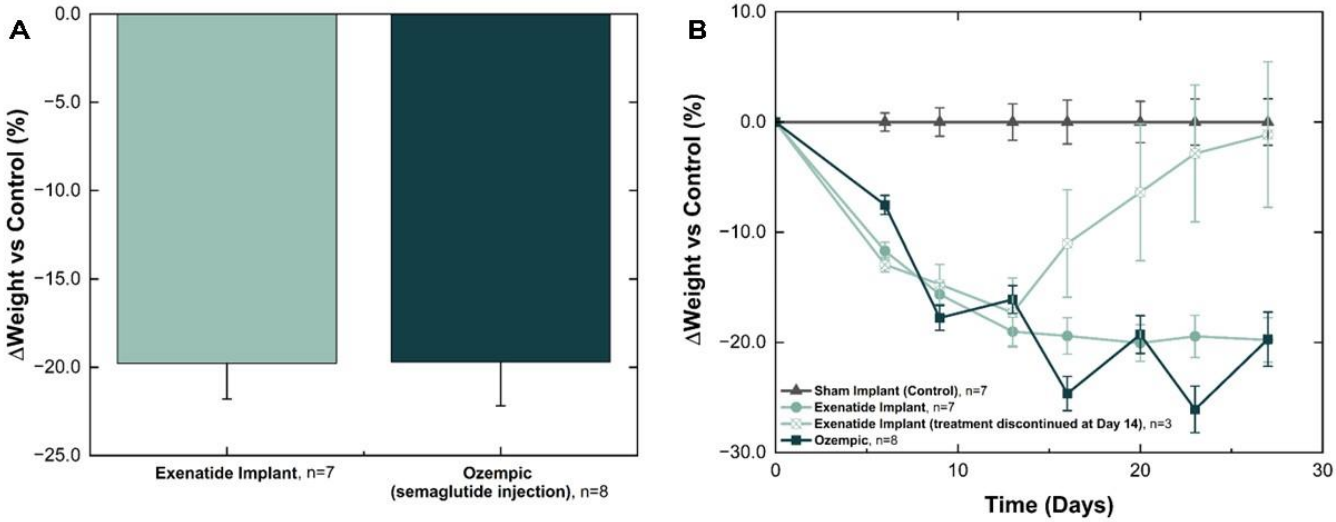
Vivani believes that higher doses of exenatide, compared to those exenatide doses currently approved to treat type 2 diabetes, can achieve similar weight loss effects as other GLP-1 products. This belief is based on the fact that semaglutide injection was originally approved at doses up to 1.0mg/week to treat type 2 diabetes (Ozempic) while semaglutide injections for chronic weight management (Wegovy) required higher doses up to 2.4mg /week to maximize weight loss effects of the treatment.

In both the treatment of obesity and type 2 diabetes, GLP-1 products have challenges associated with medication adherence and persistence which can lead to sub-optimal patient outcomes. As shown in the graph below, results from a large, retrospective cohort study published in the research journal Obesity show improved medication persistence with the newer GLP-1 weight loss products compared to previous products. That said, the one-year persistence of patients taking semaglutide was still only 40%. This highlights the potential for further improvement for the 60% of individuals who were no longer taking semaglutide after one year. The potential benefits for a long-term implant like NPM-115 are apparent when considering that body weight begins to increase shortly after GLP-1 therapy is discontinued.



Preliminary weight loss data of NPM-115 in preclinical models is encouraging. In a study in high fat diet-induced obese mice, NPM-115 generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to weight loss observed in mice treated with semaglutide in the same study. The supratherapeutic doses provided for both NPM-115 (single administration delivering exenatide at ~530 nmol/kg/day), and semaglutide (weekly injections of ~2,700 nmol/kg/week) were selected to maximize the weight-loss potential of both exenatide and semaglutide.

Exenatide implant associated with comparable weight loss to semaglutide in preclinical study

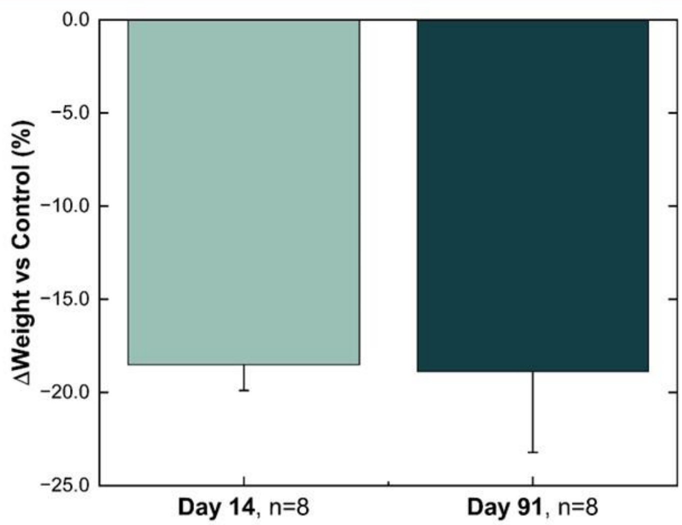


Weight loss in high fat diet-induced obese mice. (A) % weight change from baseline for a single administration of exenatide implant (~530 nmol/kg/day) vs weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant) at 28 days; **(B)** % weight change from baseline over time from a single administration of exenatide implant (~530 nmol/kg/day) vs. weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant). Values are mean ± SE.

Emerging data on the durability of effect on weight in animals with an exenatide implant provides confidence that this treatment modality has the potential as a treatment for chronic weight management and potentially, the maintenance of weight loss after obese or overweight individuals have already lost sufficient weight on other GLP-1 monotherapy. The dose configuration of the exenatide implant test article in the ongoing LIBERATE-1 study is expected to be supportive of both the NPM-115 and NPM-119 programs. Additional information supporting the NPM-119 program is provided below.

NPM-139: Semaglutide based products are the largest selling GLP-1 products on the U.S. market today with combined 2024 sales of over $25 billion. NPM-139 (semaglutide implant) is a highly differentiated, GLP-1 product candidate specifically designed to improve medication adherence and, potentially, patient tolerability to their medicine. NPM-139 is in feasibility stage testing and has recently generated encouraging preclinical weight loss data consistent with weight loss reported with semaglutide injections in similar preclinical models (see figure below).

Semaglutide implant preclinical proof-of-concept achieved in ongoing study



Body weight measurements of semaglutide implant in male Sprague-Dawley rats (n=8)
Weight difference versus control group in healthy Sprague-Dawley Rats. % weight change from baseline for NPM-139 (semaglutide implant) corrected to control (sham implant). Values are mean ± SE.

In this ongoing study in healthy rats, a single administration of thesemaglutide implant NPM-139 resulted in body weights that were nearly 20% lower than a sham implant control group throughout a 91-day treatment period. Like NPM-119 and NPM-115, NPM-139 has demonstrated smooth, non-fluctuating *in vivo* release; this was confirmed by pharmacokinetic data from this study which demonstrated continuous and steady semaglutide exposure throughout the study period. NPM-139 has previously demonstrated therapeutic semaglutide exposure levels in pharmacokinetic data over a six-month duration in healthy rats.*In vitro* chemical and physical stability measurements for durations exceeding one year indicate the potential for once-yearly administration of NPM-139. Together, these data demonstrate the versatility of the NanoPortal technology beyond NPM-115 (exenatide implant) and provide significant encouragement for continued development of each program.

NPM-119: This exenatide implant candidate is a miniature, six-month, subdermal GLP-1 implant under development for the treatment of type 2 diabetes.According to the CDC, more than 37 million Americans have diabetes and 90-95% have type 2 diabetes. The total number of people living worldwide with diabetes today is 537 million and is projected to rise to 643 million by 2030 and 783 million by 2045. Of the 537 million people with diabetes today, only 15% have good glycemic control. According to the American Diabetes Association (“ADA”), the total cost of diabetes in the U.S. was $413 billion in 2022, including $307 billion for direct medical costs and $106 billion for reduced productivity in premature mortality. In 2024, global sales of GLP-1 receptor agonists products (all indications) were over $50 billion and are projected to reach over $250B per year by 2034. Because the current drug adherence rate for type 2 diabetes is only 40-60% for oral and injectable GLP-1 products, Vivani believes there is significant unmet need for a GLP-1 implant that could address non-adherence.

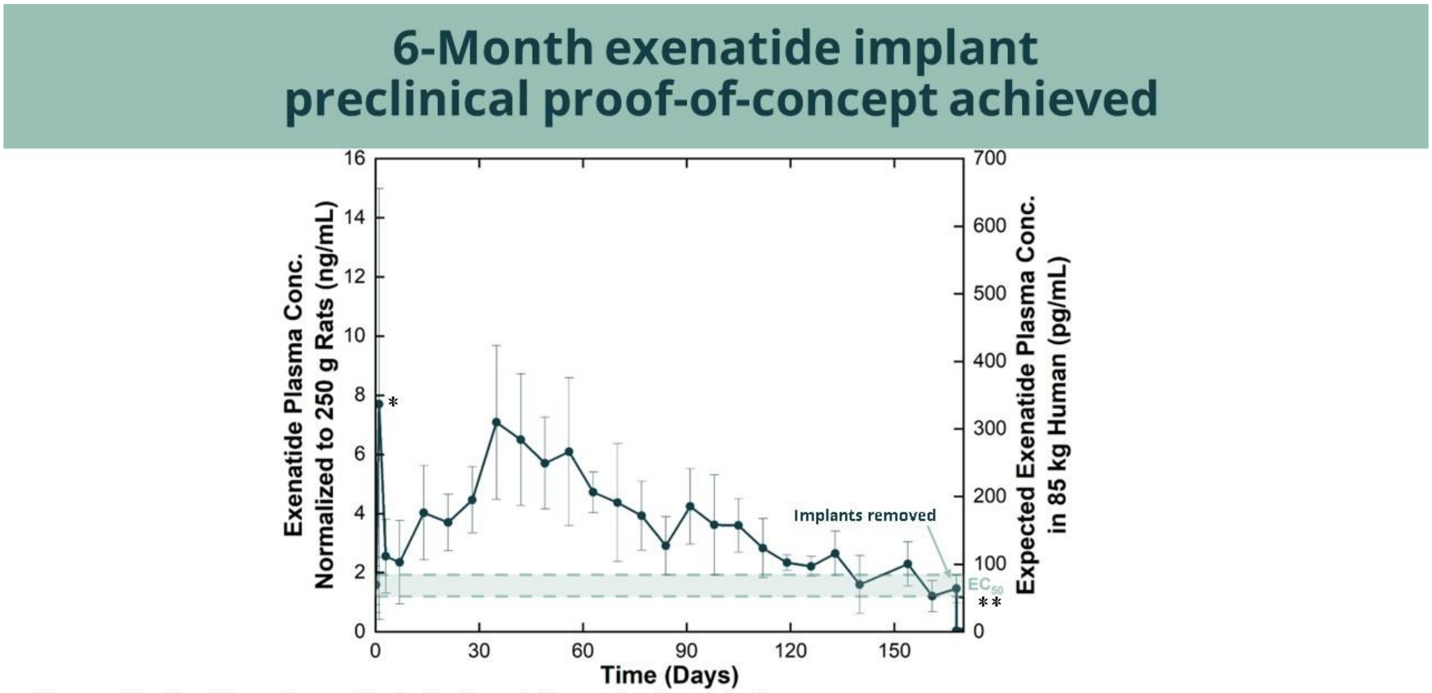
NPM-119 was initially intended to support a first-in-human study in patients with type 2 diabetes and has an open IND with a clinical trial that was cleared to proceed by the FDA. This clinical study was temporarily postponed so that Vivani could prioritize the NPM-115 program in development for chronic weight management in obese and overweight individuals. The exenatide implant used in the NPM-115 program is the same configuration intended for use in the initial NPM-119 study. As a result, study results from the initial exenatide implant study, LIBERATE-1, are expected to be supportive for both the NPM-115 and NPM-119 programs. Exenatide is a GLP-1 receptor agonist (GLP-1 RA or GLP-1) and was originally approved as the twice-daily subdermal injection, Byetta® (exenatide) injection, in 2005 by the FDA as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea but have not achieved adequate glycemic control. In 2005, Byetta was the first GLP-1 product approved for use in the U.S. marketplace.Bydureon BCise (exenatide extended-release) injection is a once-weekly administration and was approved for use in the U.S. in 2017.

In July 2023, we submitted an IND to support the initiation of clinical studies with NPM-119. The proposed first-in-human study, called LIBERATE-1, was initially designed as a 12-week, randomized, clinical study to investigate the safety, tolerability, and full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes. In August 2023, FDA provided written notification that the LIBERATE-1 study was on full clinical hold due primarily to insufficient CMC information. In June 2024, FDA lifted the clinical hold on the NPM-119 study and provided clearance to proceed with the originally designed LIBERATE-1 trials in patients with type 2 diabetes.

In parallel, Vivani decided to redesign the LIBERATE-1 study to support the NPM-115 program which resulted in changing the study population from type 2 diabetes patients to individuals with obesity and overweight. The main objectives of the goals of LIBERATE-1, namely, to study the safety, tolerability, and full pharmacokinetic profile of the exenatide implant, did not change. In addition to changing the LIBERATE-1 study population, the Company decided to conduct this newly designed LIBERATE-1 trial in Australia. On September 26, 2024, Vivani announced the receipt of regulatory approval to initiate the first-in-human, LIBERATE-1 clinical trial with a GLP-1 implant in obese and overweight individuals in Australia. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines and data generated in Australia may be 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 United States.

Vivani has also made progress towards preparing for future clinical development of NPM-119. In September 2023, Vivani relocated into a new facility designed to provide suitable capacity for manufacturing of clinical materials for registration studies as well as commercial-scale supply. Based on preliminary discussions with the FDA, Vivani intends to explore the potential use of the 505(b)(2) pathway and believes that a single pivotal trial evaluating a 6-month NPM-119 configuration that is representative of the proposed commercial configuration may be sufficient to support registration in the United States. That said, as NPM-119 development proceeds, we intend to further engage with regulatory authorities on the timing, duration, endpoints, number of enrolled patients and other aspects of trial design for future clinical trials of NPM-119.

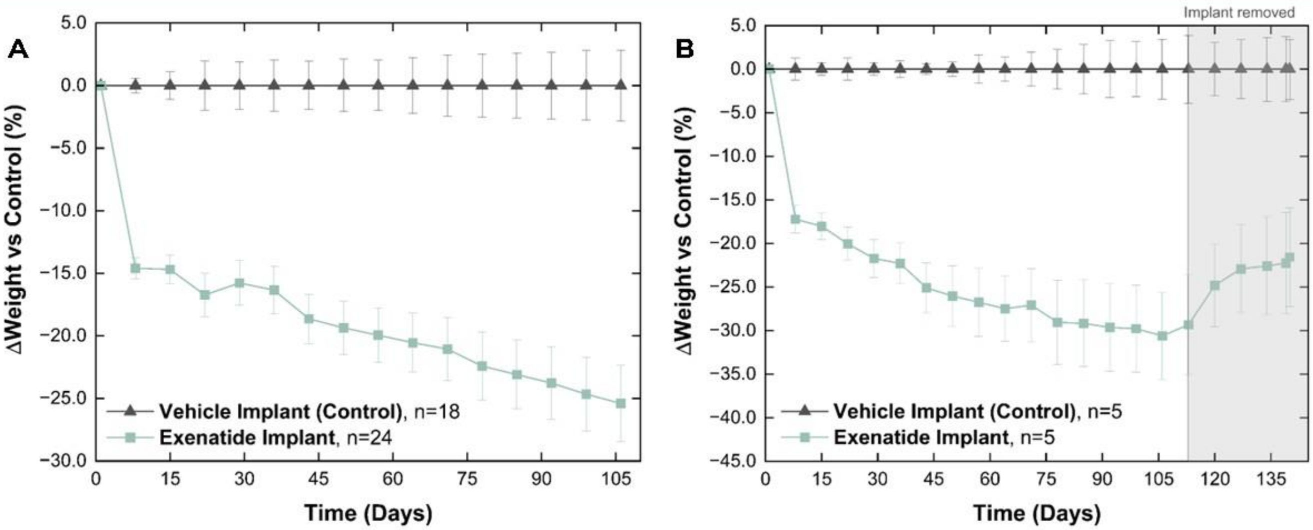
We have conducted a preclinical study to evaluate proof-of-concept activity of NPM-119. In that study, a six-month implantation of NPM-119 into rats was associated with steady exenatide concentration over the duration of the implant, as depicted in the figure below.



Pharmacokinetics of 6-month exenatide implant in male Sprague-Dawley rats (n=6)
Exenatide antibody-positive animals are not included in this data set. Values are mean ± SD.
*2 of 6 implants are responsible for higher Day 1 exenatide concentrations which is not expected to occur in the configuration to be used in the clinic.
** The estimated exenatide EC50 is 51.4 pg/mL when exenatide antibody titers are < 125 and 84 pg/mL when exenatide antibody titers are >= 125. These exenatide EC50 estimates are consistent with the exenatide EC50 estimate, 83.5 pg/mL, from the FDA Clinical Pharmacology review of BYDUREON

As depicted in the graph below, in a study in healthy rats, a single administration of the Company's exenatide implant NPM-119, in development for the treatment of type 2 diabetes, resulted in body weights that were approximately 25% lower than a vehicle implant control after 15 weeks of treatment. NPM-119 delivered exenatide at a rate of approximately 320 nmol/kg/day and has demonstrated smooth, non-fluctuating release of exenatide in both *in vitro* and *in vivo* studies. NPM-119 has previously demonstrated pharmacokinetic data exhibiting continuous and therapeutic exenatide exposure levels over a 6-month duration in healthy rats. Since NPM-115 is a higher-dose version of an otherwise similar product as NPM-119, the durability of the effect on weight demonstrated in this study is expected to translate to future studies utilizing NPM-115.

Exenatide delivered with NanoPortal™ technology is associated with durable body weight effects



Weight difference from control in healthy Sprague-Dawley Rats. % weight change from baseline for a single administration of exenatide implant in a study associated with NPM-119 (~320 nmol/kg/day) corrected to control (vehicle implant). **(A)** All animals measured through 105 days of treatment; **(B)** 5 animals measured in each group through 112 days of treatment followed by a 28-day recovery period. Values are mean ± SE.

OKV-119: This exenatide implant is under development for cardiometabolic diseases in companion cats, including the treatment of obesity and diabetes. In 2017, there were over 90 million cats in the U.S. It is estimated that up to 40% of cats are clinically obese, and 1-4 million cats have diabetes. Americans spent $136.8 billion on their pets in 2022, an increase of 10.68% from 2021. Spending on pets is expected to triple over the next 10 years, with pet health representing the fastest-growing sub-segment of this market. Since cats and dogs can be difficult to medicate, we believe that a small subdermal implant administered by a veterinarian at a routine clinic visit can be a welcome option for many pet owners, particularly those administrating daily insulin injections.

The program is partnered with Okava who is responsible for all clinical development and regulatory activities of OKV-119 and, if approved, ultimate commercialization of this product. In 2022, OKV-119 advanced out of the feasibility stage after having produced data demonstrating adequate exenatide exposure and sustained weight loss in cats over a 12-week study. Vivani does not anticipate any significant focus or investment in this program beyond the support of implant development and manufacturing activities.

Beyond our current pipeline, Vivani intends to apply its extensive experience and proprietary implant technology to develop a pipeline of drug implant candidates that have the potential to address chronic diseases with high unmet medical needs across multiple therapeutic categories and disease areas. For example, Vivani is also following the evaluation of the GLP-1 agonist semaglutide in the treatment of metabolic dysfunction-associated steatohepatitis ("MASH") and Alzheimer's disease. If one or more of these trials shows encouraging results, Vivani believes that a miniature long-term drug implant could have the potential to be an attractive alternative treatment option in these underserved patient populations.

Our Strategy

Vivani's mission is to provide people with the freedom to live healthier by revolutionizing the current treatment of chronic disease. Vivani develops miniaturized, ultra long-acting drug implants using its proprietary NanoPortal implant technology to enable delivery of a broad range of medicines to treat chronic diseases. These products, designed to address poor medication adherence, are anticipated to significantly improve the health of otherwise non-adherent patients and to provide assurance to their family members and to the health care professionals who treat them that the medicine prescribed to them are taken as intended.

Vivani plans to initially test its implant technology and business model through the clinical and regulatory development of its lead programs, NPM-115 (high-dose exenatide implant) and NPM-139 (semaglutide implant). The active drugs, exenatide and semaglutide, are members of the GLP-1 receptor agonist class of drugs. Drug products, including drug substances within this relatively new drug class, have already been successfully developed and marketed for the treatment of both type 2 diabetes and obesity and GLP-1 products are the category leader in revenue for both the type 2 diabetes and obesity/chronic weight management drug treatment categories. In addition, GLP-1 receptor agonists have shown promising early clinical results in fatty liver disease or MASH, various addiction disorders, and other disease areas including Alzheimer's disease. In 2024, Vivani has continued to execute its business strategy as evidenced by:

- Secured FDA clearance to conduct a Phase 1 clinical study of NPM-119 (exenatide implant) in patients with type 2 diabetes in the US;
- Secured approval from Australian regulatory authorities to conduct a Phase 1 clinical study, LIBERATE-1, to investigate the safety, tolerability, and full pharmacokinetic profile of an exenatide implant in obese and overweight individuals;
  Initiated screening and enrollment of the LIBERATE-1 study in December 2024. Results from this first-in-human study are anticipated to report in mid-2025.
- Advancing the feasibility assessments of NPM-139 (semaglutide implant) for the treatment of obesity and chronic weight management;
  Developing manufacturing capabilities and systems at Vivani's dedicated facility in Alameda, CA to produce clinical trial supply.
- Leveraging the company's proprietary NanoPortal platform technology to expand our emerging portfolio of innovative drug implants to improve the treatment of chronic diseases
- Maintaining, expanding, and protecting our intellectual property portfolio; and
- Adding operational, financial, and management information systems and personnel, including personnel to support its planned product development efforts, as well as to support its regulatory responsibilities as a public reporting company.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. Some of these companies are developing therapies that are directly competitive to our approach. We believe the key competitive factors that will affect the development and commercial success of our product candidates include ease of administration and convenience of dosing, therapeutic efficacy, safety and tolerability profiles and cost. Many of our potential competitors have substantially greater financial, technical, and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other foreign regulatory approvals of products, and the commercialization of those products. Consequently, our competitors may develop similar products to address the indications targeted by our current product candidates or for other indications we may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

The competition for Vivani will be dependent upon the individual product candidate in development. For Vivani's lead programs, NPM-115, NPM-139 and NPM-119, the competition could be defined as any drug product/manufacturer approved for use in the treatment of patients with obesity or type 2 diabetes. However, we believe that our more direct competitors are restricted to other GLP-1 receptor agonist and combination products with a GLP-1 receptor agonist component approved or in development for those respective indications. In May 2022, Lilly's Mounjaro® (tirzepatide) was approved as the first and only combination GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes and in November 2023, Lilly secured approval of a higher dose formulation of tirzepatide injection with the brand name Zepbound® for chronic weight management in adults with obesity or overweight with at least one weight-related condition. Manufacturers with approved GLP-1 receptor agonists or dual receptor agonists include Lilly, Novo Nordisk, AstraZeneca, and Sanofi.

The clinical adoption and commercial success of the GLP-1 class has been remarkable and already represents category leadership for obesity, weight management, sleep apnea in individuals with obesity, and type 2 diabetes medications from a revenue perspective. Vivani's product candidates, if approved, would compete in these large established markets. Obesity and overweight is a global epidemic. For example, over 1 billion adults and children currently live with obesity globally. The global prevalence of obesity has more than tripled since 1975. Today, less than 5% of these people are medically treated. Obesity affects both the individual and society at large. Obesity is associated with over 200 health complications and is associated with an increasing proportion of healthcare costs. According to the CDC, more than 37 million Americans have diabetes and 90-95% have type 2 diabetes. The total number of people living worldwide with diabetes today is 537 million and is projected to rise to 643 million by 2030 and 783 million by 2045. Of the 537 million people with diabetes today, only 15% have good glycemic control. According to the American Diabetes Association ("ADA"), the total cost of diagnosed diabetes in the U.S. was $327 billion in 2017, including $237 billion for direct medical costs and $90 billion for reduced productivity. In 2024, global sales of GLP-1 receptor agonists products (all indications) were over $50 billion and are projected to reach over $250 billion per year by 2034.

There are over 150 GLP-1 and dual and triple agonists and antagonists currently in clinical stage development for a wide variety of disorders including, but not limited to, obesity, chronic weight management, chronic sleep apnea associated with obesity, kidney disease, certain neurological disorders, and various addiction disorders. The listing below, while not comprehensive, provides a representative sampling of GLP-1 compounds in clinical-stage development for obesity, chronic weight management, and/or type 2 diabetes and are considered future potential competitors to Vivani's emerging portfolio of miniature, ultra long-acting GLP-1 drug implants.

- Altimmune's pemvidutide (ALT 801)
- Amgen's MariTide (maridebart cafraglutide, formerly AMG 133)
- AstraZeneca and Eccogene's ECC5004
- D&D Pharmatech's DD01
- Fractyl Health's Rejuva (GLP-1 based pancreatic gene therapy)
- Lilly's retatrutide; orforglipron;
- Lilly and Chugai's OWL833 (LY 3502970)
- Lilly and Innovent's mazdutide (LY3305677)
- Metsera's MET-097i, MET-224o
- Merck's efinopeglutide
- Novo Nordisk CagriSema
- OPKO Health's OPK88003
- Pfizer's danuglipron
- Roche's CT-388, CT-995; CT-868
- Structure Therapeutic's GSBR 1290
- Tern Pharmaceutical's TERN-601
- Viking Therapuetic's VK 2735
- Zealand Pharma's dapiglutide
- Zealand Pharma and Boehringer Ingelheim's survodutide (BI 456906)

NPM-115 and NPM-139

NPM-115 is a miniature, six-month, (high-dose) exenatide implant candidate in development for the treatment of chronic weight management in individuals with obesity or overweight. NPM-139 (semaglutide implant) candidate, the same GLP-1 active pharmaceutical ingredient as Ozempic and Wegovy, is also in development for the treatment of chronic weight management in obese and/or overweight patients. NPM-139 has the added potential benefit of once-yearly dosing.

A listing of products currently approved in the US for the treatment of obesity and/or chronic weight management are provided below:

- Teva's Adipex® (phentermine) and generics
- Roche's Xenical® (orlistat) and generics
- Vivus's Qsymia® (phentermine/topiramate extended release)
- Orexigen's Contrave® (bupropion/naltrexone)
- Lilly (Zepbound®/tirzepatide)
- Novo Nordisk (Saxenda®/liraglutide); and (Wegovy/semaglutide)

A listing of GLP-1 monotherapy agonists, dual agonists and triple agonists in various stages of clinical development is provided in the preceding section.We believe NPM-115, our lead drug implant candidate for chronic weight management, has the potential to address two important aspects of the GLP-1 category which are associated with the above-mentioned products, namely, poor real-world medication adherence and potential undesirable gastrointestinal tolerability.

NPM-119

NPM-119 (exenatide implant) candidate is a GLP-1 receptor agonist in development for the treatment of type 2 diabetes. Competition in the GLP-1 class for this indication includes the following:

- Lilly (Trulicity®/dulaglutide) and (Mounjaro®/ tirzepatide)
- Novo Nordisk (Victoza®/liraglutide); (Ozempic/semaglutide); and (Rybelsus®/semaglutide)
- AstraZeneca (Bydureon BCise®/exenatide); and (Byetta/exenatide)
- Sanofi (Adlyxin®/lixisenatide)

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Sales and Marketing

Vivani currently does not have a commercial infrastructure in any geography. As we progress our programs through development, we plan to build a commercial infrastructure in the United States or selected other territories to support the commercialization of each of our product candidates when we believe a regulatory approval in a particular territory is likely. We intend to conduct market research in connection with designing our commercialization strategy for each of our product candidates. We may seek licensing or other strategic collaborations with, for example, global pharmaceutical company partners, to support our commercialization efforts. We will consider a range of options including building a commercial capability internally, leveraging third-party biopharmaceutical commercialization organizations, other strategic partners, distributors and/or contract sales forces to expand the commercial availability of our product candidates when appropriate.

Our Corporate Information

Vivani (as Second Sight Medical Products) was incorporated on December 17, 2009 under the laws of the State of California. Its operations began in 2010. After the successful merger of Second Sight Medical Products and NanoPrecision Medical on August 30, 2022, the combined company was renamed Vivani Medical, Inc. Prior to the merger, NanoPrecision Medical was a private company.

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.

Vivani's corporate office is located at 1350 South Loop Road, Alameda, CA 94502; its telephone number is (415) 506-8462; and its website is located at www.vivani.com.

Chemistry, Manufacturing, and Controls

Vivani has developed production processes and quality systems to support the manufacture of clinical materials for its emerging portfolio of miniature, ultra long-acting GLP-1 drug implants. For example, Vivani recently initiated LIBERATE-1, a Phase 1 study of an exenatide implant in individuals who have obesity or overweight at two clinical study sites in Australia to support the NPM-115 program.

Vivani has established in-house research, development, and manufacturing capabilities in its corporate headquarters in Alameda, California, U.S. Vivani has also engaged with contract manufacturers and analytical laboratories for selected processes when appropriate. In general, Vivani purchases the drug substance from a third-party manufacturer. Vivani intends to conduct all assembly processes in which the drug substance is present, including the associated in-process testing, when producing materials for Phase 1 and Phase 2 clinical trials. Vivani anticipates that all assembly processes in which the drug substance is present, including the associated in-process testing, will be performed either in-house or by contract manufacturers when producing materials for any registration trial or commercial use. Several device components and all raw materials are purchased from outside vendors according to established specifications. The device assembly processes, including the associated in-process testing, and final product testing are anticipated to be performed by Vivani in Alameda, California. The custom applicator, which is intended to facilitate subdermal placement of the implant in patients, has been designed and will be manufactured by a contract manufacturer. Several device components and the drug substance are purchased from outside vendors according to established specifications.

As our portfolio of drug implant candidates advances, Vivani may also engage additional contract analytical and manufacturing organizations as needed. Currently, Vivani is not a party to any long-term, commercial manufacturing agreements.

Intellectual Property

As of December 31, 2024, Vivani held or controlled 16 issued U.S. patents, 10 pending U.S. patent applications, and 7 patents in various jurisdictions outside the United States. Additionally, Vivani is pursuing 24 corresponding patent applications that are pending in various foreign jurisdictions, and 4 international patent applications. Further advancement of Vivani's intellectual property portfolio will require the filing of patent applications related to its proprietary manufacturing process and product candidates. Vivani has patents extending into China, Hong Kong, India, Japan, Republic of Korea, and the United States of America, as well as trade secrets protecting Vivani's intellectual property. Vivani's patent prosecution strategy includes exploration of opportunities to expand its patent life and use cases in order to broaden its existing patent portfolio.

Below is a further description of certain of Vivani's key issued patents, including the category of protection, expiration date, number of related patents issued in foreign jurisdictions and the product candidates to which each patent relates. Vivani currently holds or controls:

- Sixteen patents issued in the United States (U.S. Patent Nos. 7,687,431, 9,511,212, 9,770,412, 9,814,867, 10,045,943, 10,105,523, 10,479,868, 10,525,248, 10,688,056, 10,792,481, 11,021,576, 11,129,791, 11,191,935, 11,478,430, 11,931,453, and 12,071,516) and 7 patents issued in foreign jurisdictions. The patents are directed to the manufacture and use of a drug delivery system and more specifically, to a titania nanotube membrane and capsule utilizing the proprietary NanoPortal technology platform. The methods include methods of drug delivery and treatment with a composition such as exenatide, methods to implant a drug delivery system, and methods of manufacturing a nanoporous membrane, as well as an implantable drug delivery system, a titania nanotube membrane, and titania nanotubes. These U.S. patents relate to an apparatus to implant a drug delivery system, an implantable drug delivery system comprising exenatide, a titania nanotube membrane, a method of making a titania nanotube membrane, and a method of making titania nanotubes, which are expected to expire in 2025-2038, while patents issued in foreign jurisdictions are expected to expire in 2032-2035;
- Four of the patents issued in the United States (U.S. Patent Nos. 9,511,212, 10,792,481, 11,129,791 and 11,478,430) are also directed to implantable drug delivery devices. These U.S. patents relate to exenatide and are expected to expire in 2035 and 2037;
- One of the patents issued in the United States (U.S. Patent Nos. 11,931,453) is also directed to the release of exenatide from an implantable device. This U.S. patent is expected to expire in 2037;
- Five of the patents issued in the United States (U.S. Patent Nos. 9,511,212, 10,105,523, 10,525,248, 10,792,481 and 11,191,935) are also directed to apparatuses and methods for promoting fluid uptake. These U.S. patents relate to an apparatus to implant a drug delivery system and are expected to expire in 2035-2038;
- Six of the patents issued in the United States (U.S. Patent Nos. 10,479,868, 11,021,576, 10,045,943, 10,688,056, 11,478,430, and 12,071,516) and 3 of the patents issued in a foreign jurisdiction are also directed to formulations. These U.S. patents relate to an exenatide composition and an implantable drug delivery system comprising exenatide and are expected to expire in 2035;
- One of the patents issued in the United States (U.S. Patent No. 9,770,412) is also directed to coated nanoporous membranes. This U.S. patent relates to a method of manufacturing a nanoporous membrane and a nanopore membrane, which is expected to expire in 2035;
- One of the patents issued in the United States (U.S. Patent No. 9,814,867) and 4 of the patents issued in foreign jurisdictions, are also directed to titania nanotube membranes. This U.S. patent relates to a method of making a titania nanotube membrane and is expected to expire in 2034;
- One of the patents issued in the United States (U.S. Patent No. 7,687,431) is also directed to nanotube fabrication. This U.S. patent relates to a method of making titania nanotubes and is expected to expire in 2025; and
- Ten pending U.S. applications, 4 international applications, and 24 applications pending in foreign jurisdictions, which are directed to implantable drug delivery devices, methods to control release, drug products, and formulations.

Wherever possible, Vivani seeks to protect its inventions by filing U.S. patents as well as foreign counterpart applications in select other countries. Because patent applications in the U.S. are maintained in secrecy for at least eighteen months after the applications are filed, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, Vivani cannot be certain that it was the first to make the inventions covered by each of its issued or pending patent applications, or that Vivani was the first to file for protection of inventions set forth in such patent applications. Vivani's planned, or potential products may be covered by third-party patents or other intellectual property rights, in which case continued development and marketing of its products would require a license. Required licenses may not be available to Vivani on commercially acceptable terms, if at all. If Vivani does not obtain these licenses, it could encounter delays in product introductions while it attempts to design around the patents, or Vivani could find that the development, manufacture, or sale of products requiring such licenses are not possible.

In addition to patent protection, Vivani also relies on know-how, trade secrets, and the careful monitoring of proprietary information, all of which can be difficult to protect. Vivani seeks to protect some of its proprietary technology and processes by entering into confidentiality agreements with its employees, consultants, and contractors. These agreements may be breached, Vivani may not have adequate remedies for any breach and its trade secrets may otherwise become known or be independently discovered by competitors. To the extent that Vivani's employees or its consultants or contractors use intellectual property owned by others in their work for Vivani, disputes may also arise as to the rights in related or resulting know-how and inventions.

Government Regulation

Regulatory authorities in the U.S. at the federal, state, and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, and export and import of drugs, medical devices and combinations of drugs and devices (combination products) such as those we are developing. Generally, before a new drug or drug-device combination product can be marketed, considerable data demonstrating its quality, safety, and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review, and approved by the relevant regulatory authority.

In the U.S., the FDA regulates drugs, devices and combination products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. These products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's, or another regulatory authority's, refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, debarment, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Drug Development

Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we plan to investigate our products through the IND framework and seek approval through the NDA pathway. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB representing each clinical site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices (“GCP”) regulations, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA which, for a combination product like our product candidates, is expected to include information and data regarding the drug delivery device technology;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA’s current good manufacturing practice requirements (“cGMP”);
- potential FDA inspection of Vivani, the clinical trial sites or other vendors that generated the data in support of the NDA;
- payment of associated user fees;
- review by an FDA advisory committee, where appropriate or if applicable;
- FDA review and approval of the NDA prior to any commercial marketing or sale; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (“REMS”), and the potential requirements to conduct post-approval studies.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. A sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an IRB must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2. Clinical trials are conducted in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies also are required to register certain clinical trials and post the results of those clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted on an expedited basis to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. In addition, for certain combination products it may be necessary to conduct human factors studies prior to NDA submission to ascertain the usability of the product by patients in real-world settings.

NDA and FDA Review Process

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product. An NDA for a new drug must contain proof of the drug's safety and efficacy. The submission of an NDA is subject to the payment of a substantial application user fee, and the sponsor of an approved NDA is also subject to an annual program user fee, although waivers of some fees may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA typically makes a decision on accepting an NDA for filing within 60 days of receipt. The decision to accept the NDA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the filing of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. During its review, the FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In reviewing the NDA for a drug-device combination product, FDA reviewers in the drug center will consult with their counterparts in the device center to ensure that the device component of the combination product meets applicable requirements regarding safety, effectiveness, durability and performance. Under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulations ("QSRs") applicable to medical devices. In addition, before approving an NDA, the FDA may inspect certain clinical trial sites and audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a complete response letter ("CRL"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes all the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to nonclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

505(b)(2) Approval Process

NDAs for most new drug products are based on at least two adequate and well-controlled clinical studies and must contain substantial evidence of the safety and effectiveness of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is authorized, however, to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. An application under 505(b)(2) provides an alternate regulatory pathway for the FDA to approve a new product and permits reliance for such approval on published literature or an FDA finding of safety and effectiveness for a previously approved similar drug product, or published literature. Specifically, Section 505(b)(2) permits the filing of an NDA where one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicantNDAs filed under Section 505(b)(2) may provide an alternative and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. Typically, 505(b)(2) applicants must perform additional trials to support the change from the previously approved drug and to further demonstrate the new product's safety and effectiveness. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Pediatric Trials

Under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

Post-Marketing Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse events, and providing updated safety and efficacy information. Moreover, each component of a combination product retains its regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion and advertising, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. In addition, a pharmaceutical company must comply with restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers and their agents may not market or promote such off-label uses or provide off-label information in the promotion of drug products that is not consistent with the approved labeling for those products. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to corrective advertising in addition to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

In the U.S., once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that combination products be manufactured in specific approved facilities and in accordance with cGMPs applicable to drugs and devices, including certain QSR requirements. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well organizational and procedural infrastructure, maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in recalls or other restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drug products must comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S.

The FDA also may require post-marketing testing, known as Phase 4 testing, a REMS to assure the safe use of the drug, or surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development and impact approved products already on the market.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications that rely on a previously approved NDA. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, such as for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active ingredient for an unprotected indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory exclusivity available in the U.S. Pediatric exclusivity provides for an additional six months of exclusivity attached to another period of regulatory exclusivity or a patent if a sponsor conducts clinical trials in children that fairly respond to a written request issued by the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Healthcare Laws & Regulations

In the U.S., the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. For example, sales, marketing, and scientific/educational grant programs must comply with the federal Anti-Kickback Statute, the federal False Claims Act, the privacy regulations promulgated under the Health Information Portability and Accountability Act of 1996 ("HIPAA"), and similar state laws. Pricing and rebate programs must also comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, provisions of the Inflation Reduction Act of 2022, and the Veterans Health Care Act of 1992, as amended. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Medicare Modernization Act ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which Vivani may receive regulatory approval. However, any negotiated prices for Vivani's products (if covered by a Part D prescription drug plan) will likely be lower than the prices Vivani might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare may result in a similar reduction in payments from non-government payors.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Vivani's products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be priced significantly lower than in the U.S.

In the U.S., once Vivani has products on the market, the company will be subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions and the potential for additional legal or regulatory change in this area, it is possible that Vivani's future sales and marketing practices or Vivani's future relationships with medical professionals might be challenged under anti-kickback laws, which could harm Vivani.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Although Vivani would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, Vivani's future activities relating to the reporting of wholesaler or estimated retail prices for Vivani's products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for Vivani's products, and the sale and marketing of Vivani's products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a federal False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $13,946 and $27,894 for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct those results in a federal False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that Vivani was, or convict Vivani of, violating these false claims laws, Vivani could be subject to a substantial fine. In addition, private individuals could bring actions under the federal False Claims Act and certain states have enacted laws modelled after the federal False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report to HHS information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals; as well as the ownership and investment interests of such physicians and their immediate family members.

Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

State laws governing the privacy and security of health information in certain circumstances may also apply, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts, and analogous foreign laws and regulations.

In addition, federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Similar healthcare laws and regulations in the European Union and other non-U.S. jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, ("GDPR"), which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data). There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals in the previous calendar year. These laws may affect Vivani's sales, marketing and other promotional activities by imposing administrative and compliance burdens on Vivani. In addition, given the lack of clarity with respect to these laws and their implementation, Vivani's reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The failure to comply with regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a company to enter into supply contracts, including government contracts.

Changes in regulations, statutes or the interpretation of existing regulations could impact Vivani's business in the future by requiring, for example: (1) changes to Vivani's manufacturing facility; (2) additions or modifications to product labeling; (3) the recall or discontinuation of Vivani's products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of Vivani's business.

Rest of the World Regulation

Outside of the United States, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Healthcare Reform & the Patient Protection and Affordable Care Act

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs, and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the PPACA, was enacted, which includes measures that significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's covered outpatient drugs furnished to Medicaid patients. Effective in 2010, the PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents to 23.1% of the AMP and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefits;
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. The PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase;

- The PPACA imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (*i.e.*, “donut hole”). This requirement was later increased to a 70% discount; and
- The PPACA imposes an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

Since its enactment, there have also been executive, judicial, and Congressional challenges to certain aspects of the PPACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case without specifically ruling on the constitutionality of the PPACA. Accordingly, the PPACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the executive branch will impact our business, financial condition, and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. Subsequent legislation extended the 2% payment reduction which remains in effect through 2031. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025 (thereby effectively eliminating the so-called “donut hole”); impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Further, healthcare reform measures have been subject to several executive orders of the Biden Administration, including orders that address pharmaceutical pricing. At the state level, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws if and when we begin commercialization after obtaining regulatory approval for any of our product candidates.

Corporate Social Responsibility

Environmental Responsibility

Vivani aims to reduce medical waste through development and commercialization of its NanoPortal implant technology

Today, GLP-1 receptor agonist medications are predominantly administered via single-use injectable pens, which, in the aggregate, present substantial environmental challenges. The component parts of these injectable pens include their plastic, metal, and residual medication. Classified as "sharps" waste due to their built-in needles, improper disposal of these pens can lead to special environmental and health risks.

The sheer scale of GLP-1 injector pen disposal in the U.S. and globally compounds those risks. By 2030, the number of patients treated with GLP-1 drugs in the United States could reach 30 million, potentially resulting in approximately 1 billion single-use autoinjectors being discarded annually. This volume of waste is estimated to equate to 35,000 tons or 50,000 cubic meters of material—enough disposed injector pens to circle the globe 3.5 times.

Vivani Medical's development of the NanoPortal implant technology offers a potential sustainable alternative to traditional injectable therapies. Our miniature biopharmaceutical implants are designed to deliver steady doses of medication over extended periods, potentially up to six months or longer. This approach has the potential to reduce the frequency of injector pen-dependent medical interventions while reducing the volume of medical waste generated. By eliminating or minimizing the need for single and multiple-use injection devices, our implant technology addresses the environmental and health challenges associated with disposable pens, contributing to a reduction in the overall environmental footprint of treatments for type 2 diabetes, obesity, chronic weight management, and potentially other treatments for chronic conditions.

Adherence to California Sustainability Standards

Vivani Medical maintains its headquarters and operations in California, a state recognized for its leadership in environmental stewardship. Our Alameda, California facility complies with the California Green Building Standards Code (CALGreen) and incorporates energy-efficient designs. Vivani also supports state-level climate change goals by implementing energy-saving practices and encouraging sustainable commuting options for employees.

Employee Commuting Pollution Mitigation

To further minimize environmental impact, Vivani provides flexible work arrangements, including remote work, which reduces vehicle emissions and Bay Area traffic congestion. The company also offers public transit benefits and on-site charging stations for employees with electric vehicles.

Social Responsibility

Human Capital Management

Compensation and Benefits

Vivani deeply values its employees and their contributions. Our total compensation and benefits package is regularly evaluated to remain competitive. Employees receive:

- Exceptional healthcare coverage with low employee contributions.
- Flexible paid time off for work-life balance.
- Annual equity grants, providing ownership in the company based on performance.
- Competitive salaries and 401(k) including a company match that are regularly benchmarked.

Vivani also promotes employee engagement through regular town halls, and internal communications to align team members with the company's vision and goals.

Recruitment and Retention

Vivani believes that we have been successful in attracting and retaining qualified personnel with the appropriate background and experience to support our business and its growth. We monitor recruiting efforts on hiring new employees and information on the retention of business-critical hires.We also track voluntary and involuntary turnover rates which have been historically low.

Diversity and Inclusion

Vivani embraces diversity as a critical asset for innovation and growth. Today, women comprise 50% of our workforce and management roles.Vivani actively fosters an inclusive culture where diverse perspectives drive creativity and excellence.

Governance

Ethics and Compliance

Vivani maintains a robust compliance framework, adhering to the California Transparency in Supply Chains Act and ensuring ethical business practices.Vivani also maintains a Code of Conduct for its employees and all those associated with the Company.

Cybersecurity and Privacy

Vivani actively monitors cybersecurity threats, implements advanced email and network security technologies, and mandates annual employee training to ensure best practices. These efforts align with California Consumer Privacy Act ("CCPA") requirements, safeguarding stakeholder data and privacy.

Supplier Oversight and Quality Assurance

Vivani enforces high standards for supplier qualification and quality management. By requiring rigorous compliance with Good Manufacturing Practices (GMP) and related quality measures, the company ensures product safety and reliability throughout the development lifecycle.

A Business Strategy Anchored to Environmental Sustainability, Social Responsibility, and Transparent and Ethical Governance

Vivani integrates sustainability and governance practices into its overarching business strategy. The company's mission to provide innovative and accessible healthcare solutions aligns closely with its commitment to environmental stewardship, social responsibility, and ethical governance. By prioritizing these principles, Vivani aims to deliver long-term value to patients, stakeholders, and society.

Vivani Medical is proud to integrate environmental, social, and governance considerations into its operations. By prioritizing sustainability, fostering a healthy work environment, and adhering to the highest ethical standards, we aim to deliver long-term value to our stakeholders while advancing healthcare innovation.

Properties

Our principal offices and facilities are located at 1350 South Loop Road, Alameda, CA 94502 and 27200 Tourney Road, Suite 315, Valencia, CA 91355 and are both leased.

In November 2022, Vivani signed a long-term lease at 1350 South Loop Road, Alameda, CA 94502 to accommodate office space, R&D, analytical labs and a GMP manufacturing suite to support our research and development activities for our Biopharm Division. Vivani moved into the new facility in September 2023.

On February 1, 2023, Cortigent, our Neurostimulation Division entered into a lease agreement, effective March 1, 2023, to sublease office space at 27200 Tourney Road, Suite 315, Valencia, CA 91355 to be utilized as its headquarters. The sublease expires on April 30, 2025. We also entered into a lease for storage space in the same facility that expires on March 31, 2025. We are not renewing the current office lease. However we are entering into another lease in the same building for a smaller space. We are renewing the lease of the storage unit. These new and renewal leases will be short-term leases with immaterial monthly costs.

Employees

As of December 31, 2024, we had 36 employees in our Biopharm Division and 6 employees in Cortigent. Of these persons, all are employed in the United States. We believe that the continued success of our business will depend, in part, on our ability to attract and retain qualified personnel, and we are committed to developing our people and providing them with opportunities to contribute to our growth and success. None of these employees is covered by a collective bargaining agreement, and we believe our relationship with our employees is good to excellent.

Available Information

Our website address is www.vivani.com. We make available free of charge through a link provided at our website our Forms 10-K, 10-Q and 8-K as well as any amendments thereto. These reports are available as soon as reasonably practicable after they are filed with the Securities and Exchange Commission.

Item 1A. Risk Factors

This Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical-stage company with a limited operating history, and have no products approved for commercial sale.

We are a clinical-stage biopharmaceutical company. In August 2022, we completed a business combination of Second Sight and NPM, to form our current company. Following the business combination, we are focusing primarily on the development of our proprietary NanoPortal technology and the development of miniaturized, subdermal drug implants capable of the long-term delivery of medicine in patients with chronic diseases with high unmet medical need. Our pipeline includes our current product candidates NPM-115, NPM-119, NPM-139 and OKV-119, which we have partnered with Okava. NPM-115 has entered clinical-stage development, and NPM-139 and NPM119 are in preclinical development. OKV-119 is in development for use in treating cardiometabolic disorders in dogs and cats. No Vivani drug candidates have been approved for marketing, or are being marketed or commercialized.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and we have not yet demonstrated an ability to successfully complete clinical trials or obtain marketing approval for any of our product candidates or otherwise successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We have not generated any revenues to date, and we continue to incur significant research and development and other expenses. As a result, we have not been profitable and have incurred operating losses in every reporting period since our inception. During the years ended December 31, 2024 and 2023, we reported net losses of $23.5 million and $25.7 million, respectively, and had an accumulated deficit of $121.9 million as of December 31, 2024.

For the foreseeable future, we expect to continue to incur significant and increasing losses as we expand our research and development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the FDA or comparable foreign regulatory authorities. Even if one or more of our product candidates complete their clinical development, achieve marketing approval and are commercialized, we may never become profitable.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies in rapidly evolving fields. If one or more of our product candidates receive marketing approval, we also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition.

We do not anticipate generating revenue from product sales for the foreseeable future and may never be profitable.

The viability of our business depends on our ability to generate revenue from product sales. Vivani’s current pipeline is focused on the development of our proprietary NanoPortal technology and the development of miniaturized, subdermal drug implants capable of the long-term delivery of medicine in patients with chronic diseases with high unmet medical need. However, we may never be able to develop or commercialize marketable products from our current pipeline or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is obtained, the accepted price for the product, the acceptance of the product by physicians and patients, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. In addition, if the market size for our product candidates is smaller than estimated, the indication or intended use approved by regulatory authorities is narrower than expected, or the target patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable. Even if we achieve profitability in the future, such profitability may not be sustained in subsequent periods.

Our ability to generate revenue and achieve profitability depends significantly on our ability, either independently or in collaboration with third parties, to achieve several objectives, including:

- successful completion of preclinical studies resulting in data that is supportive of advancing to an IND submission;
- successful submission and acceptance of INDs or comparable applications;
- successful initiation of clinical trials;
- successful and timely completion of nonclinical and clinical development of our product candidates;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing, and developing new product candidates;
- obtaining, maintaining, and expanding patent protection, trade secret protection and regulatory exclusivity in the United States and target international markets;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing, or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve or maintain profitability. Any failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, and continue our operations.

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to conduct clinical trials of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we will incur significant costs associated with sales, marketing, manufacturing, and distribution activities. Our expenses could increase beyond expectations if required by the FDA or other foreign regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate. We are not permitted to market or promote any product candidate before it receives marketing approval from the regulatory authorities. Accordingly, we will need to obtain substantial additional funding in order to continue our operations and pursue our business objectives.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit, or eliminate one or more of our business objectives, and our competitiveness, and business, financial condition and results of operations may be materially adversely affected. If we are unable to continue our business, including due to inadequate funding, you could lose your investment.

Vivani's future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of its clinical trials, preclinical studies, and other related activities;
- its ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of its current or future product candidates;
- the number and characteristics of the product candidates it seeks to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of its product candidates;
- the cost of commercialization activities if any of its current or future product candidates are approved for sale, including marketing, sales, and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of its product candidates, should any of its product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

We may raise capital in the form of equity or debt financing, partnerships, collaborations, licensing, spin-offs or other strategic transactions. If we raise additional capital by issuing equity securities, the ownership of our existing may be reduced, and accordingly these shareholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of its common stock. If we raise funding through debt instruments or facilities, lenders may require us to pledge some or all of our assets as collateral. We may also be required to observe financial, operational and other covenants that constrain our business and operations. If we enter into partnerships, collaborations, licensing or other strategic transactions, we may be required to grant rights to third parties, including rights to develop and market product candidates, that we would otherwise have retained.

Our ability to utilize its net operating loss ("NOL") carry-forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change NOL carry-forwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed a study to assess whether any ownership changes, as defined by Section 382 of the Code, have occurred. Past, current and future ownership changes may limit our ability to utilize remaining tax attributes.

As of December 31, 2024, we had federal and apportioned state NOL and federal and state R&D credit carry-forwards available to offset future taxable income and income taxes as follows (in thousands):

		As of December 31, 2024
Pre TCJA (Tax Cuts and Jobs Acts of 2017) period federal NOL carry-forward, begin expiring 2030	$	47,353
Post TCJA period federal NOL carry-forward, with no carry-forward limitation		151,315
Total federal NOL carry-forward	$	198,668
State NOL carry-forward, begin expiring 2030	$	143,717
Federal R&D tax credit carry-forward, begin expiring in 2036	$	4,907
State R&D carry-forward, no expiration date	$	8,755
Total R&E related deferred income tax assets (net of applicable amortization)	$	6,722
Reserve for uncertain income tax positions		Nil

Furthermore, under recently enacted U.S. tax legislation, although the treatment of tax losses generated in taxable years ending before December 31, 2017, has generally not changed, tax losses generated in taxable years beginning after December 31, 2017 may only be utilized to offset 80% of taxable income annually. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Risks Related to Product Development, Clinical Testing and Commercialization

We are dependent on the successful design, development, regulatory approval and commercialization of one or more of our product candidates, there can be no assurance that we may achieve any of these objectives.

We have spent significant time, money and effort onour proprietary NanoPortal implant technology which will require additional design and development to support our emerging portfolio of drug/device combination product candidates, including NPM-115 (high-dose exenatide implant), NPM-139 (semaglutide implant), NPM-119 (exenatide implant), and OKV-119 (exenatide implant for companion cats). All of our product candidates will require additional design and development, including further enhancements to our NanoPortal technology, clinical trials as well as further preclinical studies to evaluate their safety, tolerability and pharmacokinetics, and to optimize their formulation. Our product candidates may require significant additional design and testing before advancing to pivotal clinical trials that are designed to generate sufficient safety and efficacy data to support a marketing application. Even if we conduct and complete such testing of our product candidates, there can be no assurance that we will obtain marketing approval for one or more of these candidates. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory approvals will be obtained. Our drug development efforts may not lead to commercially viable products for any number of reasons, including because our product candidates fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities to support marketing approval, or because we have inadequate financial or other resources to advance our product candidates through development and approval processes. If any of our product candidates fail to demonstrate sufficient safety or efficacy data at any time to support their continued development, or we encounter other challenges in the development of our product candidates, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our product candidates will be eligible to receive regulatory approval from the FDA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we may be unable to commercialize them successfully for a variety of reasons, either independently or in collaboration with third parties. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects or the willingness of patients and healthcare providers to use or administer our drug implants. If we fail to develop, obtain approval for and commercialize one or more of our product candidates, our business would be materially and adversely impacted.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing our product candidates, and our clinical development efforts may not yield favorable results.

To receive regulatory approval for our product candidates, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA and comparable foreign regulatory authorities. We have not yet conducted clinical trials for our current product candidates and clinical testing of such product candidates may not yield results to support continued development or seeking regulatory approval. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent development and approval of our product candidates, including the following:

- we may be unable to initiate or conduct planned clinical trials on our anticipated timelines, including as a result of failing to obtain any clearances necessary to conduct clinical trials or being subject to clinical holds that prevent continuation of such trials;
- clinical trials may produce negative or inconclusive results;
- preclinical studies conducted with product candidates during clinical development to, among other things, evaluate their safety, tolerability and pharmacokinetics and optimize their formulation may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than anticipated;
- costs of development may be greater than anticipated;
- our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- if one or more product candidates are developed in collaboration with third parties, such parties may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner;
- we may face delays or other challenges associated with the availability and sourcing key raw materials and/or key components; and
- we may encounter difficulties in developing product candidates related to our proprietary NanoPortal implant technology or difficulties associated with the long-term purity, potency, safety, or stability of our product candidates.

For example, our IND for the NPM-119 program was on full clinical hold between August 2023 and June 2024.

Even if we experience success in early development for any product candidate, that experience may not be replicated in later development or with respect to any other product candidates. For example, in our industry, product candidates in later-stage clinical trials routinely fail to demonstrate adequate safety and efficacy despite having progressed through initial clinical trials or preclinical testing.

Even if our clinical trials generate data that we believe are promising, such data may not be sufficient to support seeking marketing approval by the FDA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA or comparable foreign regulatory authorities may interpret such data in different ways than we do. If we fail to generate data that adequately demonstrate the safety and efficacy of our product candidates to support marketing approval from regulatory authorities, we will not be able to market and commercialize these product candidates.

From time to time, in addition to or as an alternative to raising capital through equity or debt offerings, we may seek to selectively and opportunistically enter into collaborations with third parties to assist in the development and potential future commercialization of some or all of our product candidates. However, there can be no assurance that we will be able to establish such collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations. Even if we enter into one or more of such collaborations, the risks associated with the development of product candidates still remain, and there can be no assurance that our potential collaborators will successfully develop, seek approval for and commercialize any of our product candidates.

Our product candidates may have serious adverse, undesirable or unacceptable side effects that could delay, pause or terminate our clinical trials, or prevent us from obtaining regulatory approval for or commercialize such product candidates. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects observed in preclinical studies or clinical trials of our product candidates could interrupt, delay, or halt their development and could result in the denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval.

Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition, and results of operations.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition, and results of operations. For example:

- our collaborators may terminate any development agreements covering these product candidates;
- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization; and
- we may be subject to product liability or shareholder litigation.

In addition, even if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product, or we may decide to cease marketing and sale of the product voluntarily;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy ("REMS"), including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions and/or requiring special training for prescribers of the product;
- change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to recall or remove such products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates;
- we may fail to secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Our efforts to identify and develop product candidates beyond those in our current pipeline may not succeed, and any product candidates that we select for clinical development may not actually begin clinical trials.

We intend to expand our current pipeline of core assets by continuing to advance drug implants from future and ongoing feasibility programs into preclinical and clinical development. However, the process of identifying and developing drug implants is expensive, time-consuming, and unpredictable. Data from our current preclinical programs may not support the clinical development of its lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds that we select for clinical development may not generate sufficient safety and efficacy data that would support advancement into clinical trials or to continue clinical trials that are ongoing. Such findings would potentially impede our ability to maintain or expand our development pipeline. Our ability to identify new drug implant candidates and advance them into preclinical and clinical development also depends upon our ability to fund our research and development operations, and there can be no assurance that additional funding will be available on acceptable terms, or at all.

We could experience delays in the commencement or completion of clinical trials, which could result in increased costs or otherwise impair our research and development efforts.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs and otherwise impair our research and development efforts. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations and clinical trial sites;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our product candidates.

For instance, our IND for the NPM-119 program was on full clinical hold between August 2023 and June 2024. In addition, once a clinical trial has begun, it may be suspended or terminated by us or our collaborators, institutional review boards, or, if applicable, data safety monitoring boards charged with overseeing our clinical trials, the FDA, or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the development of product candidates will be impaired. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development process and our anticipated timelines for seeking marketing approval. Such delays could also allow our competitors to obtain marketing approval for their own product candidates before we do or may shorten the patent protection period during which we may have the exclusive right to commercialize our product, if approved. Any of these occurrences may harm our business, financial condition, and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of preclinical trials may not be predictive of the results of later-stage clinical trials, and many product candidates fail to achieve regulatory approval despite showing initial promise in early-stage testing.

The results of preclinical studies of product candidates may not be predictive of the results of clinical trials, and results from early-stage clinical testing may not be replicated in later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. We may experience similar setbacks in our development programs for these or other reasons.

As product candidates are developed through preclinical, early-stage clinical and late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late-stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our planned clinical trials or other future clinical trials less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may experience delays in the enrollment of patients in our clinical trials, which would adversely affect our ability to initiate, conduct and complete such trials on our anticipated timelines.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including:

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the therapeutic candidate under study;
- the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance;
- perceived risks and benefits of our approach to treatment of indication;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

Even once enrolled we must retain a sufficient number of patients to complete any of our trials.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which may impair the significance of such results and cause regulatory authorities to require additional testing. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay our development timelines or force us to abandon one or more of our programs altogether.

We may experience difficulty identifying, training and/or certifying an adequate number of healthcare professionals to properly implant and, when appropriate, explant our drug implants candidates, which may impair our ability to conduct our clinical trials.

Our drug implant candidates require properly trained healthcare professionals, which may include doctors, nurse practitioners and nurses, for subdermal placement into patients. These healthcare professionals would also be responsible for removal and replacement of a new drug implant. There can be no assurance that sufficient numbers of trained and/or certified healthcare professionals will be available or that the training or certification requirements will not be more burdensome than anticipated. Both factors could lead to difficulties in conducting our clinical trials and impair our development efforts for our product candidates.

If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile, or are demonstrated to be more effective than our own, our commercial opportunity may be reduced or eliminated.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience, and scientific resources enable us to compete in our industry, we face competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we develop and, if approved, commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals, and marketing approved products. Some of our competitors in the GLP-1 receptor agonist drug class include companies such as Novo Nordisk, AstraZeneca, and Eli Lilly. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than those of our own, or that would render our product candidates obsolete and non-competitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

We believe that the key competitive factors affecting the viability of product candidates, if approved, are likely to be their efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

Multiple GLP-1 receptor agonist products have been proven effective to reduce cardiovascular morbidity and mortality, including Trulicity (dulaglutide), Ozempic/Wegovy (semaglutide injection), and Victoza (liraglutide), medical guidelines may recommend preferential use of GLP-1 receptor agonists that have positive cardiovascular morbidity and mortality data in the products approved labeling. Since Bydureon did not demonstrate a reduction in cardiovascular morbidity and mortality, NPM-119 would not have this claim in the approved product label unless we generate positive cardiovascular outcomes data with NPM-119. The lack of a cardiovascular outcomes benefit in the NPM-119 label may decrease its market potential, if approved.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA"). FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate (and in some cases even this limited bioequivalence testing can be waived by the FDA). Competition from generic equivalents to our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

We are subject to a multitude of complex manufacturing challenges and risks, including reliance on third parties, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to numerous risks. For example, the process of manufacturing our product candidates is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. In addition, the manufacturing facilities in which its product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, including but not limited to wildfires, earthquakes and floods, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts, or seek costlier manufacturing alternatives.

The commercial success of our product candidates, if approved, depends upon their market acceptance among physicians, patients, healthcare payors, and the medical community.

Even if our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our product candidates, if approved, will depend on several factors, including:

- the effectiveness of our approved product candidates as compared to competitive products;
- adequately trained healthcare professionals willing to administer our product candidates;
- patient willingness to adopt our approved product candidates rather than competitive therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;
- effectiveness of our sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of their potential market opportunity. If the actual market for our product candidates is smaller than we expect, the market potential for our product candidates may be limited. If we fail to achieve market acceptance of our product candidates, the viability of our business may be limited.

If we fail to obtain and sustain an adequate level of reimbursement by third-party payors for our product candidates, if approved, potential future sales would be materially adversely affected.

Even if our product candidates receive marketing approval, there will be no viable commercial market without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our product candidates. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan, and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. Third-party payors may also limit the covered indications. Cost-control initiatives could decrease the price that we might establish for products, which could result in product revenues being lower than anticipated. If we are unable to show a significant benefit over existing therapies, Medicare, Medicaid, and private payors may not be willing to provide reimbursement for our product candidates, if approved, which would significantly reduce the likelihood of such product candidates gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety, and tolerability of our product candidates in determining whether to approve reimbursement for such product candidates and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive adequate reimbursement of our product candidates, if approved, from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that generates cost-effectiveness or health economics data of our product candidates in comparison to other available therapies.

If the prices for our product candidates, if approved, are reduced or if governmental and other third-partypayors do not provide adequate coverage and reimbursement of our products, our future revenue, cash flows and prospects for profitability will suffer.

Since our product candidates are designed to deliver active medication for up to six months or longer, there may be additional risks associated with the third-party payor's willingness or desire to reimburse the full product cost at the time of purchase. We may develop customized reimbursement practices or policies to address potential concerns from payors if appropriate. There are no assurances that customized reimbursement practices or policies, if needed, will be effective and the potential impact on revenues and profits is difficult to project.

Risks Related to Regulatory Approval and Other Legal and Compliance Matters

Our product candidates are subject to extensive regulation under the FDA, the EMA and comparable foreign regulatory authorities, and must undergo extensive clinical testing that can be costly and time consuming, with no assurance that regulatory approval will be obtained for any of our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies or comparable authorities in foreign markets. In the U.S., neither we nor any collaborators are permitted to conduct clinical testing in humans with our product candidates until the appropriate clearance is received under an investigational new drug application (IND) from the FDA or other appropriate authorizations are received from relevant foreign regulatory authorities abroad. In addition, marketing of such product candidates may not occur unless and until approval of a new drug application (NDA) from the FDA or similar approvals by comparable foreign regulatory authorities are secured.

The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, with respect to our current pipeline, we have filed only one US IND, one clinical trial authorization request in Australia. Both requests have been granted (although our IND for the NPM-119 program was on full clinical hold between August 2023 and June 2024). No NDAs with the FDA or similar applications with other foreign regulatory agencies have been submitted. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates.

Despite the time and expense invested, and even if we observe promising results from clinical testing of our product candidates, regulatory approval is never guaranteed. In our industry, many companies have experienced significant setbacks when seeking marketing approval from regulatory agencies, despite having generated promising data from clinical testing of their product candidates. For example, the FDA has rejected both original and resubmitted NDAs from Intarcia Therapeutics for its exenatide implant candidate for the treatment of type 2 diabetes. Based on public correspondence from the FDA, the agency asserted that the data submitted in the applications did not show that the product would be safe under the proposed conditions of use and that the methods used in, and the facilities and controls used for, the manufacture, processing, or packing of the product were not shown to be adequate to preserve its identity, strength, quality, and purity. Further correspondence disclosed additional deficiencies, including that data that did not demonstrate adequate device reliability in regard to dose delivery. While we seek to avoid such outcomes in developing our product candidates based on our proprietary NanoPortal technology, there can be no assurance that such product candidates will not experience similar setbacks if and when we apply for regulatory approval. Similar results would significantly jeopardize the approvability of our product candidates that employ the NanoPortal technology.

Any inability to obtain these approvals would prevent us from commercializing our product candidates. The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the FDA could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our lead product candidate;
- agency officials of the FDA or comparable foreign regulatory authorities may find the data from non-clinical or preclinical studies, chemistry, manufacturing, and controls, and/or clinical trials generated during development is inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- the FDA or comparable foreign regulatory authorities may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- the FDA or comparable foreign regulatory authorities may not approve in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our product candidates;
- the FDA or comparable foreign regulatory authorities may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- the FDA or a comparable foreign regulatory authorities may approve our lead product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- the FDA or a comparable foreign regulatory authorities may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our lead product candidate.

With respect to our lead program, NPM-115 (high-dose exenatide implant) in development for chronic weight management in obese or overweight individuals, we plan to consult FDA's recent draft guidance document "Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction" issued in January 2025. In addition, we are preparing briefing materials to gain further clarity from FDA on our proposed NPM-115 development program. Early and ongoing dialog with FDA will be critical for this program since the proposed doses for weight loss and chronic weight management may be higher than those doses approved for the currently marketed-exenatide products Bydureon and/or Bydureon BCise, for patients with type 2 diabetes.

With respect to NPM-119 (exenatide implant), which is in development to treat patients with type 2 diabetes, we plan to seek regulatory approval in the U.S. by filing an NDA under Section 505(b)(2) of the FDCA, which is referred to as the 505(b)(2) pathway. The 505(b)(2) pathway allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. For NPM-119, we intend to rely on certain information from the Bydureon and/or Bydureon BCise applications. If we are unable to reference data generated for Bydureon and/or Bydureon BCise, additional clinical studies, including a cardiovascular outcomes ("CVOT") study, may be required and would add significant additional costs and a significant delay in our efforts to seek and secure marketing approval. Further, if a CVOT study were conducted, there can be no assurance that the study would generate favorable results and support U.S. registration.

Although we have discussed our intention to use the 505(b)(2) regulatory pathway with the FDA, there can be no assurance that this pathway will be acceptable, and there can be no assurance that the FDA will not require additional testing to support seeking approval in the U.S. If the 505(b)(2) regulatory pathway is not available, the costs of development may significantly increase and the projected timeline to approval and launch would be significantly delayed.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidate.

We may utilize the 505(b)(2) pathway for the regulatory approval of NPM-115, NPM-119 and, potentially, other of our product candidates. Final marketing approval of NPM-115, NPM-119, or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We may pursue a regulatory pathway pursuant to Section 505(b)(2) of the FDCA for the approval of NPM-115, NPM-119 and other product candidates, which allows us to rely on existing preclinical and/or clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

Final marketing approval of NPM-115 or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

In the case of NPM-119, if the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for our product candidates, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. Even if we are allowed to pursue the 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA’s interpretation of Section 505(b)(2) to allow reliance on the FDA’s prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA’s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA’s interpretation, the approval of NPM-119 or other of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with NPM-119 or our other product candidate, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Even if we are successful in pursuing the 505(b)(2) regulatory pathway for NPM-119, or other of our product candidates, we cannot assure you that we will receive the requisite or timely approval for commercialization of NPM-119 or other of our product candidates. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved listed drugs or on published literature for which we do not have a right of reference, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of NPM-119 or other of our product candidates is insufficient or not applicable to our application or that additional studies will need to be conducted. To the extent that we are relying on the 505(b)(2) regulatory pathway based on the approval of a listed drug for a similar indication, the FDA may require that we include in the labeling of NPM-119 or another of our product candidates, if approved, some or all of the safety information that is included in the labeling of the approved listed drug. Moreover, even if any of our product candidates are approved via the 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, such as a Risk Evaluation and Mitigation Strategy, or REMS, which is a risk mitigation plan which could include medication guides, physician communication plans, or elements to assure safe use, or ETASU, such as restricted distribution methods, patient registries and other risk minimization tools.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

Some of our product candidates are drug-device combination products which require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. In the European Union, depending on the nature of the drug-device combination product, an opinion may be required from a notified body on the device element of the product (for single integral products) or from the EMA on the medicinal product element (for medical devices with an ancillary medicinal substance), as part of the approval process for the applicable product. Any issues identified in such opinion or any delays in the provision of such opinion could independently affect our ability to market our combination products in the European Union. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMPs. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application ("MAA") on a timely basis and must adhere to good laboratory practices ("GLP") and cGMP regulations enforced by the FDA, the EMA or comparable foreign regulatory authorities through their facilities inspection program. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers that we use, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, and our development efforts would be impaired.

Even if one or more of our product candidates receive regulatory approval in the U.S., we may never receive comparable approvals outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among countries and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these risk factors regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to commercialize our product candidates in territories outside of the U.S.

Even if any of our product candidates receive regulatory approval, we will be subject to ongoing legal and regulatory compliance requirements, and regulatory agencies may impose post-approval requirements or, under certain circumstances, withdraw such approval. We may be subject to substantial penalties regulatory requirements or if we experience unanticipated problems with our products following approval.

Even if one or more of our product candidates receive regulatory approval, the FDA or comparable foreign regulatory authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer’s facilities to continual review and periodic inspections. Manufacturers and manufacturers’ facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, on our company or on any of our collaborators, including requiring withdrawal of the product from the market.

Our product candidates will also be subject to ongoing FDA or comparable foreign regulatory authorities’ requirements, including those related to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are approved for commercialization. If our product candidates fail to comply with applicable regulatory requirements, or there is later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, a regulatory agency may:

- issue warning or untitled letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations;
- refuse to approve pending applications or supplements to approved applications that we submit;
- recall our products;
- refuse to permit the import or export of products; or
- seize or detain products or require a product recall.

Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

The FDA, the EMA and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for one or more of our product candidates for any particular indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal, or administrative penalties, and seek fines against us. The FDA, the EMA or comparable foreign regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, and results of operations.

Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices that we may obtain if our product candidates are approved for commercialization.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict, or regulate post-approval activities and affect our ability to profitably sell any product candidates that obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any of our collaborators, may receive for any approved products. For more information, see "*Business-Government Regulation – Healthcare Reform & the Patient Protection and Affordable Care Act.*"

Current and future legislation may increase the difficulty and cost to commercialize our product candidates, if approved, and affect the prices obtained, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult to sell our product candidates, if approved, profitably. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our product candidates, if approved, profitably.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition, and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2031. Under the current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if approved;
- our ability to receive or set a price that it believes is fair for its products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we will be required to pay; and
- the availability of capital.

We expect that the ACA, the Inflation Reduction Act of 2022, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any product candidates, if approved. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

At the state level, individual states are also increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business.

Inadequate funding for the FDA, the SEC, and other government agencies, including from government shutdowns, substantial leadership, personnel and/or policy changes, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and the acceptance of user fees payments, layoffs, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, if there are substantial leadership or policy changes, or if agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other disruptions at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Additionally, disruptions at the NIH or changes to the NIH's budget may negatively impact our operations and ongoing clinical trials. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be exposed to product liability risks which could place a substantial financial burden on our business.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of medical products and the subsequent sale of these products. In addition, the use in our clinical trials of pharmaceutical and related products and the subsequent sale of these products may cause us to bear a portion of or all product liability risks. If a products liability claim is brought against us, we will be required to expend significant time and resources in defending against such a claim, and such defense may not ultimately be successful. We currently have clinical trial liability insurance coverage in connection with our ongoing LIBERATE-1 clinical trial supporting our NPM-115 program. There can be no assurance that we will secure clinical trial liability insurance on commercially reasonable terms or at all. As a result, products liability risks could have a material adverse effect on our business, financial condition, and results of operations.

Our research and development activities involve the use of hazardous materials, which are subject to regulation, related costs and delays and potential liabilities.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. If an accident occurs, we could be held liable for resulting damage, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state, and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

Risks Relating to Our Intellectual Property

We may not be able to adequately protect our proprietary or licensed technology.

Our business depends on our ability to protect our proprietary technology. We rely on a combination of trade secret, patent, copyright and trademark laws, and confidentiality, licensing, and other agreements with employees and third parties, all of which offer only limited protection. We may also in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business.

We plan to seek, through prosecution of patent applications covering our owned technology, adequate patent protection for our proprietary drug technology. If we are compelled to spend significant time, money and resources protecting or enforcing our patents and future patents that we may possess, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition, and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition, and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our product candidates, if approved.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the U.S. Patent and Trademark Office (the “USPTO”) and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications that we may file in the future, our competitors might be able to use its technologies, which would have a material adverse effect on our business, financial condition, and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our product candidates may prevent us from obtaining or enforcing patents relating to these product candidates.

Patents that we currently own or license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our own product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates;
- we or our licensors may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents that we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents, or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing. If we encounter delays in our development efforts or clinical trials, the period of time during which we could market our product candidates, if approved, under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable, or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents, or any future patents we may own, including by filing lawsuits alleging patent infringement by such third parties. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity, or enforceability. In this regard, third parties may challenge our licensed patents, or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

We may not be successful in obtaining or maintaining necessary rights to develop and commercialize our product candidates.

We utilize our NanoPortal technology to develop long-term drug implant candidates that are designed to deliver active compounds to patients. Some of our product candidates may deliver active compounds that are proprietary to one or more third parties. For example, from our current pipeline, NPM-139 delivers an active ingredient that is proprietary to another company, although we do not anticipate submitting an application for marketing approval with NPM-139 until the relevant intellectual property owned by another company has expired. Similarly, in the future, we may develop one or more additional product candidates that utilize active ingredients that are proprietary to another third party. If we advance future programs utilizing compounds that are proprietary to another company for further development, we will need to negotiate and enter into one or more licenses with the relevant third parties in order to conduct such activities. However, there can be no assurance that we can enter into such agreements on commercially reasonable terms or at all.

We may also need to partner, acquire or in-license additional intellectual property in the future with respect to other product candidates. Moreover, we may be unable to acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our product candidates. We may face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on commercially acceptable terms or at all.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

We may infringe the intellectual property rights of others, which may prevent or delay our development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our business depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our product candidates infringe. There also could be patents that we believe are not infringed, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made, and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our activities either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our activities, the holders of any of these patents may be able to block our ability to commercialize our product candidates, if approved, unless it we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements on reasonable terms or at all. Any inability to secure licenses or alternative technology could result in delays in the commercialization of our product candidates, if approved, or lead to the prohibition of their manufacture or sale. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys’ fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition, and results of operations.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

We expect to submit NDAs under Section 505(b)(2) of the FDCA for our product candidates. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables the applicant to reference published literature for which the applicant does not have a right of reference and the FDA’s previous findings of safety and effectiveness for a previously approved drug. For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply.

Accordingly, if the applicant relies for approval on the safety or effectiveness on information for a previously approved drug, referred to as a listed drug, the applicable is required to include patent certifications in our 505(b)(2) NDA regarding any applicable patents covering the listed drug. If there are applicable patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and the applicant seeks to obtain approval prior to the expiration of one or more of those patents, the applicant is required to submit a Paragraph IV certification indicating its belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug.

If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner. Under the Hatch-Waxman Amendments, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner’s or NDA holder’s receipt of notice (whichever is later), a one-time, automatic stay of the FDA’s ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) NDAs and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit a Section 505(b)(1) NDA or a Section 505(j) ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours and determines that our product is inappropriate for review through the 505(b)(2) pathway. These factors, among others, may limit our ability to commercialize our product candidates successfully.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on maintaining and protecting our intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming, and inherently uncertain. For example, the U.S. previously enacted and implemented wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our patents and future patent applications and the enforcement or defense of our licensed and future patents.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all jurisdictions throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending its licensed and owned intellectual property both in the U.S. and abroad. For example, China currently affords less protection to a company’s intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

To protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We expect to employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, and to date none our employees have been subject to such claims, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration, and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. In certain instances, the Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application IND (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. However, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing therapies sooner than we expect. As a result, our revenue from applicable therapies could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed.

Risks Related to Our Reliance on Third Parties

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients, or API, in our product candidates, and our other drug components, as well as the device components of our drug-device combination product candidates. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage, or plan to engage, third-party manufacturers to manufacture our product candidates and related supplies and packaging. There is no guarantee that we can maintain our relationships with these manufacturers and we may incur added costs and delays in identifying and qualifying any replacements for such manufacturers. There is no assurance that we will be able to timely secure further needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed ability to commercialize our product candidates.

Reliance on third-party manufacturers entails additional risks, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships or if our third-party manufactures fail to comply with applicable regulations, we may need to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers and enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA, the EMA and other foreign regulatory authorities.

If any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our product supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not regard these facilities as satisfactory for the manufacture of our product candidates, we may need to find alternative manufacturing facilities, which could cause significant delays in our operating timelines and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully perform carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates on the timelines that we anticipate or at all.

We have relied and intend to continue to rely upon third-party CROs, medical institutions, clinical investigators, and contract laboratories to monitor and manage data for our ongoing research and development efforts. Nevertheless, we remain responsible for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP and GLP, which are a collection of laws and regulations enforced by the FDA, the EMA, and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials. We cannot guarantee that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs are not our own employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether they devote sufficient time and resources to our ongoing research and development activities. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and our development activities will be impaired. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be harmed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition, or results of operations.

Our efforts to seek, secure and maintain partnerships, collaborations or other strategic initiatives with respect to one or more of our programs may not be successful.

As part of our business strategy, we have entered into, and seek to enter into partnerships, collaborations and other strategic initiatives with respect to one or more of our programs, with the goal of maximizing the value of such assets. For example, we have a collaboration with Okava with respect to OKV-119. However, there can be no assurance that these arrangements will yield their intended benefits or that we will receive any return on our efforts and resources invested into these arrangements.

In addition, we may from time to time in the future enter into additional arrangements with biopharmaceutical companies for the development or commercialization of our product candidates. We face significant competition in seeking such transactions with such collaborators. Moreover, collaboration arrangements are complex, and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, and the terms of these arrangements may not be favorable to us. If collaborate with a third party for development and commercialization of a product candidate, we may be required to relinquish some or all of the control over that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition, and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, if approved, we may be unable to generate significant revenues.

We currently do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing, and distribution of approved products. If any of our product candidates are approved for commercialization, we may be required to develop its sales, marketing, and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force that we do establish may not be capable of generating sufficient demand for our product candidates, if approved. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, we may be required to relinquish a portion of the revenues from product sales to those third parties. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws. Failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through our prescribers, consultants, customers, and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how it researches, markets, sells and distributes its product candidates for which it obtains marketing approval. For more information, see "*Business – Government Regulation – Healthcare Laws & Reimbursement.*"

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If we are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, and individual imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Ownership of Our Common Stock

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2024, our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 39.5% of our common stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Vivani resulted from the August 2022 business combination of Second Sight and NPM. Vivani’s main priority is the further development of the company’s lead programs NPM-115 and NPM-119, which are miniature, 6-month, GLP-1 implant candidates for the treatment of chronic weight management and patients with type 2 diabetes, respectively. In parallel, Vivani’s management team remained committed to identifying and exploring strategic options for the Neurostimulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

Because the NPM business did not become a reporting company by conducting an underwritten initial public offering of our common stock, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement we enter into may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

The designation of our common stock as “penny stock” would limit the liquidity of our common stock.

Our common stock may be deemed a “penny stock” (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a “penny stock” is a common stock that is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stock in start-up companies is among the riskiest equity investments. Broker-dealers who sell penny stock must provide purchasers with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stock and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser’s written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. If our common stock is deemed “penny stock”, because of penny stock rules, there may be less trading activity in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.

The Financial Industry Regulatory Authority ("FINRA") has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

The market price of our common stock may be highly volatile, and may be influenced by numerous factors, some of which are beyond our control.

The market price for our common stock may from time to time fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

General Risk Factors

If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, our ability to conduct our business will be impaired.

Our business depends on our ability to attract, retain, and motivate highly qualified management and scientific personnel. However, competition for qualified personnel is intense. We may not be successful in attracting qualified personnel to fulfill our current or future needs and there is no guarantee that any of these individuals will join our company. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We currently do not maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management, and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. In addition, the replacement of key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to our company. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We will need to increase the size of our organization and may not successfully manage our growth.

We are an early-stage biopharmaceutical company with a relatively small number of employees, and our management systems currently in place are not likely to be adequate to support our growth in the future. Our ability to grow and to manage that growth effectively will require us to hire, train, retain, manage, and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems, it could have a material adverse effect on our business, financial condition, and results of operations.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, or, collectively, Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"). We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), our management is required to annually report upon the effectiveness of our internal control over financial reporting. If we lose our status as a "smaller reporting company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. As we grow, we expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify significant deficiencies and/or material weaknesses in our internal controls. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2024, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We will continue to incur increased costs as a result of being a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”), was enacted. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced coverage or incur substantially higher costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company and for as long as we remain a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including the ability to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our registration statements, if applicable, and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain a “smaller reporting company,” for so long as the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a “smaller reporting company” until (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company’s current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the “FDIC”), as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. In addition, if any of our contract organizations, vendors, suppliers or other parties with whom we conduct business are unable to access funds pursuant to their own arrangements with such a financial institution, such parties’ ability to perform their obligations could be adversely affected. In this regard, counterparties to credit agreements and arrangements with distressed financial institutions, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect our company, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Impairment in the ability to enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our contract organizations, vendors, suppliers or other parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, contract organizations, vendors, suppliers or other parties with whom we conduct business could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on our company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any bankruptcy or insolvency involving our contract organizations, vendors, suppliers or other parties with whom we conduct business, or any breach or default by such parties, or the loss of any significant relationships with such parties, could result in a material adverse impact on our business.

Our business, results of operations and future growth prospects could be materially and adversely affected byglobal economic and political developments, including inflation and capital market disruption, global geopolitical disruptions, including various armed conflicts, economic sanctions and economic slowdowns or recessions, potential global health crises, or the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business.

Any global financial crisis or slowdown could cause volatility and disruptions in the capital and credit markets. Similarly, any global health epidemic could cause disruptions in our operations and in the operations of third-party manufacturers, CROs, and other third-parties on whom we rely. More recently, the global economy has been impacted by increasing interest rates and high inflation, as well as by global geopolitical disruptions, including various armed conflicts. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, or at all. Additionally, a weak or declining economy or international trade disputes could strain our suppliers, some of whom are located outside the United States, potentially resulting in supply disruption. Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-parties on which we rely. We cannot precisely determine or quantify the lingering impact the COVID-19 pandemic, or the future outbreak of any other highly infectious our contagious diseases, will have on our business operations in the future, which will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration, scope and severity of the pandemic, the duration and extent of travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and the pandemic. In addition, the short and long-term implications of military conflict, including the Russia's invasion of Ukraine and/or the Israel-Hamas war, are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

Rising inflation rates could negatively impact our expenses.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

We rely on information technology systems and data processing that we or our service providers, collaborators, consultants, contractors or partners operate to collect, process, transmit and store electronic information in our day-to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and potentially clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to host or otherwise process some of our anticipated future clinical data and that of users, develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors or partners, including future CROs may be vulnerable to a cyber-attack (including supply chain cyber-attacks), malicious intrusion, breakdown, destruction, loss of data privacy, actions or inactions by our employees or contractors that expose security vulnerabilities, theft or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents. As the cyber-threat landscape evolves, these attacks are growing in frequency, level of persistence, sophistication and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), phishing and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may be increased as a result of any lingering effects or impacts from the COVID-19 pandemic, owing to an increase in personnel working remotely and higher reliance on internet technology. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

There can be no assurance that we, our service providers, collaborators, consultants, contractors or partners will be successful in efforts to detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients' personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research, delays to commercialization of our product candidates, lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cashflow. For example, the loss or alteration of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidence in our services or security measures by our business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security or security breaches.

We may not be able to complete the spin-off of Cortigent on the terms anticipated or at all.

On March 12, 2025, we announced the proposed spin-off of our wholly owned subsidiary, Cortigent, to be effected as a distribution of the shares of common stock of Cortigent to the holders of our common stock. We expect the spin-off to be completed by mid 2025. Completion of the Spin-Off will be subject to a number of factors and conditions, and there can be no assurance that the spin-off will be completed as anticipated or at all. A failure to complete the spin-off could negatively affect the price of the shares of our common stock.

The spin-off may not have the benefits we anticipate.

The spin-off may not have the full or any strategic and financial benefits that we expect, or such benefits may be delayed or may not materialize at all. The anticipated benefits of the spin-off are based on a number of assumptions, which may prove incorrect. In the event that the spin-off does not have expected benefits, the costs associated with the transaction, including an expected increase in operating expenses, could have a negative effect on our financial condition. In addition, the Company cannot predict the effect of the spin-off on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the spin-off.

There could be significant income tax liability if the spin-off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The Company expects that prior to completion of the spin-off it will receive an opinion from its U.S. tax counsel that concludes, among other things, that the spin-off of Cortigent and certain related transactions will qualify as tax-free to the Company and its shareholders under Sections 355 and 368 of the U.S. Internal Revenue Code, subject to exceptions. Any such opinion is not binding on the Internal Revenue Service ("IRS"). Accordingly, while the Company believes the risk is low, the IRS may reach conclusions with respect to the Spin-Off that are different from the conclusions reached in the opinion. The opinion will rely on certain facts, assumptions, representations and undertakings from the Company and Cortigent regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such opinion.

If the proposed spin-off ultimately is determined to be taxable, which the Company believes is unlikely, the spin-off could be treated as a taxable dividend to the Company's shareholders for U.S. federal income tax purposes, and the Company's shareholders could incur significant U.S. federal income tax liabilities. In addition, the Company's would recognize a taxable gain to the extent that the fair market value of Cortigent common stock exceeds the Company's tax basis in such stock on the date of the spin-off.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity Risk Management.

Overview

We recognize the critical importance of maintaining the safety and security of our information technology systems and data and maintain a cybersecurity risk management program as a part of our overall risk management strategy that is focused on identifying, assessing and managing cybersecurity risks. We engage an Managed Services Provider ("MSP"), with a highly experienced and responsive staff including a virtual Chief Information Officer ("vCIO"), to assist us with the identification, monitoring and management of risks from cybersecurity threats. They assist us with our technology, infrastructure and risk management through the deployment of a number of security controls and tools. We also take steps to limit third-party vendors' access to our systems, and we are in the process of developing additional vendor risk management procedures.

Board Oversight of Cyber Risk

The Audit Committee of our Board of Directors oversees our policies and procedures with respect to risk management, including our management of risks from cybersecurity threats. The Audit Committee administers this cybersecurity risk oversight function through the receipt and review of reports from the management team and the vCIO on the Company's information technology systems and the status of the cybersecurity risk management tools.

Cybersecurity Risk Management and Strategy

We rely on information technology systems and data processing so that we or our service providers, collaborators, consultants, contractors or partners can operate to collect, process, transmit and store electronic information in our day-to-day operations. Our internal computer systems and data processing along with those of our third-party vendors, consultants, collaborators, contractors or partners may be vulnerable to risks from cybersecurity threats. To help manage these risks, we engage and rely on external experts, including an Information Technology MSP. We are also in the process of developing additional cybersecurity policies and procedures, as we continually work to enhance and evolve our program in light of the constantly evolving threats to our environment.

Our MSP assists us with our technology, infrastructure and risk management through the deployment of a number of security controls and tools, including, but not limited to, endpoint protection tools, phishing protection and access controls. We also take steps to limit third-party vendors' access to our systems, and we are in the process of developing additional vendor risk management procedures.

Program highlights include:

- Aligning with various government and industry standards such as: National Institute of Standards and Technology ("NIST") Cybersecurity Framework, HIPAA, 21 CFR Part 11 and Sarbanes-Oxley ("SOX"),
- Conducting ongoing Security Awareness Training to keep employees informed of threats and how to spot them,
- Evaluating the cybersecurity policies of third-party vendors and service providers,
- Implementing redundant systems for mission critical operations,
- Developing and implementing Business Continuity/Disaster Recovery plans and procedures, and
- Ensuring robust protective measures such as:
  - Email security including phishing protection
  - Endpoint Security
  - Perimeter Firewalls
  - Physical Access controls
  - Rapid Ransomware monitoring and recovery
  - Multi-Factor Authentication
  - Non-administrative computer access for typical users
  - Encryption of computing systems

To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents that could affect our information or systems.

Governance Related to Cybersecurity Risks

In addition to the services provided by our MSP, we have also formed an IT Steering Committee, whose members include representatives from our management team as well as our MSP, to review our cybersecurity program initiatives and related program metrics. Our IT Steering Committee provides cybersecurity updates and reports to our Audit Committee at each quarterly meeting or would report more frequently if there was a need to do so.

Item 2. Properties

Our principal offices and facilities are located at 1350 South Loop Road, Alameda, CA 94502 and 27200 Tourney Road, Suite 315, Valencia, CA 91355 and both are leased.

In November 2022, Vivani signed a long-term lease at 1350 South Loop Road, Alameda, CA 94502 to accommodate office space, R&D, analytical labs and a GMP manufacturing suite to support our research and development activities for our Biopharm Division. We moved into the new facility in September 2023.

On February 1, 2023, Cortigent, our Neurostimulation Division entered into a lease agreement, effective March 1, 2023, to sublease office space at 27200 Tourney Road, Suite 315, Valencia, CA 91355 to be utilized as its headquarters. The sublease expires on April 30, 2025. We also entered into a lease for storage space in the same facility that will expire on March 31, 2025. We are not renewing the current office lease. However we are entering into another lease in the same building for a smaller space. We are renewing the lease of the storage unit. These new and renewal leases will be short-term leases with immaterial monthly costs.

Item 3. Legal Proceedings

Three oppositions filed by Pixium Vision are pending in the European Patent Office, each challenging the validity of a European patent owned by Cortigent. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing Cortigent’s neurostimulation patented technology. We believe a successful challenge will not have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent’s neurostimulation operations.

As described in the Company’s 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding (“MOU”) for a proposed business combination with Pixium Vision SA (“Pixium”). In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our shareholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company’s offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgement, including finding that the Company’s termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium’s claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium’s application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained converted into euros at the date of the judgment. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile, the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium’s receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium’s liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment. The hearing took place on June 4, 2024 and on October 23, 2024, the pre-trial judge issued his order, striking out Vivani's appeal for failure to enforce the decision. Within two years, Vivani will have to request that the case be reinstated on the court's docket, providing evidence that the judgment has been fully enforced or, at the very least, that an agreement has been reached. Failing this, the appeal proceedings will lapse.

The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to continue its appeal against the preliminary judgment.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our financial statements, however the results of litigation and claims are inherently unpredictable. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Vivani's common stock par value $0.0001 per share, is traded on the Nasdaq Capital Market under the symbol "VANI."

Holders

On March 28, 2025 there were approximately 106 shareholders of record.

Dividends

We have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on theNasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors. The consolidated results of operations for the years ended December 31, 2024 and 2023 are not necessarily indicative of the results that may be expected for any future period. The following discussion should be read in conjunction with the consolidated financial statements and the notes thereto included in Part IV, Item 15 of this Form 10-K and in conjunction with the "Risk Factors" included in Part I, Item1A of this Form 10-K.

Business Overview

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a clinical stage biopharmaceutical company which develops miniaturized, subdermal drug implants utilizing its proprietary NanoPortal™ technology, which is designed to enable ultra long-acting, near constant-rate delivery of a broad range of medicines to treat chronic diseases. Vivani uses this platform technology to develop and potentially commercialize drug implant candidates, alone or in collaboration with pharmaceutical company partners, to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injection) discontinue therapy within the first year of treatment, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, subdermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. In addition, our aim is to minimize fluctuations in patients' drug levels through the use of our NanoPortal technology, which may improve the tolerability profiles for medicines, including GLP-1 receptor agonists, that produce side effects associated with fluctuating drug levels in the blood.

Our emerging portfolio of miniature, ultra long-acting drug implants have the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving patient tolerability to their treatments which has the potential to translate into better health outcomes for patients in the real-world setting. Vivani's lead program, NPM-115, is a miniature, six-month, GLP-1 (high-dose exenatide) implant currently in clinical-stage testing for chronic weight management in obese and overweight individuals. Other programs include, NPM-139 (semaglutide implant) also in development for chronic weight management, NPM-119 (exenatide implant) in development for the treatment of type 2 diabetes and OKV-119, another GLP-1 based implant in development for the treatment of cardiometabolic disorders in cats and dogs in collaboration with animal health partner Okava.

Vivani resulted from the business combination of Second Sight Medical Products, Inc. ("Second Sight") and Nano Precision Medical, Inc. ("NPM"). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani's main priority is the further development of its lead program NPM-115, a miniature, 6-month, GLP-1 implant candidate for chronic weight management in obese or overweight patients with one or more risk factors and further development of the balance of the company's miniature, ultra long-acting drug implant portfolio. In parallel, Vivani's management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight aimed at helping patients recover critical body functions.

In December 2022, we contributed our neurostimulation assets from legacy company Second Sight and certain liabilities to Cortigent, Inc. ("Cortigent"), a wholly owned subsidiary of Vivani to advance the Company's pioneering neurostimulation technology. Cortigent has 5,000,000 shares of common stock outstanding, all owned by Vivani. In March 2023, Vivani announced the filing of a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission ("SEC") for the proposed initial public offering of Cortigent. In March 2025, Vivani announced a change in strategy to discontinue efforts to pursue a proposed initial public offering and shift focus to file a Form 10 with the SEC to support the spin-off of Cortigent into a fully 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. If the spinoff is successful, the loan payable from Cortigent to Vivani would be forgiven.

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. As part of this change of incorporation the Company established a par value of $0.0001 per share and all periods have been retroactively adjusted to reflect this change.

An IND for NPM-119 (GLP-1 implant) was filed with FDA on July 14, 2023, to support the initiation of a first-in-human study of an exenatide implant in patients with type 2 diabetes. On August 18, 2023, FDA provided written notification that the study was on full clinical hold, primarily due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. After providing additional information to sufficiently address the FDA's requests, the FDA lifted the clinical hold on NPM-119 on June 13, 2024 allowing for the proposed study to proceed. The primary objective of this first-in-human clinical study was to evaluate the safety, tolerability and pharmacokinetics of NPM-119 in type 2 diabetes patients. The initial study design also incorporated Bydureon BCise® (exenatide injection) for comparison purposes.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the "Amendment") to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the "TFSSA"). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner in which business operations of Cortigent were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, at the discretion of Vivani or after the closing of an initial public offering of Cortigent. If an initial public offering of Cortigent closes, Cortigent has agreed to repay $1,500,000 to Vivani and enter into a five-year promissory note at 5% interest for $2,000,000 in favor of Vivani. Consequently, Vivani will forgive any remaining amounts due by Cortigent. Efforts to support a successful initial public offering of Cortigent ceased in March 2025 and efforts are now focused on a potential spinoff with the filing of a Form 10 registration statement. The TFSSA terminated effective December 31, 2024.

In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia was established to support studies of our product candidates.

In February 2024, Vivani announced positive preclinical weight loss data with its exenatide implant that was comparable to semaglutide, the active ingredient in Ozempic®/Wegovy, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections in the same study.

In February, the Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, another miniature, long term subdermal GLP-1 implant in development for chronic weight management further demonstrating our prioritization on obesity. NPM-139 also has the added potential benefit of once-yearly administration.

On March 1, 2024, the Company entered into a securities purchase agreement ("Securities Purchase Agreement") with an institutional investor to purchase 3,947,368 shares of common stock, par value $0.0001 per share (the "Common Stock") and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering (the "Offering"). The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance.

On April 22, 2024, the Company entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the company's miniature, long-acting GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration.

As stated previously, on June 13, 2024, Vivani announced that the FDA cleared the IND and lifted the clinical hold for NPM-119, the Company's miniature, six-month GLP-1 implant under development for the treatment of patients with type 2 diabetes.

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company has redesigned the first-in-human study, LIBERATE-1™, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight patients.

On September 4, 2024, Vivani announced positive preclinical liver fat results with its miniature, ultra long-acting GLP-1 implant currently under development for chronic weight management in obese and overweight individuals and type 2 diabetes. The Company's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. These liver fat data are consistent with published results from similar investigations with semaglutide, the active pharmaceutical ingredient in Ozempic and Wegovy.

On September 26, 2024, the Company reported receiving regulatory approval to initiate its first-in-human clinical trial with a miniature, ultra long-acting GLP-1 (exenatide) implant in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1, is part of the NPM-115 program and will investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant. The trial also represents the first clinical application of the Company's proprietary NanoPortal drug implant technology. LIBERATE-1 was redesigned to enroll participants who will 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 (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured. The trial was initiated at the end of 2024 with data projected to be available in mid-2025.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

On December 19, 2024, Vivani announced that screening and enrollment of LIBERATE-1, the First-in-Human clinical trial with a GLP-1 implant in obese and overweight patients, was initiated at two study centers in Australia. The primary objective of the study is to investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant in obese or overweight individuals. Consistent with previous guidance, study results are anticipated to be reported in mid-2025.

On March 13, 2025, Vivani 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.

On March 26, 2025, the Company entered into a private sale transaction with an entity affiliated with one of itsindependent directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in one or more closings as provided in the purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on the Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $8.25 million.

Funding and Liquidity

Capital Funding

From inception, our operations have been funded primarily through the sales of our common stock and warrants.

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of3,947,368 shares of the Company's common stock, Common Stock and warrants to purchase up to an aggregate of 3,947,368 shares of common stock (the "Warrants"), to such investor at a purchase price of $3.80 per share and accompanying warrants in a registered direct offering (the "Offering"). The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. Simultaneously, the Company also entered into a placement agency agreement with Maxim Group LLC ("Maxim" and such agreement, the "Placement Agency Agreement," and together with the Securities Purchase Agreement, the "Agreements"), who acted as the sole placement agent for the Offering. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this Annual Report on Form 10-K.

On April 22, 2024, the Company entered into an Open Market Sale Agreement[SM] (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

During the twelve months ended December 31, 2024, the Company issued 287,970 shares of common stock for gross proceeds of $504,000 as part of the Sales Agreement with Jefferies. The Company paid expenses of $344,000, resulting in net proceeds of $160,000.

On November 8, 2024, the Company entered into a private sale transaction withone of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

On March 26, 2025, the Company entered into a private sale transaction with an entity affiliated with one of its independent directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in one or more closings as provided in the purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on the Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $8.25 million.

Non-Capital Funding

From time to time, we receive grants that help fund specific development programs. Any amounts received pursuant to grants are offset against the related operating expenses as the costs are incurred. Commencing in January 2018, we were awarded a grant from the National Institutes of Health (the "NIH") to fund the "Early Feasibility Clinical Trial of a Visual Cortical Prosthesis". The final year of the grant ended in March 2024, however the NIH issued us a no-cost extension allowing us to utilize the unfunded amount through March 2025. During the years ended December 31, 2024and 2023 total grants offsetting against operating expenses were $0.2 million and $0.5 million, respectively. As of December 31, 2024, we expect $35,000 will be available to offset future operating expenses

Liquidity

We have experienced recurring operating losses and negative operating cash flows since inception and have financed our working capital requirements through the recurring sale of our equity securities. Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

To finance our operations, we will need to raise additional capital, which cannot be assured. Our operating plan may change as a result of many factors currently unknown to us, and we will need to seek additional funds through public or private equity offerings or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, or we may be unable to expand or maintain our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially and adversely affect our business, financial condition and results of operations.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations for at least the next twelve months. Our ability to continue as a going concern is dependent on our ability to raise additional capital and/or develop profitable operations through implementation of our business initiatives, however, there can be no assurances that we will be able to do so.

Recently Adopted Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, Improvements to Reportable Segment Disclosures (Topic 280). This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Adoption of the ASU should be applied retrospectively to all prior periods presented in the financial statements. We adopted this ASU for the year ending December 31, 2024.

Critical Accounting Policies and Estimates

The following discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. Certain accounting policies and estimates are particularly important to the understanding of our financial position and results of operations and require the application of significant judgment by our management or can be materially affected by changes from period to period in economic factors or conditions that are outside of our control. As a result, they are subject to an inherent degree of uncertainty. In applying these policies, our management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. See Note 2 of notes to our consolidated financial statements for a more complete description of our significant accounting policies.

Stock-Based Compensation. Pursuant to Financial Accounting Standards Board ASC718, *Share-Based Payment* ("ASC 718"), we record stock-based compensation expense for all stock-based awards. Under ASC 718, we estimate the fair value of stock options granted using option pricing models. The fair value for awards that are expected to vest is then amortized on a straight-line basis over the requisite service period of the award, which is generally the option vesting term. The Company accounts for forfeitures as they occur.

- The grant price of the issuances is determined based on the fair value of the shares at the date of grant.
- The risk free interest rate for periods within the contractual life of the option is based on the U.S. treasury yield in effect at the time of grant.
- We calculate the expected term of options using a weighted average of option vesting periods and an estimate of one-half of the period between vesting and expiration of the option.
- Volatility is determined based on our average historical volatilities since our trading history, supplemented with average historical volatilities of comparable companies in our similar industry.
- Expected dividend yield is based on current yield at the grant date or the average dividend yield over the historical period. We have never declared or paid dividends and have no plans to do so in the foreseeable future.

For stock options or restricted stock units with market vesting conditions, the awards were valued using the Monte-Carlo Simulation model.

Results of Operations

Operating Expenses. We recognize our operating expenses as incurred in two general operational categories: research and development and general and administrative. Our operating expenses also include a non-cash component related to the amortization of stock-based compensation for research and development and general and administrative personnel. From time-to-time we have received grants from institutions or agencies, such as the National Institutes of Health, to help fund some of the cost of our development efforts. We have recorded these grants as reductions to operating expenses.

- Research and development expense consist primarily of employee compensation and consulting costs related to the design, development, and enhancements of our current and potential future products, as well as internal and external costs associated with conducting clinical trials and maintaining relationships with regulatory agencies, as well as facilities costs, which include expenses for rent, maintenance of facilities and depreciation of equipment, offset by grant revenue received in support of specific research projects. We expense our research and development costs as they are incurred. We expect research and development expenses to increase in the future as we pursue further enhancements of our existing product and develop technology for our potential future products.
- General and administrative expense consist primarily of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as recruiting and professional fees, patent filing and annuity costs, insurance costs and other general corporate expenses, including rent and other facility related costs. We expect general and administrative expenses to increase as we add personnel and incur additional costs related to the growth of our business and operate as a public company.

Comparison of the Years Ended December 31, 2024 and 2023

Research and development expense. Research and development expense during the year ended December 31, 2024 was $15.7 million, compared to $17.0 million during the year ended December 31, 2023. The decrease of $1.2 million, or 7%, was primarily attributable to staffing reduction and reduced use of outside services from our Neurostimulation Division, partially offset by the increase in the clinical trial related expense from our Biopharm Division.

General and administrative expense. General and administrative expense during the year ended December 31, 2024 was $8.9 million, compared to $10.0 million during the year ended December 31, 2023. The decrease of $1.1 million, or 11%, was primarily attributable to staffing reductions along with reduced outside legal services from our Neurostimulation Division, partially offset by the increase in the professional services from our Biopharm Division.

Other income (expense), net. Other income (expense), net during the year ended December 31, 2024 was $1.2 million, compared to $1.3 million during the year ended December 31, 2023. The change was insignificant and relates to less interest being earned on deposits.

Net loss. The net loss during the year ended December 31, 2024 was $23.5 million, compared to $25.7 million during the year ended December 31, 2023. The decrease in net loss of $2.2 million was primarily attributable to staffing reduction and reduced use of outside services from our Neurostimulation Division, partially offset by increased clinical trial related expense and professional services from our Biopharm Division.

Liquidity and Capital Resources

We have experienced recurring operating losses and negative operating cash flows since inception and have financed our working capital requirements through the recurring sale of our equity securities. Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Company's common stock, par value of $0.0001 per share and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrants in a registered direct offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. In connection with the Placement Agency Agreement, the Company agreed to pay Maxim an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of common stock and accompanying warrants. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse Maxim up to $65,000 for its legal expenses. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other estimated offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million, during the year ended December 31, 2024. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this Annual Report on Form 10-K.

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements. During the twelve months ended December 31, 2024, the Company received net proceeds of $160,000 from issuing common stocks under the Sales Agreement with Jefferies.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations for at least the next twelve months. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

We are subject to the risks and uncertainties associated with a business with no revenue that is developing a novel pharmaceutical product candidates and medical device candidates, including limitations on our operating capital resources and uncertain demand for our products. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future. We expect our operating expenses to increase significantly as we continue our business operations, particularly as we prepare to and initiate our planned clinical trial and conduct our other research and development activities. Conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete and we may never generate the necessary data or results required to obtain marketing approval. We do not expect revenues until we are successful in completing the development and obtaining marketing approval for our products. We expect expenses to increase in connection with our ongoing activities, particularly as we initiate clinical trials, initiate new research and development projects and seek marketing approval for any product candidates that we successfully develop. If we are required to conduct additional nonclinical or clinical activities preclinical or IND-enabling activities such as additional pre-clinical, our overall expenditures would increase. In addition, if we obtain marketing approval, we expect to incur significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize such product. In addition, our product candidates, if approved, may not achieve commercial success. We incur significant costs associated with operating as a public company in a regulated industry.

Until such time, if ever, we can generate product revenues, we anticipate that we will seek to fund our operations through public or private equity or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity, convertible debt or other equity-linked securities, the ownership interests of some or all of our common stockholders will be diluted, the holders of new equity securities may have priority rights over our existing stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If adequate funds are not available, we may be required to curtail operations significantly or to obtain funds by entering into agreements on unattractive terms. If, for example, we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. Our inability to raise capital could have a material adverse effect on our business, financial condition and results of operations.

Cash, cash equivalents and restricted cash decreased by $2.3 million from $22.0 million as of December 31, 2023 to $19.7 million as of December 31, 2024. Working capital was $14.5 million as of December 31, 2024, as compared to $17.3 million as of December 31, 2023. We use our cash and cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

During 2024, we used $20.8 million of cash in operating activities, consisting primarily of a net loss of $23.5 million, partially offset by $0.4 million from a net change in operating assets and liabilities, and non-cash items totaling $2.3 million for stock-based compensation, lease expense, depreciation and amortization of property and equipment, fixed assets write-off.

During 2023, we used $23.7 million of cash in operating activities, consisting primarily of a net loss of $25.7 million and $1.3 million used from a net change in operating assets and liabilities, partially offset by non-cash items totaling $3.2 million for depreciation and amortization of property and equipment, stock-based compensation, loss on disposal of fixed assets and lease expense.

Cash Flows from Investing Activities

Net cash used in investing activities during 2024 and 2023 was $0.6 million and $0.9 million, respectively, for the purchase of equipment.

Cash Flows from Financing Activities

In 2024, financing activities provided $19.1 million of cash primarily attributable to $13.7 million from a securities purchase agreement with an institutional investor and $5.0 million from another securities purchase agreement with one of our independent directors.

In 2023, financing activities provided $0.1 million of cash primarily from stock option exercises.

Off-Balance Sheet Arrangements

At December 31, 2024, we did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

The primary objective of our investment activities is to maintain the safety of principal and preserve liquidity without incurring significant risk. We invest cash in excess of our current needs in money market funds and short-term certificates of deposits (“CDs”). In general, money market funds are not considered to be subject to interest rate risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of December 31, 2024 and 2023, our cash equivalents consisted money market funds deposited at Merrill Lynch, CDs at JPMorgan Chase bank, and restricted cash as collateral for our lease.

Exchange Rate Sensitivity

In 2024 and 2023, the majority of our operating expenses were denominated in U.S. dollars. We have not entered into foreign currency forward contracts to hedge our operating expense exposure to foreign currencies, but we may do so in the future.

Item 8. Financial Statements and Supplementary Data

Our financial statements and supplementary data required by this Item are provided in the consolidated financial statements included in this Form 10-K as listed in Item 15(a) of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow for timely decisions regarding required disclosure. Due to inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Further, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies and procedures may deteriorate. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

As of December 31, 2024, management has concluded that our disclosure controls and procedures were effective based upon testing of our key internal controls. Our management, including our CEO and CFO, has concluded that the consolidated financial statements included in this Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in this Form 10-K in conformity with GAAP.

This Form 10-K does not include an attestation report from our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to our non-accelerated filer status.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

1. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

2. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with the authorization of our management and directors; and

3. Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

As of December 31, 2024, based on the criteria established in "Internal Control — Integrated Framework" (2013 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission, management has completed written documentation of its internal control policies, procedures and controls and has completed its testing of its key controls. Based upon the results of this testing we have concluded that our internal control over financial reporting was effective as of the end of the period covered by this Form 10-K.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during or subsequent to our fourth quarter of the year ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

The design of any system of control is based upon certain assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated objectives under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Because of its inherent limitations, disclosure controls and procedures may not prevent or detect all misstatements. Accordingly, even effective disclosure controls and procedures can provide only reasonable assurance of achieving their control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Item 9B. Other Information

Rule 10b5-1 Trading Plan Disclosure.

On July 8, 2024, Lisa Porter, the Company's Chief Medical Officer, entered into a 10b5-1 trading plan. Dr. Porter's plan provides for the sale of up to 93,000 shares of the Company's common stock. Sales of the shares of the Company's common stock set forth in Dr. Porter's trading plan, if any, will be made at or above specified market prices. The trading plan will expire on or before June 30, 2025. Dr. Porter's trading plan was entered into during an open insider trading window and is intended to satisfy Rule 10b5-1(c) under the Exchange Act and the Company's policies regarding insider transactions.

Apart from as disclosed above, no Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements were adopted, modified, or terminated by officers or directors of the Company, nor were there any material changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors, during the quarter ended December 31, 2024.

Item 9C. Disclosure regarding foreign jurisdictions that prevent inspections

Not Applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated by reference from our definitive proxy statement relating to our 2025 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Annual Report on Form 10-K as our 2025 Proxy Statement, which we will file with the SEC not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

Information regarding our directors, including the audit committee and audit committee financial experts, and executive officers, and compliance with Section 16(a) of the Exchange Act will be included in an amendment to this Form 10-K or in our 2025 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct that applies to all officers, directors and employees in connection with their work for us. The full text of our Code of Business Conduct is posted on the investors page of our website at https://investors.vivani.com/investors/corporate-governance/governance-documents.

We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct by posting such information on our website, at the Internet address and location specified above.

The Company has adopted an insider trading policythat governs the purchase, sale, and/or other transactions of our securities by our directors, officers and employees. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K. In addition, with regard to the Company's trading in its own securities, it is the Company's policy to comply with the federal securities laws and the applicable exchange listing requirements.

There are no material changes to the procedures by which security holders may recommend nominees to the Company's board of directors, during the quarter ended December 31, 2024.

Item 11. Executive Compensation

The information required by Item 402 and Item 407(e)(4) and (e)(5) of Regulation S-K will be included in the 2025 Proxy Statement and is incorporated herein by reference (excluding the information required by Item 402(v) of Regulation S-K relating to pay versus performance).

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item regarding security ownership of certain beneficial owners and management will be included in an amendment to this Form 10-K or in our 2025 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item regarding certain relationships and related transactions and director independence will be included in an amendment to this Form 10-K or in our 2025 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item regarding principal accounting fees and services will be included in an amendment to this Form 10-K or in our 2025 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are included in this Annual Report on Form 10-K:

1. The consolidated financial statements listed in the accompanying Index to Consolidated Financial Statements are filed as part of this report.

2. All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

3. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the exhibits and are incorporated herein. We have identified in the Exhibit Index each management contract and compensation plan filed as an exhibit to this Annual Report on Form 10-K in response to Item 15(a)(3) of Form 10-K.

EXHIBIT INDEX

Exhibit No.	Exhibit Description
2.1	Agreement and Plan of Merger by and among Second Sight Medical Products, Inc. and Nano Precision Medical, Inc., dated February 4, 2022 (incorporated by reference to Exhibit 2.1 in the Registrant's Current Report on Form 8-K filed with the SEC on February 8, 2022).
2.2	Waiver of Available Cash Requirement to the Merger Agreement dated June 15, 2022 (incorporated by reference to Exhibit 2.1 in the Registrant's Current Report on Form 8-K filed with the SEC on June 21, 2022).
2.3	Plan of Conversion of Vivani Medical, Inc. (a California corporation) to Vivani Medical, Inc. (a Delaware corporation), dated July 5, 2023 and effective July 5, 2023 (incorporated by reference to Appendix A in the Registrant's revised definitive proxy statement filed with the SEC on May 1, 2023).
3.1	Certificate of Incorporation of Vivani Medical, Inc., filed with the Secretary of State of Delaware and effective, July 6, 2023 (incorporated by reference to Exhibit 3.1 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
3.2	Bylaws of Vivani Medical, Inc. (a Delaware Corporation) effective July 6, 2023 (incorporated by reference to Exhibit 3.2 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
4.1	Form of the Registrant's Common Stock Certificate (incorporated by reference to Exhibit 4.1 in the Registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2024).
4.2	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.2 in the Registrant's Registration Statement on Form S-1, File no. 333-198073, originally filed with the SEC on August 12, 2014, as amended).
4.3	Form of Warrant Agreement and Form of Warrant Certificate (incorporated by reference to Exhibit 4.4 in the Registrant's Registration Statement on Form S-1, File no. 333-215463, originally filed with the SEC on January 9, 2017, as amended).
4.4	Form of Amendment No. 1 to Warrant Agreement (incorporated by reference to Exhibit 99.2 in the Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2019).
4.5	Description of Capital Stock (incorporated by reference to Exhibit 4.5 in the Registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2024).
10.1	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.15 in the Registrant's Proxy Statement/Prospectus on Form S-4, (File no. 333-264959), originally filed with the SEC on May 13, 2022).
10.2	Registrant's Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.2 in the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 14, 2022)
10.3	Offer Letter by and between Jonathan Adams and Cortigent, Inc., dated March 11, 2023 (incorporated by reference to Exhibit 10.4 in the Registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2024).
10.4	Lease Agreement Between 1350 South Loop LLC and the Registrant, dated November 21, 2022 (incorporated by reference to Exhibit 10.1 in the Registrant's Current Report on Form 8-K filed with the SEC on November 28, 2022).
10.5	Cost Reimbursement Consortium Research Agreement, by and between Registrant and Doheny Eye Institute, dated as of June 1, 2006 (incorporated by reference to Exhibit 10.12 in the Registrant's Registration Statement on Form S-1 (File No. 333-198073) originally filed with the SEC on August 12, 2014, as amended).
10.6	SAFE Agreement, by and between Second Sight Medical Products, Inc. and Nano Precision Medical, Inc., dated February 4, 2022 (incorporated by reference to Exhibit 10.1 in the Registrant's Current Report on Form 8-K filed with the SEC on February 8, 2022).
10.7	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 in the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2024).
10.8	Open Market Sale Agreement[SM] by and between the Company and Jefferies LLC, dated April 22, 2024 (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed on April 22, 2024).
10.9*	Share Purchase Agreement by and between the Company and Gregg Williams, dated November 8, 2024.
19.1*	Insider Trading Policy.

21.1	List of Registrant's Subsidiaries (incorporated by reference to Exhibit 21.1 in the Registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2024).
23.1*	Consent of BPM LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included in the signature page to this report).
31.1*	Certification of Principal Executive Officer of Vivani Medical, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certifications of Principal Executive Officer and Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Rule 13a-14(b) under the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 in the Registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2024).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herein.

** This certification will 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 liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

\+ Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Dated: March 31, 2025	Vivani Medical, Inc.
	/s/ Adam Mendelsohn
	Adam Mendelsohn Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

The undersigned officers and directors of Vivani Medical, Inc., each hereby severally constitutes and appoints Adam Mendelsohn and Brigid Makes as their true and lawful attorney-in-fact and agent, with full power of substitution to sign and execute on behalf of the undersigned any and all amendments to this Annual Report on Form 10-K, and to perform any acts necessary in order to file the same, with all exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requested and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their or his or her substitutes, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Adam Mendelsohn Adam Mendelsohn	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2025
/s/ Brigid A. Makes Brigid A. Makes	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025
/s/ Gregg Williams Gregg Williams	Chairman of the Board	March 31, 2025
/s/ Aaron Mendelsohn Aaron Mendelsohn	Director	March 31, 2025
/s/ Dean Baker Dean Baker	Director	March 31, 2025
/s/ Alexandra Larson Alexandra Larson	Director	March 31, 2025
/s/ Daniel Bradbury Daniel Bradbury	Director	March 31, 2025

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Vivani Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vivani Medical, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ BPM LLP

We have served as the Company's auditor since 2014.

Walnut Creek, California
March 30, 2025

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except per share data)

	December 31, 2024		December 31, 2023	
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$	18,352	$	20,654
R&D tax credit incentive receivable		253		—
Prepaid expenses and other current assets		1,837		2,408
Total current assets		20,442		23,062
Property and equipment, net		1,693		1,729
Operating lease right-of-use assets, net		17,957		19,616
Restricted cash		1,338		1,338
Deposits and other assets		131		52
TOTAL ASSETS	$	41,561	$	45,797
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable	$	817	$	542
Accrued expenses		1,803		1,727
Litigation accrual		1,675		1,675
Accrued compensation expense		343		396
Lease liability, current portion		1,348		1,383
Total current liabilities		5,986		5,723
Lease liability, noncurrent portion		17,965		19,313
TOTAL LIABILITIES		23,951		25,036
Commitments and contingencies (Note 13)				
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:59,235 and 51,031 as of December 31, 2024 and 2023, respectively		6		5
Additional paid-in capital		139,480		119,054
Accumulated other comprehensive gain		48		140
Accumulated deficit		(121,924)		(98,438)
TOTAL STOCKHOLDERS' EQUITY		17,610		20,761
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	41,561	$	45,797

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Operations
(In thousands, except per share data)

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development, net of grants	$ 15,745	$ 16,968
General and administrative, net of grants	8,932	9,997
Total operating expenses	24,677	26,965
Loss from operations	(24,677)	(26,965)
Other income (expense), net	1,191	1,313
Net loss	$ (23,486)	$ (25,652)
Net loss per common share - basic and diluted	$ (0.43)	$ (0.50)
Weighted average shares outstanding - basic and diluted	54,981	50,853

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2024	**2023**
Net loss	$ (23,486)	$ (25,652)
Other comprehensive income:		
Foreign currency translation adjustments	(92)	105
Comprehensive loss	$ (23,578)	$ (25,547)

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2023	50,736	$ 5	$ 117,054	$ 35	$ (72,786)	$ 44,308
Option exercises	295	—	136	—	—	136
Stock-based compensation expense	—	—	1,864	—	—	1,864
Foreign currency translation adjustments	—	—	—	105	—	105
Net loss	—	—	—	—	(25,652)	(25,652)
Balance, December 31, 2023	51,031	$ 5	$ 119,054	$ 140	$ (98,438)	$ 20,761

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2024	51,031	$ 5	$ 119,054	$ 140	$ (98,438)	$ 20,761
Issuance of common stock and warrants in connection with Securities Purchase Agreement, net of issuance costs of $1,300	3,947	—	13,687	—	—	13,687
Issuance of common stock in connection with the Sales Agreement, net of issuance costs of $344	288	1	159	—	—	160
Issuance of common stock in connection with private purchase, net of issuance costs of $30	3,969	—	4,970	—	—	4,970
Stock-based compensation expense	—	—	1,610	—	—	1,610
Foreign currency translation adjustments	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	(23,486)	(23,486)
Balance, December 31, 2024	59,235	$ 6	$ 139,480	$ 48	$ (121,924)	$ 17,610

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2024	Year Ended December 31, 2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (23,486)	$ (25,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	400	357
Stock-based compensation	1,610	1,864
Equipment write-off and loss on equipment disposal	60	121
Non-cash lease expense	276	904
Changes in operating assets and liabilities:		
R&D tax credit incentive receivable	(253)	—
Prepaid expenses and other assets	491	264
Accounts payable	248	(602)
Accrued compensation expenses	(53)	(261)
Accrued expenses	(79)	(694)
Net cash used in operating activities	(20,786)	(23,699)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(556)	(887)
Net cash used in investing activities	(556)	(887)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants in connection with Securities Purchase Agreement, net of issuance costs	13,687	—
Proceeds from issuance of common stock in connection with the Sales Agreement, net of issuance costs	160	—
Gross proceeds from insurance premium loan	426	—
Principal payment for insurance premium loan	(189)	—
Proceeds from issuance of common stock in connection with director private securities purchase agreement, net of issuance costs	4,970	—
Proceeds from exercise of common stock options	—	133
Net cash provided by financing activities	19,054	133
Effect of exchange rate changes on cash and cash equivalents	(14)	3
Net (decrease) increase in cash, cash equivalents and restricted cash	(2,302)	(24,450)
Cash, cash equivalents and restricted cash balance at beginning of year	21,992	46,442
Cash, cash equivalents and restricted cash balance at end of year	$ 19,690	$ 21,992
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Income taxes paid	$ 2	$ 1
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Establishment of operating right-of-use assets through operating lease obligations	$ —	$ 20,755
Receivables for cash in-transit on exercise of common stock under equity incentive plan	$ —	$ 3
Purchase of property and equipment in accrued expenses	$ —	$ 132

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Notes to Consolidated Financial Statements

1. Organization and Business Operations

Vivani Medical, Inc. (“Vivani,” the “Company,” “we,” “us,” “our” or similar terms) is a clinical stage biopharmaceutical company which develops miniaturized, subdermal drug implants utilizing its proprietary NanoPortal™ technology, which is designed to enable ultra long-acting, near constant-rate delivery of a broad range of medicines to treat chronic diseases. Vivani uses this platform technology to develop and potentially commercialize drug implant candidates, alone or in collaboration with pharmaceutical company partners, to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual’s behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injection) discontinue therapy within the first year of treatment, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, subdermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. In addition, our aim is to minimize fluctuations in patients’ drug levels through the use of our NanoPortal technology, which may improve the tolerability profiles for medicines, including GLP-1 receptor agonists, that produce side effects associated with fluctuating drug levels in the blood.

Our emerging portfolio of miniature, ultra long-acting drug implants have the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving patient tolerability to their treatments which has the potential to translate into better health outcomes for patients in the real-world setting. Vivani's lead program, NPM-115, is a miniature, six-month, GLP-1 (high-dose exenatide) implant currently in clinical-stage testing for chronic weight management in obese and overweight individuals. Other programs include, NPM-139 (semaglutide implant) also in development for chronic weight management, NPM-119 (exenatide implant) in development for the treatment of type 2 diabetes and OKV-119, another GLP-1 based implant in development for the treatment of cardiometabolic disorders in cats and dogs in collaboration with animal health partner Okava Pharmaceuticals, Inc. ("Okava").

Vivani resulted from the business combination of Second Sight Medical Products,Inc. (“Second Sight”) and Nano Precision Medical, Inc. (“NPM”). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani’s main priority is the further development of its lead program NPM-115, a miniature, 6-month, GLP-1 implant candidate for chronic weight management in obese or overweight patients with one or more risk factors and further development of the balance of the company’s miniature, ultra long-acting drug implant portfolio. In parallel, Vivani’s management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight aimed at helping patients recover critical body functions.

In December 2022, we contributed our neurostimulation assets from legacy company Second Sight and certain liabilities to Cortigent, Inc. (“Cortigent”), a wholly owned subsidiary of Vivani to advance the Company’s pioneering neurostimulation technology. Cortigent has 5,000,000 shares of common stock outstanding, all owned by Vivani. In March 2023, Vivani announced the filing of a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission (“SEC”) for the proposed initial public offering of Cortigent. In March 2025, Vivani announced a change in strategy to discontinue efforts to pursue a proposed initial public offering and shift focus to file a Form 10 with the SEC to support the spin-off of Cortigent ;into a fully 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.

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. As part of this change of incorporation the Company established a par value of $0.0001 per share and all periods have been retroactively adjusted to reflect this change.

An IND for NPM-119 (GLP-1 implant) was filed with FDA on July 14, 2023, to support the initiation of a first-in-human study of an exenatide implant in patients with type 2 diabetes. On August 18, 2023, FDA provided written notification that the study was on full clinical hold, primarily due to insufficient Chemistry, Manufacturing, and Controls (“CMC”) information to assess the risk to human subjects. After providing additional information to sufficiently address the FDA's requests, the FDA lifted the clinical hold on NPM-119 on June 13, 2024 allowing for the proposed study to proceed. The primary objective of this first-in-human clinical study was to evaluate the safety, tolerability and pharmacokinetics of NPM-119 in type 2 diabetes patients. The initial study design also incorporated Bydureon BCise® (exenatide injection) for comparison purposes.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the “Amendment”) to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the “TFSSA”). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner in which business operations of Cortigent were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, at the discretion of Vivani or after the closing of an initial public offering of Cortigent. If an initial public offering of Cortigent closes, Cortigent has agreed to repay $1,500,000 to Vivani and enter into a five-year promissory note at 5% interest for $2,000,000 in favor of Vivani. Consequently, Vivani will forgive any remaining amounts due by Cortigent. Efforts to support a successful initial public offering of Cortigent ceased in March 2025 and efforts are now focused on a potential spinoff with the filing of a Form 10 registration statement. The TFSSA terminated effective December 31, 2024.

In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia was established to support studies of our product candidates.

In February 2024, Vivani announced positive preclinical weight loss data with its exenatide implant that was comparable to semaglutide, the active ingredient in Ozempic®/Wegovy, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections in the same study.

In February, the Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, another miniature, long term subdermal GLP-1 implant in development for chronic weight management further demonstrating our prioritization on obesity. NPM-139 also has the added potential benefit of once-yearly administration.

On March 1, 2024, the Company entered into a securities purchase agreement (“Securities Purchase Agreement”) with an institutional investor to purchase 3,947,368 shares of common stock, par value $0.0001 per share (the “Common Stock”) and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering (the “Offering”). The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance.

On April 22, 2024, the Company entered into an Open Market Sale Agreement[SM] (the “Sales Agreement”) with Jefferies LLC (“Jefferies”), under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the company's miniature, long-acting GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration.

As stated previously, on June 13, 2024, Vivani announced that the FDA cleared the IND and lifted the clinical hold for NPM-119, the Company's miniature, six-month GLP-1 implant under development for the treatment of patients with type 2 diabetes.

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company has redesigned the first-in-human study, LIBERATE-1™, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight patients.

On September 4, 2024, Vivani announced positive preclinical liver fat results with its miniature, ultra long-acting GLP-1 implant currently under development for chronic weight management in obese and overweight individuals and type 2 diabetes. The Company's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. These liver fat data are consistent with published results from similar investigations with semaglutide, the active pharmaceutical ingredient in Ozempic® and Wegovy®.

On September 26, 2024, the Company reported receiving regulatory approval to initiate its first-in-human clinical trial with a miniature, ultra long-acting GLP-1 (exenatide) implant in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1, is part of the NPM-115 program and will investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant. The trial also represents the first clinical application of the Company’s proprietary NanoPorta drug implant technology. LIBERATE-1 was redesigned to enroll participants who will 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 (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured. The trial was initiated at the end of 2024 with data projected to be available in mid-2025.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company’s common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company’s common stock on the Nasdaq or the 5-day average closing price of the Company’s common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

On December 19, 2024, Vivani announced that screening and enrollment of LIBERATE-1, the First-in-Human clinical trial with a GLP-1 implant in obese and overweight patients, was initiated at two study centers in Australia. The primary objective of the study is to investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant in obese or overweight individuals. Consistent with previous guidance, study results are anticipated to be reported in mid-2025.

On March 12, 2025, the Company 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.

On March 13, 2025, Vivani 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.

Liquidity and Capital Resources

From inception, our operations have been funded primarily through the sales of our common stock and warrants.

Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business with no revenue that is developing novel medical devices, including limitations on our operating capital resources. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future.

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the common stock and warrants to purchase up to an aggregate of 3,947,368 shares of common stock (the “Warrants”), to such investor at a purchase price of $3.80 per share and accompanying warrants in the Offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. Simultaneously, the Company also entered into a placement agency agreement with Maxim Group LLC (“Maxim” and such agreement, the “Placement Agency Agreement,” and together with the Securities Purchase Agreement, the “Agreements”), who acted as the sole placement agent for the Offering. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement. During the year ended December 31, 2024, the Company issued 287,970 shares of common stock for gross proceeds of $504,000 as part of the Sales Agreement with Jefferies. The Company paid expenses of $344,000, resulting in net proceeds of $160,000.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company’s common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company’s common stock on the Nasdaq or the 5-day average closing price of the Company’s common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations for at least the nextwelve months. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. We base our estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Significant estimates include those related to assumptions used in accruals for potential liabilities, valuing equity instruments and stock-based compensation, and the realization of deferred tax assets. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Restricted Cash

We consider all highly liquid investments with a maturity ofthree months or less at the date of purchase to be cash equivalents. Cash is carried at cost, which approximates fair value, and cash equivalents are carried at fair value. We generally invest funds that are in excess of current needs in high credit quality instruments such as money market funds. As of December 31, 2024 and 2023 restricted cash of $1.3 million and $1.3 million, respectively, relates to a letter of credit as a condition of our facilities lease guarantee requirements and is classified as long-term restricted cash on the consolidated balance sheets.

Property and Equipment

Property and equipment are recorded at historical cost less accumulated depreciation and amortization.When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheets and any resulting gains or losses are reflected in the consolidated statements of operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Depreciation amortization is computed using the straight-line method over the estimated useful lives of the respective assets

Lab equipment	5 – 7 years
Computer hardware and software	3 – 7 years
Furniture, fixtures and equipment	5 – 10 years

We review our property and equipment for impairment annually or whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable.

Depreciation and amortization of property and equipment amounted to $0.4 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively.

Leases

Leases are accounted for under FASB ASC 842, *Leases* ("ASC 842"). Under ASC 842, the Company determines if an arrangement contains a lease at inception. Right of use assets ("ROU assets") represent the right to use an underlying asset for the lease term while lease liabilities represent the obligation to make lease payments for the lease term. Leases are then classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations and comprehensive loss. All leases greater than 12 months result in the recognition of a ROU asset and liability at the lease commencement date based on the present value of the lease payments over the lease term. The present value of the lease payments is calculated using the applicable weighted-average discount rate. The weighted-average discount rate is based on the discount rate implicit in the lease, or if the implicit rate is not readily determinable from the lease, the applicable incremental borrowing rate is estimated. The incremental borrowing rate is estimated using the currency denomination of the lease, the contractual lease term and the Company's applicable borrowing rate. To determine the incremental borrowing rate, reference is made to interest rates that would be available to finance assets similar to the assets under lease in their related geographical location. The Company does not have finance leases.

The Company has elected not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with a lease as a single lease component. It also elected to be exempt from balance sheet recognition of all leases with an initial term of 12 months or less.

Certain leases include one or more options to renew with renewal terms that can extend the lease term. The exercise of the lease renewal options is at the Company's discretion and are included in the determination of the ROU asset and lease liability when the option is reasonably certain of being exercised.

Research and Development

Research and development costs are charged to operations in the period incurred and amounted to $15.7 million and $17.0 million, net of grant revenue, for the years ended December 31, 2024 and 2023, respectively.

Patent Costs

Due to the uncertainty associated with the successful development of one or more commercially viable products based on our research efforts and any related patent applications, all patent costs, including patent-related legal, filing fees and other costs, including internally generated costs, are expensed as incurred. Patent costs were $0.3 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively, and are included in general and administrative expenses in the consolidated statements of operations.

NIH Grant

From time to time, we receive grants that help fund specific development programs. Any amounts received pursuant to grants are offset against the related operating expenses as the costs are incurred.

During the year ended December 31, 2024 grants offset against operating expenses were $0.2 million, of which $0.2 million were offset against research and development expenses. During the year ended December 31, 2023 grants offset against operating expenses were $0.5 million, of which $0.4 million were offset against research and development expenses, and $0.1 million were offset against general and administrative expenses.

Concentration of Credit Risk

Financial instruments that subject us to concentrations of credit risk consist primarily of cash and money market funds. We maintain cash and money market funds with financial institutions that management deems credit worthy, and at times, cash balances may be in excess of FDIC and SIPC insurance limits of $250,000 and $500,000 (including cash of $250,000), respectively.

We also maintain cash at a bank in Switzerland. Accounts at said bank are insured up to an amount specified by the deposit insurance agency of Switzerland.

Foreign Operations

The accompanying consolidated financial statements as of December 31, 2024 and 2023 include assets amounting to approximately $26,000 and $49,000, respectively, relating to our operations in Switzerland. In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia was established to support studies of our product candidates. The accompanying consolidated financial statements as of December 31, 2024 and 2023 include assets amounting to approximately $446,000 and $0, respectively, relating to our operations in Australia. Unanticipated events in foreign countries could disrupt our operations and impair the value of these assets.

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that we have the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently traded non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

We determine the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, we perform an analysis of the assets and liabilities at each reporting period end.

Cash equivalents, which include certificates of deposit and money market funds, are the only financial instrument measured and recorded at fair value in assets or liabilities on our consolidated balance sheet, and they are valued using Level 1 inputs.

Stock-Based Compensation

Pursuant to FASB ASC 718 *Share-Based Payment* ("ASC 718"), we record stock-based compensation expense for all stock-based awards. Under ASC 718, we estimate the fair value of stock options granted using the option pricing models. The fair value for awards that are expected to vest is then amortized on a straight-line basis over the requisite service period of the award, which is generally the option vesting term. The Company accounts for forfeitures as they occur.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option valuation model. The assumptions used in the Black-Scholes valuation model are as follows:

- The grant price of the issuances is determined based on the fair value of the shares at the date of grant.
- The risk-free interest rate for periods within the contractual life of the option is based on the U.S. treasury yield in effect at the time of grant.
- We calculate the expected term of options using a weighted average of option vesting periods and an estimate of one-half of the period between vesting and expiration of the option.
- Volatility is determined based on our average historical volatilities since our trading history, supplemented with average historical volatilities of comparable companies in our similar industry.
- Expected dividend yield is based on current yield at the grant date or the average dividend yield over the historical period. We have never declared or paid dividends and have no plans to do so in the foreseeable future.

For stock options or restricted stock units ("RSUs") with market vesting conditions, the awards were valued using the Monte-Carlo Simulation model.

Comprehensive Loss

We comply with provisions of FASB ASC220, *Comprehensive Income*, which requires companies to report all changes in equity during a period, except those resulting from investment by owners and distributions to owners, for the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events from non-owner sources.

Comprehensive loss is reported on the face of the financial statements. For the year endedDecember 31, 2024 and 2023, comprehensive loss is the total of net loss and other comprehensive income which, consists entirely of foreign currency translation adjustments and there were no material reclassifications from other comprehensive loss to net loss during the year ended December 31, 2024 and 2023.

Foreign Currency Translation and Transaction Gains and Losses

The financial statements and transactions of the subsidiary's operations are reported in the local (functional) currency of Swiss francs (CHF) and of Australian dollars (AUD) and translated into U.S. dollars in accordance with U.S. GAAP. Assets and liabilities of those operations are translated at exchange rates in effect at the balance sheet date. The resulting gains and losses from translating foreign currency financial statements are recorded as other comprehensive income. Revenues and expenses are translated at the average exchange rate for the reporting period. Foreign currency transaction gains (losses) resulting from exchange rate fluctuations on transactions denominated in a currency other than the foreign operations' functional currencies are included in other expenses in the consolidated statements of operations.

Income Taxes

We account for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, we recognize deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. In the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made. We have incurred losses for tax purposes since inception and have significant tax losses and tax credit carry-forwards.

Net Loss per Share

Our computation of earnings per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) available to common shareholders divided by the weighted average number of shares of common stock outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., convertible notes payable, convertible preferred stock, common stock warrants and stock options) as if they had been converted at the beginning of the periods presented, or the issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share is the same for all periods presented because all common stock warrants and common stock options outstanding were anti-dilutive.

As of December 31, 2024 and 2023, we excluded the outstanding securities summarized below, which entitle the holders thereof to ultimately acquire shares of common stock, from our calculation of earnings per share, as their effect would have been anti-dilutive (in thousands).

	December 31,	
	2024	2023
Shares underlying warrants outstanding	9,340	9,733
Shares underlying stock options outstanding	6,809	6,091
Shares underlying restricted stock units outstanding	695	403
Total	16,844	16,227

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. Our chief operating decision-maker, our Chief Executive Officer, reviews financial information presented for each of our segments. We have two reporting segments, specifically the Biopharm Division and Neurostimulation Division. Neither division is revenue producing. The Biopharm Division includes activities from NPM and Vivani Medical Australia Pty Ltd. The Neurostimulation Division includes activities from Cortigent and our subsidiary in Switzerland.

During the year ended December 31, 2024, the Biopharm Division and the Neurostimulation Division incurred operating expenses of $22.6 million and $2.1 million, respectively. During the year ended December 31, 2024, consolidated net loss for the Biopharm Division was $21.3 million and for the Neurostimulation Division was $2.2 million. As of December 31, 2024, total assets for the Biopharm Division and the Neurostimulation Division were $40.5 million and $1.0 million, respectively. For further discussion related to segment reporting, please refer to Note 14. Segment Information.

The Company's long-term assets are located in the United States.

Recently Adopted Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No.2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for the Company for fiscal years beginning on January 1, 2024, and interim periods within fiscal years beginning on January 1, 2025. The Company currently operates two reportable segments and the impact of the adoption of this standard was limited to certain enhanced disclosures in the consolidated financial statements. Segment Information for disclosures related to the adoption of this guidance, please refer to Note. 14 Segment Information.

Recently Issued Accounting Pronouncements Not Yet Adopted as of December 31, 2024

In December 2023, the FASB issued ASU No. 2023-09,*Improvements to Income Tax Disclosures (Topic 740).* The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. This ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted.

In November 2024, the FASB issued Accounting Standards Update No. 2024-03 *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which will improve the disclosures about a public business entity's expenses and requires detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions such as cost of sales, selling, general and administrative, and research and developmenton the face of the income statement. ASU 2024-03 is effective for the Company or fiscal years beginning on January 1, 2027, and for interim periods within fiscal years beginning on January 1, 2028. Early adoption is permitted. The guidance may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements and continues to evaluate disclosure presentation alternatives.

3. Fair Value Measurements

Cash equivalents, which include certificates of deposit and money market funds, are the only financial instruments measured and recorded at fair value on our condensed consolidated balance sheet, and are valued using Level 1 inputs. As of December 31, 2024 and 2023, we did not have any Level 1 and Level 2 financial liabilities or Level 3 financial assets or liabilities measured at fair value on a recurring basis. We did not have any transfers between Level 1 and Level 2 or transfers in or out of Level 3 during the twelve months ended December 31, 2024 and 2023.

The following table presents certificates of deposit and money market funds at their level within the fair value hierarchy as ofDecember 31, 2024 and 2023 (in thousands).

	December 31, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents				
Certificates of deposit	$ 9,996	$ 9,996	$ —	$ —
Money market funds	7,441	7,441	—	—
Total	$ 17,437	$ 17,437	$ —	$ —

	December 31, 2023			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents				
Money market funds	$ 18,629	$ 18,629	$ —	$ —
Total	$ 18,629	$ 18,629	$ —	$ —

4. Insurance Premium Financing

In September 2024, we entered into a finance agreement with First Insurance Funding in order to fund a portion of our insurance premiums for our professional liability policies. The amount financed is approximately $426,000 and incurs interest at a rate of7.2%. The Company is required to makenine monthly payments of approximately $47,000 through May 2025. The outstanding balance as ofDecember 31, 2024 was approximately $237,000 and is included in accrued expenses in the accompanying condensed consolidated balance sheet.

5. Selected Balance Sheet Detail

Property and equipment, net of accumulated depreciation and amortization

Property and equipment consisted of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Equipment	$ 3,937	$ 3,511
Furniture and fixtures	367	354
Computer software	30	7
Construction in progress	—	299
Total property and equipment	4,334	4,171
Accumulated depreciation and amortization	(2,641)	(2,442)
Property and equipment, net	$ 1,693	$ 1,729

Contract Liabilities

Contract liabilities amounted to $335,000 and $335,000 as of December 31, 2024 and 2023, respectively, and are included in accrued expenses on the balance sheet.

6. Grants

We received an award for $1.6 million grant (with the intent to fund $6.4 million over five years subject to annual review and approval) from the National Institutes of Health ("NIH") to fund the "Early Feasibility Clinical Trial of a Visual Cortical Prosthesis" that commenced in January 2018. The final year of the grant ended in March 2024, however the NIH issued us a no-cost extension allowing us to utilize the unfunded amount through March 2025The NIH grant funds ongoing and planned clinical activities and are being used to conduct and support clinical testing of six subjects implanted with the Orion™ Cortical Visual Prosthesis ("Orion"), submit and obtain Investigational Device Exemption approval from the U.S. Food and Drug Administration ("FDA"). During the year ended December 31, 2024 grants offset against operating expenses were $0.2 million, of which $0.2 million were offset against research and development expenses. During the year endedDecember 31, 2023 grants offset against operating expenses were $0.5 million, of which $0.4 million were offset against research and development expenses, and $0.1 million were offset against general and administrative expenses. As of December 31, 2024, we expect $35,000 will be available to offset future operating expenses.

7. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with59,234,688 issued as of December 31, 2024. In addition, we are authorized to issue 10,000,000 shares of preferred stock with none issued.

Securities Purchase Agreement

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of3,947,368 shares of the common stock and Warrants to purchase up to an aggregate of 3,947,368 shares of common stock, at a purchase price of $3.80 per share and accompanying warrants in the Offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expirethree years following the date of issuance. The Company also entered into a Placement Agency Agreement with Maxim, who acted as the sole placement agent for the Offering. In connection with the Placement Agency Agreement, the Company agreed to pay Maxim an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of common stock and accompanying warrants. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse Maxim up to $65,000 for its legal expenses. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other estimated offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million.

Pursuant to the terms of the Securities Purchase Agreement, until 45 days following the closing of the Offering, the Company agreed not to issue (or enter into any agreement to issue) any shares of common stock or common stock equivalents, subject to certain exceptions. The Company has further agreed not to enter into an agreement involving a variable rate transaction until one year following the closing of the Offering. In addition, the Company's directors and officers have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 90 days from the closing of the Offering, offer, sell, transfer or otherwise dispose of the Company's securities, subject to certain exceptions.

Private Sale Transactions

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on the Nasdaq or the 5-day average closing price of the Company's common stock on the Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

The Sales Agreement

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement.

The Company may sell the common stock under the Sales Agreement (A) in privately negotiated transactions; (B) as block transactions; or (C) by any other method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Capital Market or sales made into any other existing trading market for the shares of Common Stock. Jefferies will use commercially reasonable efforts to place the shares of common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions we may impose). The Company will pay Jefferies a commission of up to three percent (3.0%) of the gross sales proceeds of any common stock sold through Jefferies under the Sales Agreement, and also has provided Jefferies with customary indemnification rights. In addition, the Company has agreed to reimburse certain legal expenses and fees incurred by Jefferies in connection with the offering.

The Company is not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

During the year ended December 31, 2024, the Company issued 287,970 shares of common stock for gross proceeds of $504,000 as part of the Sales Agreement with Jefferies. The Company paid expenses of $344,000, resulting in net proceeds of $160,000.

8. Warrants

NPM, prior to the Merger with Second Sight, issued common stock and warrants (collectively, the "unit" or "units") in 2019, 2020 and 2021 for $3.15 per unit. Outstanding warrants to purchase common stock are shown in the table below and generally expire 5 years from the date of issuance at $3.15 per share exercise price, split adjusted, are transferable into one share of common stock and may be exercised on a cashless basis.

In connection with the Securities Purchase Agreement entered on March 1, 2024, relating to the issuance of 3,947,368 shares of the common stock, par value of $0.0001 per share, the Company issued Warrants to purchase 3,947,368 shares of common stock at an exercise price of $3.80 per share. These Warrants are exercisable immediately upon issuance and will expire three years following the date of issuance. The Warrants may be exercised on a cashless basis.

The warrants outstanding as of December 31, 2024 have no intrinsic value.

A summary of warrant activity for the year ended December 31, 2024 and 2023 is presented below (in thousands, except per share and contractual life data).

	Number of Shares		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding as of December 31, 2022	10,311	$	11.13	
Issued	—			
Exercised	—	$	—	
Forfeited or expired	(578)	$	3.15	
Warrants outstanding as of December 31, 2023	9,733	$	11.60	1.4
Issued	3,947	$	3.80	
Exercised	—			
Forfeited or expired	(4,340)	$	22.10	
Warrants outstanding as of December 31, 2024	9,340	$	3.42	1.6
Warrants exercisable as of December 31, 2024	9,340	$	3.42	1.6

9. Employee Benefit Plans

We have a 401(k) Savings Retirement Plan (the “401(k) Plan”) that covers substantially all full-time employees who meet the 401(k) Plan’s eligibility requirements and provides for an employee elective contribution. The 401(k) Plan provides for employer matching contributions. Employer contributions are discretionary and determined annually by the Board of Directors. During the years ended December 31, 2024 and 2023, employer contributions to the 401(k) Plan totaled $0.2 million and $0.3 million, respectively.

10. Stock-Based Compensation

Equity Incentive Plans

The Vivani Medical, Inc. 2022 Omnibus Incentive Plan (the “2022 Plan”) became effective on August 30, 2022. Under the 2022 Plan, 10,033,333 shares were authorized for issuance at its effective date. The maximum number of shares with respect to which stock awards could be granted is offset and reduced by stock awards previously granted under the Plan. As of December 31, 2024 2,165,958 shares of common stock were available for future issuance under the 2022 Plan pursuant to stock awards that had not previously been granted.

For stock option grants, the option price is determined by the Board of Directors but cannot be less than the fair value of the shares at the grant date. Generally, the options vest ratably over four years and expire ten years from the grant date. The 2022 plan provides for accelerated vesting if there is a change of control, as defined in the 2022 Plan.

Stock Options

A summary of stock option activity is presented below (in thousands, except per share and contractual life data).

	Number of Shares		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Options outstanding at December 31, 2022	5,272	$	3.07	
Granted	1,384	$	1.22	
Exercised	(333)	$	0.52	
Forfeited or expired	(232)	$	8.12	
Other adjustment	—	$	—	
Options outstanding at December 31, 2023	6,091	$	2.60	
Granted	1,093	$	1.57	
Exercised	—	$	—	
Forfeited or expired	(375)	$	1.19	
Options outstanding, vested and expected to vest as of December 31, 2024	6,809	$	2.52	6.55
Options exercisable as of December 31, 2024	4,813	$	2.91	5.69

The estimated aggregate intrinsic value of stock options exercisable as of December 31, 2024 was $0.1 million.

Restricted Stock Units (RSUs)

A summary of restricted stock activity and related information (in thousands, except per share data):

	Number of Shares		Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2023	403	$	0.93
Granted	292	$	1.69
Vested and released	—	$	—
Forfeited and canceled	—	$	—
Outstanding as of December 31, 2024	695	$	1.25

During the years ended December 31, 2024 and 2023, the Company granted 292,500 and 402,500 RSUs, respectively, subject to market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest. Upon achievement of the market condition, one-third of the award will vest, and thereafter, one-third of the award will vest on the first and second anniversary of the achievement date, subject to the recipient's continued service through each applicable vesting date.

Stock-Based Compensation Expense

The following table summarizes total stock-based compensation expense for stock options and RSUs, which is included in the statements of operations (in thousands).

	Year Ended December 31,			
		2024		2023
Research and development	$	1,001	$	1,219
General and administrative		609		645
Total stock-based compensation expense	$	1,610	$	1,864

As of December 31, 2024, there was $1.9 million of total unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over a weighted average period of 1.3 years. As of December 31, 2024, there was $0.2 million of total unrecognized compensation expense related to outstanding RSUs that will be recognized over a weighted average period of 0.8 years.

Stock Options

During the year ended December 31, 2024 and 2023, we granted stock options to purchase shares of common stock to certain employees and board members at a weighted average price of $1.26 and $0.93 per share, respectively, which was calculated at the fair value of our common stock on the respective grant date. The options generally vest over a period of four years.

Stock Options (Service Vesting)

During the year ended December 31, 2024, 1,092,836 stock options subject to service vesting, were issued and valued at $1.4 million using the Black-Scholes option-pricing model. During the year ended December 31, 2023, 1,183,817 stock options subject to service vesting, were issued and valued at $1.2 million using the Black-Scholes option-pricing model. The calculated value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions.

	2024	2023
Risk-free interest rate	3.79% to 5.53%	3.99% – 4.79%
Expected dividend yield	—%	—%
Expected volatility	100%	100%
Expected term	5.04-6.08 years	4.00-6.20 years

Stock Options (Market Conditions Vesting)

During the year ended December 31, 2023, 200,000 stock options were granted and subject to market conditions which required our stock price to exceed $6.30 per share for three consecutive days in the four years from grant date for the stock option to vest. These stock options with market conditions vesting were valued at $0.1 million. The fair value of these options subject to market conditions were valued using the Monte-Carlo Simulation model with the following assumptions:

- **Beginning Stock Price.** We utilized the Company’s publicly traded share price as of the Valuation Date as the beginning stock value. At the Valuation Date, the publicly traded common share price was $1.09 per share.
- **Drift Rate.** In determining the value of the instrument in the risk-neutral framework, risk-free rates were estimated based on the applicable treasury rate for the projection period. For each simulation, the term of the risk-free rate was based on the term from the Valuation Date through the latest date on which the award could vest (i.e., two years following the Performance Period End Date). Please note that, for the purposes of calculating the service period associated with the Subject Interest, the Company’s cost of equity was utilized as the drift rate.
- **Volatility.** The total equity volatility (standard deviation) was based on a total equity volatility analysis.
- **Period.** The period was measured as the number of years from the Valuation Date through the PSO expiration date (10 years following the date of grant).
- **Dividends.** The Company has not historically paid dividends. In addition, the Company does not expect to pay dividends going forward. As such, no dividends were considered in our analysis.

Restricted Stock Units (RSUs)

During the year ended December 31, 2024, the Company granted 292,500 RSUs. These RSUs are subject to market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest.

The assumptions used to estimate the fair value of the performance-based restricted stock units granted during the years ended December 31, 2024 and 2023 and valued using a Monte Carlo simulation were as follows:

	Year Ended December 31,	
	2024	2023
RSUs Granted	292,500	402,500
Valuation date stock price	$1.81	$0.93
Risk-free interest rate	4.53%	4.13%
Expected divided yield	0%	0%
Expected volatility	100%	100%
Simulation term	4 years	1.1 years

The steps involved in utilizing the Monte Carlo simulation in order to value the performance-based RSUs included the following:

1. Projection of the Company's Common Stock Value. The performance-based RSUs were measured based on the Company's underlying common stock value over the performance period (four years following the Valuation Date).

Additionally, we considered the two-year vesting period following achievement of the performance condition. Accordingly, our common stock value was simulated over a six-year period to capture iterations through which the performance condition was satisfied on the Performance Period End Date. The analysis involved projecting our common stock value starting with our current common stock value. The forecasted stock price was based on the Geometric Brownian motion ("GBM"), and the Monte Carlo simulation generated random variables using the GBM to forecast our stock price on a daily basis over the specified period assuming 252 trading days per year. The Monte Carlo simulation for the PSO utilized the following assumptions:

- **Beginning Stock Price.** As of the Valuation Date, we were a publicly traded company with an observable share price. Therefore, we utilized our publicly traded share price as of the Valuation Date as the beginning stock value.
- **Drift Rate.** In determining the value of the instrument in the risk-neutral framework, risk free rates were estimated based on the applicable treasury rate for the projection period. For each simulation, the term of the risk-free rate was based on the term from the Valuation Date through the latest date on which the award could vest (i.e., two years following the Performance Period End Date). Please note that, for the purposes of calculating the service period associated with the Subject Interest, our cost of equity was utilized as the drift rate.
- **Volatility.** The total equity volatility (standard deviation) was based on a total equity volatility analysis.
- **Period.** The period was measured as the number of years from the Valuation Date through the latest date on which the award could vest.
- **Dividends.** We have not historically paid dividends nor do we expect to pay dividends going forward. As such, no dividends were considered in our analysis.

2. Consideration of the Performance-Vesting Schedule. As previously discussed, our publicly traded common share price must equal or exceed the Stock Price Hurdle amount of $3.15 over a three-consecutive-trading-day rolling period on or before the Performance Period End Date. If such performance condition is achieved, one-third of the award shall vest on the Hurdle Achievement Date, one-third of the award shall vest one year following the Hurdle Achievement Date, and one-third of the award shall vest two years following the Hurdle Achievement Date.

3. Performance-Based RSU Value Conclusion The proceeds from the vesting of common shares were then discounted to the Valuation Date using the applicable risk-free rate, which is consistent with the assumption utilized to project stock prices in our Monte Carlo simulation. For the purposes of calculating the weighted service period associated with the Subject Interest, a separate simulation was performed using our cost of equity as the drift rate. The service period was then determined based on the median Hurdle Achievement Date.

11. Income Taxes

As discussed in *Note 1, Organization and Business Operations,* Nano Precision Medical, Inc. and Second Sight Medical Products, Inc. merged on August 30, 2022. The transaction was accounted for as a reverse merger business combination under GAAP. Accordingly, the consolidated income tax provision includes NPM for all periods presented, and the legacy Second Sight business of Vivani since the date of the merger.

Due to the net losses in 2024 and 2023, the provision for income taxes consists only of minimum California franchise taxes presented in general and administrative expenses.

The components of deferred income assets and liabilities as of December 31, 2024 and 2023 are as follows (in thousands):

	December 31, 2024	December 31, 2023
Deferred Tax:		
Accruals and reserves	$ 523	$ 1,101
Capitalized R&E §174	6,722	5,120
Lease ROU	379	302
Stock compensation	1,992	1,541
Net operating loss	52,588	48,170
R&D credit	9,459	6,770
Gross deferred tax assets	71,663	63,004
Investment in subsidiary	(1,924)	(1,924)
Accumulated depreciation and amortization	(158)	(200)
Gross deferred tax liabilities	(2,082)	(2,124)
Valuation Allowance	(69,581)	(60,880)
Total Deferred Tax Assets, Net	$ —	$ —
Change in Valuation Allowance for the Year Ended	$ 8,702	$ 6,046

The reconciliation of income tax computed at the expected U.S. federal statutory tax rate of 21% to income tax expense (benefit) and the corresponding rate from operations consist of the following (in thousands) for the year ended December 31, 2024 and 2023:

	For the Year Ended December 31, 2024		2023	
Pre-tax loss	$ (23,487)		$ (25,652)	
Federal tax (benefit) at statutory rate	$ (4,932)	21.0%	$ (5,387)	21.0%
State tax (benefit), net of federal tax benefit	(1,568)	7.0%	(1,791)	7.0%
R&D tax credit from current year	(2,591)	11.0%	(1,050)	4.1%
Impact on effective rate of loss eliminated in consolidation	—	—%	—	—%
Other	392	(1.7)%	2,184	-8.5%
Change in valuation allowance	8,702	(37.1)%	6,046	-23.6%
Total provision for income taxes	$ 3	0.0%	2	0.0%

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. Based on this evaluation, as of December 31, 2024 and 2023, a full valuation allowance has been recorded because deferred tax assets have been assessed to be less than "more likely than not" to be realized.

As of December 31, 2024, we had federal and apportioned state net operating loss ("NOL") and federal and state R&D credit carry-forwards available to offset future taxable income and income taxes as follows (in thousands):

		December 31, 2024
Pre TCJA (Tax Cuts and Jobs Acts of 2017) period federal NOL carry-forward, begin expiring 2030	$	47,353
Post TCJA period federal NOL carry-forward, with no carry-forward limitation		151,315
Total federal NOL carry-forward	$	198,668
State NOL carry-forward, begin expiring 2030	$	143,717
Federal R&D tax credit carry-forward, begin expiring in 2036	$	4,907
State R&D carry-forward, no expiration date	$	8,755
Total R&E related deferred income tax assets (net of applicable amortization)	$	6,722
Reserve for uncertain income tax positions		Nil

As of December 31, 2024, the Company has Federal and California research and development credit carryforwards of $4.9 million and $8.7 million, respectively. The Federal research and development credit carryforwards will expire beginning in 2036 if not utilized. The California research and development credits have no expiration date.

Under recently enacted U.S. tax legislation, although the treatment of tax losses generated in taxable years ending before December 31, 2017, has generally not changed, tax losses generated in taxable years beginning after December 31, 2017, may only be utilized to offset 80% of taxable income annually. This change may require NPM and Legacy SSMP to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

To the extent that each of the tax filers continue to generate taxable losses, unused losses will carry-forward to offset future taxable income, if any, until these unused losses expire. However, the tax filers may be unable to use these losses to offset taxable income before our unused losses expire at various dates that range from 2030 through 2037 for federal net operating losses generated before 2018. Federal net operating losses generated for year 2018 and forward do not expire. State net operating losses expire from 2030 through 2042. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carry-forwards to offset its post-change taxable income may be limited. Limitations may also apply to the utilization of other pre-change tax attributes as a result of an ownership change.

Second Sight Medical Products, Inc. experienced an "ownership change" within the meaning of Section 382(g) of the Code during the third quarter of 2022 as a result of the merger. The ownership change will subject its net operating loss carry-forwards to an annual limitation, which will significantly restrict its ability to use them to offset taxable income in periods following the ownership change. In general, the annual use limitation equals the aggregate value of stock at the time of the ownership change multiplied by a tax-exempt interest rate specified by the Internal Revenue Service. We have not yet fully analyzed the available information to determine the amount of the annual limitation.

The Company has the following activity relating to unrecognized tax benefits (in thousands):

	Year Ended December 31,			
	2024		2023	
Balance at beginning of year	$	1,692	$	—
Increases based on tax positions related to the current year		648		262
Increases based on tax positions related to prior years		24		1,430
Reductions based on tax positions related to prior years		—		—
Balance at end of year	$	2,364	$	1,692

As of December 31, 2024, the Company had $2.4 million of unrecognized tax benefits which are comprised of federal of $1.0 million and California of $1.4 million. The Company's unrecognized gross tax benefits would not reduce its annual effective tax rate if recognized because the Company has recorded a full valuation allowance on deferred tax assets. The Company does not foresee any material changes to its gross unrecognized tax benefit within the next 12 months. The Company recognizes interest and/or penalties related to income tax matters in income tax expense. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the year ended December 31, 2024 and 2023. All years are open for examination by federal and state authorities. The Company currently has no federal or state tax examinations in progress.

Beginning January 1, 2022, we are required to capitalize certain research and development expenditures in accordance with section 174 of the Internal Revenue Code, as amended by the Tax Cuts and Jobs Act of 2017, instead of previously being allowed to expense. Amortization of such capitalized expenditures are allowed over a 5-year period if incurred in the U.S. or a 15-year period if incurred outside the United States.

We file income tax returns in the U.S. federal jurisdiction and various states and are subject to income tax examinations by federal tax authorities for tax years ended 2017 and later and by state authorities for tax years ended 2016 and later. We currently are not under examination by any tax authority. Our policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2024 and 2023, we have no accrued interest or penalties related to uncertain tax positions. Second Sight Switzerland, our foreign subsidiary, has not had any taxable income in the prior and current years.

12. Right-of-use Assets and Operating Lease Liabilities

We lease certain office, laboratory, research and development space for our use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Operating lease cost for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the consolidated statements of operations and comprehensive loss. Our lease agreements do not contain any material residual value guarantees or restrictive covenants. As most of our leases do not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

On November 21, 2022, Vivani entered into a triple net lease agreement for a single building with 43,645 square feet of space in Alameda, California. The stated term of the lease commenced on June 1, 2023 and terminates on September 30, 2033, ten years and 4 months. The lease term is based on the non-cancellable period in the lease agreement. There are two options to extend the lease, each for a term of five years; however, the extension options were not included in the measurement of the ROU asset and lease liability since it is not reasonably certain that the Company will exercise such extension options. Payments increase annually from $2,676,311 to $3,596,784, or 124 monthly payments less the first four which are abated, totaling approximately $31.0 million. Vivani will be responsible for insurance, property taxes and common area maintenance charges. Vivani deposited $1.3 million to guarantee a letter of credit to secure the lease and this amount is included in long-term assets on the balance sheet as of December 31, 2024. The lease in Emeryville, California expired on September 30, 2023.

On February 1, 2023, we entered into a lease agreement, effective March 1, 2023, to sublease office space to replace Cortigent's existing headquarters. Our rental payments amount to $22,158 per month plus operating expenses, to lease 14,823 square feet of office space at 27200 Tourney Road, Valencia, California 91355. The sublease has a term of two years and two months. The sublease expires on April 30, 2025. We also entered into a lease for storage space on January 25, 2023, in the same building at a cost of $6,775 per month for a term of two years and one month. The lease expires on March 31, 2025. We are not renewing the current office lease. However we are entering into another lease in the same building for a smaller space at a cost of $1,700 per month for six months. We are renewing the lease of the storage unit. These new and renewal leases will be short-term leases with immaterial monthly costs.

On July 3, 2024, we entered into a short-term sublease agreement for access to manufacturing facility with an extension option that is not expected to be exercised. The sublease expires on June 30, 2025.

The following table summarizes supplemental balance sheet information related to the Company's operating leases (in thousands):

	Balance Sheet Classification	December 31, 2024	December 31, 2023
Assets			
Non-current assets	Right-of-use assets	$ 17,957	$ 19,616
Liabilities			
Current	Current operating lease liabilities	$ 1,348	$ 1,383
Long-term	Long-term operating lease liabilities	$ 17,965	$ 19,313

Operating lease cost was $3.3 million and $2.8 million during 2024 and 2023, respectively. Variable lease cost, comprising primarily of common area maintenance charges and taxes, for the operating lease was $0.4 million and $1.1 million during 2024 and 2023, respectively. Short-term sublease costs were $200,000 during 2024.

The following table summarizes a maturity analysis of our lease liabilities showing the aggregate lease payments as of December 31, 2024 (in thousands except weighted average data):

Year Ending December 31,	
2025	$ 2,914
2026	2,889
2027	2,976
2028	3,065
2029	3,156
Thereafter	12,704
Total lease payments	27,704
Less imputed interest	(8,391)
Total lease liabilities	$ 19,313
Weighted average remaining lease term	8.70 years

Other information related to leases are as follows (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023
Cash paid for operating lease liabilities	$ 3,070	$ 1,932
Weighted average discount rate	8.40%	8.41%

13. Commitments and Contingencies

Indemnification Agreements

We maintain indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law.

Clinical Trial Agreements

Based upon FDA approval of Argus II, which was obtained in February 2013, we were required to collect follow-up data from subjects enrolled in our pre-approval trial for a period of up to ten years post-implant, which was extended through the year2019. This requirement to collect follow-up data was halted in2020 with FDA approval. In addition, we conducted three post-market studies to comply with U.S. FDA, French, and European post-market surveillance regulations and requirements and are conducting an early feasibility clinical study of Orion. We have contracted with various universities, hospitals, and medical practices to provide these services. Payments are based on procedures performed for each subject and are charged to clinical and regulatory expense as incurred. Total amounts expensed for the year ended December 31, 2024 and 2023 were $17,000 and $0.1 million, respectively.

Litigation, Claims and Assessments

Three oppositions filed by Pixium Vision are pending in the European Patent Office, each challenging the validity of a European patent owned by Cortigent. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing Cortigent's neurostimulation patented technology. We believe a successful challenge will not have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding ("MOU") for a proposed business combination with Pixium Vision SA ("Pixium"). In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our shareholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company's offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately € 5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgement, including finding that the Company's termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium's claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile,the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium's receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium's liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment.The hearing took place on June 4, 2024, and on October 23, 2024, the pre-trial judge issued his order, striking out Vivani's appeal for failure to enforce the decision. Within two years,Vivani will have to request that the case be reinstated on the court's docket, providing evidence that the judgment has been fully enforced or, at the very least, that an agreement has been reached. Failing this, the appeal proceedings will lapse.

The Company recorded a charge of $1,675,000 for the year ended December 31, 2022 related to this matter but plans to continue its appeal against the preliminary judgment.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our results of operations, however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

14. Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has two operating and reporting segments, the Biopharm Division and the Neurostimulation Division. The Company's CODM is its Chief Executive Officer who reviews the Company between Biopharm and Cortigent. Our primary focus is the Biopharm Division. We are trying to spin off Cortigent. The measure of segment loss is reported on the Consolidated Statements of Operations and Comprehensive Loss as net loss. The measure of segment assets is reported on the Consolidated Balance Sheets as total assets.

The Company has not generated any product revenue to date. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it is a clinical stage biopharmaceutical company.

The following table provides information related to our operating segments based upon the Company's net loss for the two years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,					
	2024			2023		
	Biopharm Division	Neurostimulation Division	Total	Biopharm Division	Neurostimulation Division	Total
Operating expenses:						
Personnel and related expenses	$ 10,053	$ 1,752	$ 11,805	$ 9,722	$ 3,300	$ 13,022
Office space rental related expenses	3,999	—	3,999	3,990	—	3,990
Development expenses	2,765	294	3,059	2,577	1,934	4,511
Professional services and insurance	4,600	—	4,600	4,146	—	4,146
Depreciation and amortization	378	30	408	307	44	351
Other general and administrative expenses	806	—	806	945	—	945
Other (income) expense, net	(1,347)	156	(1,191)	(1,426)	113	(1,313)
Segment net loss	$ 21,254	$ 2,232	$ 23,486	$ 20,261	$ 5,391	$ 25,652

15. Subsequent Event

The Company evaluated subsequent events for recognition and disclosure through the date the financial statements were issued or filed. Nothing has occurred outside normal operations that required recognition or disclosure in these financial statements except as follows:

Private Sale Transaction

On March 26, 2025, the Company entered into a private sale transaction with an entity affiliated with one of its independent directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in one or more closings as provided in the purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on the Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $8.25 million.

Vivani Medical, Inc. (the "Company") has adopted the following policy and procedures for securities trading by Company directors and employees as amended and/or restated from time to time, (our "Insider Trading Policy"). Our Insider Trading Policy is intended to prevent the misuse of material nonpublic information, insider trading in securities, and the severe consequences associated with violations of insider trading laws. It is your obligation to review, understand and comply with this Insider Trading Policy and applicable laws. Our Board of Directors has approved this Insider Trading Policy, and appointed the Company's Chief Financial Officer as the Compliance Officer (with their designees, the "Compliance Officer") to administer the policy and to be available to answer your questions.

PART I. OVERVIEW

A. Who Must Comply?

This Insider Trading Policy applies to all of our employees, officers and members of our Board of Directors, including anyone employed by or acting as a director, officer, employee, contractors or consultants of any of the Company's subsidiaries.

In addition, all of our directors, executive officers (as defined by Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), our employees with the title of Vice President or above, all members of the finance department, director/manager of operations, director/manager of order management, in-house legal counsel, and anyone else who has been notified of designed by the Compliance Officer because they have access to material nonpublic information about the Company must comply with the Trading Procedures included in Part II of this Insider Trading Policy (the "Trading Procedures"); we will refer to these individuals in this policy as "Insiders." The Trading Procedures provide rules for when Insiders can trade in our securities and explain the process for mandatory pre-clearance of proposed trades. You will be notified if you are considered to be an Insider who is required to comply with the Trading Procedures.

This Insider Trading Policy and, for Insiders, the Trading Procedures also apply to the following persons ("Affiliated Persons"):

- your "Family Members" ("Family Members" are (a) your spouse or domestic partner, children, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws who reside in the same household as you, (b) your children or your spouse's children who do not reside in the same household as you but are financially dependent on you, (c) any of your other family members who do not reside in your household but whose transactions are directed by you, and

  (d) any other individual over whose account you have control and to whose financial support you materially contribute. (Materially contributing to financial support would include, for example, paying an individual's rent but not just a phone bill.).);

- all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family and over which you have the ability to influence or direct investment decisions concerning securities;

- all persons who execute trades on your behalf; and
- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures do not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if the entity has established its own insider trading controls and procedures in compliance with applicable securities laws and it (or an affiliated entity) has represented to the Company that its affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with securities laws; and (c) are aware the securities laws prohibit any person or entity who has material nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, by all of your Affiliated Persons.

B. What is Prohibited by this Insider Trading Policy?

You and your Affiliated Persons are prohibited from engaging in insider trading and from otherwise trading in securities in violation of this Insider Trading Policy. "Insider trading" is (1) trading (buying or selling) the securities of a company whether for your account or for the account of another, while in the possession of material nonpublic information (see definition below) about that company or (2) disclosing material nonpublic information about a company to others who may trade on the basis of that information. Insider trading can result in criminal prosecution, jail time, significant fines and public embarrassment for you and the Company.

Prohibition on Trading in Company Securities

When you are in possession of material nonpublic information about the Company, whether positive or negative, you are prohibited from trading (whether for your account of for the account of another) in the Company's securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants and exchange- traded options), and any derivative securities that provide the economic equivalent of ownership of any the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, except for trades made pursuant to plans approved by the Compliance Officer in accordance with this policy that are intended to comply with Rule 10b5-1 under the Exchange Act.

The trading prohibitions in this Insider Trading Policy do not apply to: (1) an exercise of an employee stock option when payment of the exercise price is made in cash or (2) the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

The trading prohibitions in this Insider Trading Policy do apply, however, to the use of outstanding Company securities to pay part or all of the exercise price of a stock option, any sale of stock as part of a broker- assisted cashless exercise of an option and any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Prohibition on Tipping

Providing material nonpublic information about the Company to another person who may trade or advise others to trade on the basis ofthat information is known as "tipping" and is illegal. You are prohibited from providing material nonpublic information about the Company to a friend, relative or anyone else who might buy or sell a security or other financial instrument on the basis of that information, whether or not you intend to or actually do realize a profit (or any other benefit) from such tipping. Additionally, you are prohibited from recommending to any person that such person engage in or refrain from engaging in any transaction involving the Company's securities, or otherwise give trading advice concerning the Company's securities, if you are in possession of material nonpublic information about the Company.

While the Company encourages its stockholders and potential investors to obtain as much information as possible about the Company, the Company believes that this information should come from its reports publicly-filed with the U.S. Securities and Exchange Commission (the "SEC"), press releases and external website, or from a designated spokesperson, rather than from speculation or unauthorized disclosures by its directors, officers, employees or consultants. For this reason, the Company has designated certain members of management to respond to inquiries regarding its business and prospects. This centralization of communication is designed to ensure that the information that is discloses is accurate and considered in light of previous disclosures. Management and legal counsel generally review formal announcements before they are made public. Any communications that do not go through this review process create an increased risk to the Company, as well as to the individual responsible for the communication, of civil and criminal liability.

In addition, on the Internet, and particularly through social media, including electronic bulletin boards and chat rooms, electronic discussions about companies and their business prospects have become common. Inappropriate communications disseminated on the Internet may pose an inherently greater risk due to the size of the audience they can reach. These forums have the potential to move a stock price significantly, and very rapidly, yet the information disseminated through the Internet and social media forums often is unreliable. In some cases, information may be deliberately false. The SEC has investigated and prosecuted a number of fraudulent schemes involving communications in these forums. An individual may encounter information about the Company on the Internet that he or she believes is harmful or inaccurate, or other information that he or she believes is true or beneficial for the Company. Although an individual may have a natural tendency to deny or confirm such information on an electronic bulletin board or in a chat room, any sort of response, even if it presents accurate information, could be considered improper disclosure and could result in legal liability to the individual and/or the Company.

The Company is committed to preventing inadvertent disclosures of material, nonpublic information, preventing unwitting participation in Internet-based securities fraud, and avoiding the appearance of impropriety by persons associated with the company. Accordingly, this procedure prohibits Insiders from discussing material, nonpublic information about the Company with anyone, including other employees or consultants, except as required in the performance of job duties or functions. Insiders should not under any circumstances provide information or discuss matters involving the Company with the news media, any broker- dealer, analyst, investment banker, investment advisor, institutional investment manager, investment company or stockholder, even if contacted directly by such persons, without express prior authorization. This restriction applies whether or not an individual has an identifiable association with the Company. All such contact or inquiries should be referred to the Compliance Officer.

Insiders should avoid making any comments or postings about the Company on any Internet bulletin boards, chat rooms or websites, or responding to comments or postings about the company's business made by others, unless it is part of a job duty to do so or if clearance is received from the Compliance Officer. This restriction applies whether or not an individual has an identifiable association with the Company.

Prohibition on Trading in Securities of Other Companies

Whenever, during the course of your service to or employment by the Company, you become aware of material nonpublic information about another company (1) with which the Company has an existing business relationship, including but not limited to, the Company's distributors, vendors, customers or suppliers or collaboration, marketing, research, development or licensing partners, or (2) with which the Company is in active discussions concerning a potential transaction or business relationship, neither you nor your Affiliated Persons may trade in any securities of that company, give trading advice about that company, tip or disclose that information, pass it on to others or engage in any other action to take advantage of that information. If your work regularly involves handling or discussing confidential information of companies in either of the foregoing categories, you should consult with the Compliance Officer before trading in any of those company's securities.

Additionally, if you believe you may be in possession of nonpublic information about the Company that could potentially have a material effect on the stock price of a company with which the Company does not have an existing business relationship or with which the Company is not discussing a potential transaction or business relationship, you should exercise caution when trading in the securities of that company because the SEC has successfully brought an insider trading claim against an insider in those circumstances.

Other Prohibited Transactions

- **No Short Sales**. You may not at any time sell any securities of the Company that are not owned by you at the time of the sale (a "short sale"). Short sales of Company securities may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company securities by any person subject to this procedure are prohibited. In addition, the Exchange Act prohibits officers and directors from engaging in short sales.

- **No Purchases or Sales of Derivative Securities or Hedging Transactions**. You may not buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of our securities or engage in any other hedging transaction with respect to our securities.

- **No Company Securities Subject to Margin Calls**. You may not use the Company's securities as collateral in a margin account.

- **No Pledges**. You may not pledge Company securities as collateral for a loan (or modify an existing pledge).

- **Standing and Limit Orders**. Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an Insider, or other person subject to this policy, is in possession of material nonpublic information. The Company, therefore, discourages placing standing or limit orders on Company securities. If a person subject to this procedure determines that they must use a standing order or limit order, the order should be limited to short duration and should otherwise comply with the restrictions and procedures outlined in Part II, Section B below.

Duration of Trading Prohibitions

These trading prohibitions continue whenever and for as long as you know or are in possession of material nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider even the appearance of improper insider trading and how enforcement authorities and others might view the transaction in hindsight.

This Insider Trading Policy applies to you and your Affiliated Persons so long as you are associated with the Company. If you leave the Company for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures described in Part III, will continue to apply to you and your Affiliated Persons until the later of: (1) the first trading day following the public release of earnings for the fiscal quarter in which you leave the Company or (2) the first trading day after any material nonpublic information known to you has become public or is no longer material.

C. What is Material Nonpublic Information?

This Insider Trading Policy prohibits you from trading in a company's securities if you are in possession of information about the company that is both "*material*" and "*nonpublic*." If you have a question whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer.

"Material" Information

Information about our Company or any other company is "material" if it could reasonably be expected to affect the investment decisions of a stockholder or potential investor or if disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about us or any other company. We speak mostly in this Insider Trading Policy about determining whether information about us is material and nonpublic, but the same analysis applies to information about other companies covered by this policy that would preclude you from trading in their securities.

In simple terms, material information is any type of information that could reasonably be expected to affect the market price of our securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are examples of the types of information that could be material:

- projections of future earnings or losses, or other earnings guidance;
- quarterly and/or annual financial results that are known but have not been publicly disclosed;
- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;
- changes in senior management or member of our Board of Directors;
- actions by and interactions with regulatory authorities such as the U.S. Food and Drug Administration;
- development of a significant new product, process, technical innovation or service;
- significant preclinical, clinical, or other scientific results;

- significant actual or threatened litigation or governmental investigations or major developments in such matters;
- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;
- a restructuring;
- significant related party transactions;
- bank borrowings or other financing transactions out of the ordinary course;
- a change in management;
- a change in auditors or notification that the auditor's report may no longer be relied upon;
- cybersecurity risks and incidents, including the discovery of significant vulnerabilities or breaches;
- significant developments regarding products, customers, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);
- changes in dividend policy, declarations of stock splits or proposed securities offerings or other financings;
- potential defaults under our credit agreements or indentures or potential material liquidity issues;
- bankruptcies or receiverships;
- the imposition of a ban on trading the Company securities or the securities of another company with which the Company does business;
- forward-looking information regarding the financial performance, such as earnings guidance, projections, or "outlook" for future financial results;
- business plans and strategies with respect to the company's pipeline and product candidates; and
- any significant developments or changes regarding any repurchase program for the Company's securities (such as planned repurchases, increases, or decreases in the program's authorization, suspensions, and similar changes).

The above items will not always be material. For example, some new products or contracts may clearly be material while others may not be. No "bright-line" standard or list of items can adequately address the range of situations that may arise; information and events should be carefully considered in terms of their materiality to the Company.

“Nonpublic” Information

Material information is “nonpublic” if it has not been disseminated in a manner making it available to investors generally.

To demonstrate that information is public, one must be able to point to some fact that establishes that theinformation has become publicly available, such as the filing of a report with the SEC, the distribution of a press release, publishing the information on our website or posting on social media if those are regular ways we communicate with investors, or by other means that are reasonably designed to provide broad public access. Before a person with material nonpublic information can trade, the market must have adequate time to absorb the information that has been disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the completion of two full days of trading following our public release of the information. For that purpose, a full day of trading means a session of regular trading hours on the Nasdaq Stock Market (“Nasdaq”) between 9:30 a.m. and 4:00 p.m. Eastern Time (or such earlier closing time as has been set by exchange rules) has occurred.

For example, if the Company publicly discloses material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on the following Thursday. However, if the Company publicly discloses material information after trading begins on a Tuesday, the first time that you can buy or sell Company securities is the opening of the market on the following Friday.

D. What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority (“FINRA”), investigate and are very effective at detecting insider trading. The U.S. government pursues insider trading violations vigorously, successfully prosecuting, for example, trading by employees in foreign accounts, trading by family members and friends of insiders and trading involving only a small number of shares.

The penalties for violating rules against insider trading can be severe and include:

- forfeiting any profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of a violation, have purchased or sold securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to paycivil penalties or fines of $2.5 million or more, up to three times the profit made or loss avoided, as well as criminal penalties of up to $25,000,000, and could under some circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject you to disciplinary action by the Company, including termination of your employment or other relationship with the Company. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy whether or not it also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against an alleged violator before taking disciplinary action.

E. How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer. In addition, if you violate this Insider Trading Policy or any federal or state laws governing insider trading or know of any such violation by any director or employee of the Company, you should report the violation immediately to the Compliance Officer.

PART II. TRADING PROCEDURES

A. Special Trading Restrictions Applicable to Insiders

In addition to needing to comply with the restrictions on trading in our securities set forth above, Insiders and their Affiliated Persons are subject to the following special trading restrictions:

No Trading During Blackout Periods.

The announcement of the Company's quarterly financial results almost always has the potential to have a material effect on the market for the Company's securities. Although an Insider may not know the financial results prior to public announcement, if an Insider engages in a trade before the financial results are disclosed to the public, such trades may give an appearance of impropriety that could subject the Insider and the Company to a charge of insider trading. Therefore, subject to limited exceptions described herein, Insiders may not trade in Company securities during four quarterly blackout periods ("Blackout Periods"), and then only after obtaining pre-clearance from the Compliance Officer in accordance with the procedures set forth below. Notwithstanding the foregoing, the Compliance Officer shall have the discretion to waive the Blackout Periods for any quarter and shall provide a notice at least 3 calendar days prior to the beginning of the Blackout Periods of their intention to waive such Blackout Period for any applicable quarter. Unless otherwise advised, the four Blackout Periods consist of the periods that begin at the close of trading on the tenth (10) calendar day prior to the scheduled meeting of the Board of Directors following the end of each quarter, and ending after the close of trading on the second full trading day following the Company's issuance of a press release (or other method of broad public dissemination) announcing its quarterly or annual earnings for that quarter. For the purposes of the foregoing, a full trading day means an entire calendar day in which a session of regular trading hours on Nasdaq between 9:30 a.m. and 4:00 p.m. Eastern Time (or such earlier close time as has been set by exchange rules) has occurred. Insiders may be allowed to trade during the Blackout Periods only (a) pursuant to a pre- approved Rule 10b5-1 Plan as described below or (b) if granted a waiver in accordance with the procedure for granting waivers as described below.

For example, if we release earnings results before the market opens on a Tuesday, the first time an Insider can buy or sell Company securities is after the market opens on the following Thursday. However, if our earnings release occurs after trading begins on a Tuesday, the first time that an Insider can buy or sell Company securities is the opening of the market on the following Friday.

Of course, if an Insider has material nonpublic information about the Company outside one of these Blackout Periods, the Insider may not trade in the Company's securities.

2. Special Closed Trading Periods.

From time to time, in connection with an announcement of material information about the Company or when significant developments or announcements are anticipated, the Compliance Officer may designate, a "Special Closed Window" wherein the Compliance Officer may impose a temporary prohibition on trading in our securities that applies to specified groups of employees or, in rare instances, all persons covered by this policy during what would otherwise be a permitted trading window. In such event, you will be notified by e- mail and/or other means of the imposition and expected duration of the trading prohibition. During a Special Closed Window, such designated Insiders (which could be all Insiders or a subset of them) may not trade in the Company's securities.

In addition, financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the Compliance Officer, designated persons should refrain from trading in Company securities even sooner than the typical Blackout Period described above. In that situation, the Compliance Officer may notify these persons that they should not trade in the Company's securities, without disclosing the reason for the restriction

The Compliance Officer may also impose a Special Closed Window on Insiders or a subset of them to prohibit trading in the securities of other companies to ensure compliance with this policy. The imposition of a Special Closed Window will not be announced to the Company generally, should not be communicated to any other person, and may itself be considered under this Insider Trading Policy to be material nonpublic information about the Company. Even if the Compliance Officer has not designated an individual as a person who should not trade due to an event-specific restriction, an individual should not trade while aware of material nonpublic information. Exceptions will not be granted during a Special Closed Window.

3. OptionTrax.

The Company has named OptionTrax as its stock plan platform for recording and tracking stock options. Each employee will have a stock option account with OptionTrax to assist with the administration of those stock options. OptionTrax also offers access to several brokerage firms with whom employees could exercise and trade their stock options and stock. The Chief Compliance Officer will block trading through these accounts during any Blackout Period. These accounts are intended to assist employees in complying with this procedure. However, employees should not rely solely on trades being allowed on OptionTrax or their designated brokerage platform to ensure compliance with this procedure.

4. Exceptions

The quarterly Blackout Period and Special Closed Window restrictions do not apply to those transactions to which this procedure does not apply, as described below under Part II Section C, transactions under company plans, and transactions not involving a purchase or sale. Further, the requirement for pre- clearance, the quarterly Blackout Period and Special Closed Window restrictions do not apply to transactions conducted pursuant to approved Rule 10b5-1 plans, as described in Part II, Section C.1.

5. Gifts and Other Distributions in Kind.

No Insider may donate or make any other transfer of Company securities without consideration when the Insider is not permitted to trade. In addition to charitable donations or gifts to family members, friends, trusts or others, this prohibition applies to distributions to limited partners by limited partnerships that are subject to this Insider Trading Policy. Making a gift shall be considered trading in securities for purposes of the Pre-Clearance Procedures and Post-Trade Reporting Procedures in Section II.B. below.

6. No Trading During Retirement Plan Blackout Periods

If we adopt a policy to allow ownership of Company stock in our 401(k) or other retirement plan, then during a retirement plan “Blackout Period,” no Insider may trade in any Company securities that were acquired in connection with the Insider’s service or employment with the Company except as specifically permitted below. A Blackout Period includes any period of more than three (3) consecutive business days during which at least fifty percent (50%) of all participants and beneficiaries under all of the individual account plans maintained by the Company and members of the Company’s controlled group are prohibited from trading in Company securities through their plan accounts. Insiders will receive advance notice of any such Blackout Period from the Compliance Officer.

B. Pre-Clearance Procedures

No Insider may trade in our securities, even if outside a Blackout Period or Special Closed Window, unless the trade has been approved by the Compliance Officer in accordance with the procedures described below. In reviewing trading requests, the Compliance Officer may consult with our other officers and/or outside legal counsel and will seek approval of their own trades from the Chief Executive Officer.

1. Procedures.

No Insider may trade in our securities unless:

- The Insider has notified the Compliance Officer of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy or via email with the Stock Transaction Request form, in the form attached hereto as Exhibit A, to follow as soon as practicable. To provide adequate time for the preparation of any required reports under Section 16 of the Exchange Act, a Stock Transaction Request form should, if practicable, be received by the Compliance Officer at least one (1) business day before the intended trade date;

- The Insider has certified to the Compliance Officer in writing via email or memo before the proposed trade(s) that the Insider does not possess material nonpublic information concerning the Company;

- If the Insider is an executive officer or director, the Insider has informed the Compliance Officer, using the Stock Transaction Request form, whether, to the Insider's best knowledge, (a) the Insider has (or is deemed to have) engaged in any opposite way transactions within the previous six (6) months that were not exempt from Section 16(b) of the Exchange Act and (b) if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144"))[1]), whether the transaction meets all of the applicable conditions of Rule 144;

- The Compliance Officer has approved the trade(s) and has certified their approval in writing (which may be by email).

- Pre-clearance approvals will go "stale" if more than three (3) business days have lapsed before the transaction is executed, if the Compliance Officer deems that the trading window should be closed for whatever reason, or if the Insider obtains material non-public information prior to executing the transaction, and he or she will then need to seek a new pre-clearance. However, in specific instances where the Insider has previously informed the Compliance Officer of proposed transactions that exceed the three (3) business days window using a Stock Transaction Request form, then such pre- clearance approvals transactions, will not go stale after three (3) business days until the Compliance Officer notifies the Insider if pre-clearance needs to be reapproved.

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1 SEC Rule 144 - Provides an exemption and permits the public resale of restricted or control securities if a number of conditionsare met, including how long the securities are held, the way in which they are sold, and the amount that can be sold at anyone time. Even if all the conditions of the rule are met, restricted securities cannot be sold to the public until a transfer agent has removed the restrictive legend.

- The Insider must notify the Compliance Officer following completion of the transaction and must be prepared to report the transaction on appropriate reports under Section 16 of the Exchange Act (if applicable).

The Compliance Officer does not assume responsibility for, and approval by the Compliance Officer does not protect the Insider from, the consequences of prohibited insider trading.

Notwithstanding the foregoing, the Compliance Officer, in their discretion, may waive the requirement to provide the Stock Transaction Request form, including but not limited to accepting a pre-clearance request by email and other means.

2. Additional Information.

Insiders shall provide to the Compliance Officer any documentation the Compliance Officer reasonably requires in furtherance of the foregoing procedures. Any failure to provide such information will be grounds for the Compliance Officer to deny approval of the trade request.

3. Notification of Brokers of Insider Status

Insiders who are required to file reports under Section 16 of the Exchange Act shall inform their broker- dealers that the Insider is subject to Section 16. The broker shall confirm that any trade by the Insider or any of their affiliates has been precleared by the Company andthe broker is expected to provide transaction information to the Insider and/or Compliance Officer on the day of a trade.

4. No Obligation to Approve Trades.

The foregoing approval procedures do not in any way obligate the Compliance Officer to approve any trade. The Compliance Officer has sole discretion to reject any trading request.

From time to time, an event may occur that is material to the Company and is known by only by a limited number of directors and employees. The Compliance Officer may decline an Insider's request to preclear a proposed trade based on the existence of a material nonpublic development – even if the Insider is not aware of that material nonpublic development. If any Insider engages in a trade before a material nonpublic development is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute even if the Insider was unaware of the development. So long as the event remains material and nonpublic, the Compliance Officer may decide not to approve any transactions in the Company's securities. The Compliance Officer will subsequently notify the Insider once the material nonpublic development is disclosed to the public or resolved. If an Insider requests preclearance of a trade during the pendency of such an event, the Compliance Officer may reject the trading request without disclosing the reason.

5. Completion of Trades.

After receiving written clearance to engage in a trade approved by the Compliance Officer, an Insider must complete the proposed trade within three (3) business days or make a new trading request. However, in specific instances where the Insider has previously informed the Compliance Officer of proposed transactions that exceed the three (3) business days window using a Stock Transaction Request form, then such pre-clearance approvals transactions, will not go stale after three (3) business days until the Compliance Officer notifies the Insider if pre-clearance needs to be reapproved. Even if an Insider has received clearance, the Insider may not engage in a trade if (i) such clearance has been rescinded by the Compliance Officer, (ii) the Insider has

otherwise received notice of a Blackout Period or Special Closed Window or (iii) the Insider has or acquires material nonpublic information.

6. Post-Trade Reporting.

The details of any transactions in our securities (including transactions effected pursuant to a Rule 10b5-1 Plan) by an Insider (or an Affiliated Person) who is required to file reports under Section 16 of the Exchange Act must be reported to the Compliance Officer by the Insider or their brokerage firm on the same day on which a trade order is placed or such a transaction otherwise is entered into. The report shall include the date of the transaction, quantity of shares, the price, the name of the broker-dealer that effected the transaction and whether the trade was made pursuant to a valid Rule 10b5-1 Plan (as defined below). This reporting requirement may be satisfied by providing (or having the Insider's broker provide) a trade order confirmation to the Compliance Officer if the Compliance Officer receives such information by the required date. Compliance by directors and executive officers with this provision is imperative given the requirement of Section 16 of the Exchange Act that these persons generally report changes in ownership of Company securities within two (2) business days. The sanctions for noncompliance with this reporting deadline include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

C. Exemptions

1. Pre-Approved Rule 10b5-1 Plan.

Transactions made pursuant to an approved Rule 10b5-1 Plan (as defined below) will not be subject to our Blackout Periods, Special Closed Windows, retirement plan blackout periods or pre-clearance procedures and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5- 1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet specified requirements. A trading plan, arrangement or instruction that meets the requirements of the SEC's Rule 10b5-1 (a "<u>Rule 10b5-1 Plan</u>") enables Insiders to trade in Company securities during our Blackout Periods or Special Closed Windows, even when in possession of material nonpublic information.

The Company has adopted a separate Rule 10b5-1 Trading Plan Policy that sets forth the requirements for putting in place a Rule 10b5-1 Plan with respect to Company securities.

2. Employee Equity and Retirement Plans.

Exercise of Stock Options. The trading prohibitions and restrictions set forth in the Trading Proceduresdo not apply to the exercise for cash of an option to purchase securities of the Company. However, the exercise is subject to the current reporting requirements of Section 16 of the Exchange Act and, therefore, Insiders must comply with the post-trade reporting requirement described in Section C above for any such transaction. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures. Moreover, the Trading Procedures apply to the use of outstanding Company securities to pay part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding and any sale of stock as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Tax Withholding on Restricted Stock/Units. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy tax withholding requirements if (a) withholding is required by the applicable plan or award agreement or (b) the election to exercise the tax withholding right was made by the Insider in compliance with the Trading Procedures.

Employee Stock Purchase Plan. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to periodic wage withholding contributions by the Company or its employees that are used to purchase Company stock pursuant to the employees' advance instructions under the Company's 2022 Omnibus Incentive Plan. However, an Insider may not: (a) elect to participate in the plan or alter their instructions regarding the level of withholding or purchase by the Insider of Company securities under the plan; or (b) make cash contributions to the plan (other than through periodic wage withholding) without complying with the Trading Procedures. Any sale of securities acquired under the plan is subject to the prohibitions and restrictions of the Trading Procedures. In addition, the Company has the right to impose a company-wide Blackout Period that could restrict all participation in any employee stock purchase plan.

Retirement Plan. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to purchases of Company securities in the 401(k) Savings Retirement Plan (the "Retirement Plan") resulting from periodic contributions by Insiders to the Retirement Plan pursuant to payroll deduction elections. Such prohibitions and restrictions do apply, however, to some elections Insiders may make under the Retirement Plan, including an election (a) to increase or decrease the percentage of periodic contributions to be allocated to the Company stock fund; (b) to make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (c) to borrow money against or receive a distribution from their Retirement Plan account if the loan or distribution will result in a liquidation of some or all of their Company stock fund balance; and (d) to pre-pay a plan loan if the pre-payment will result in an allocation of loan proceeds to the Company stock fund.

D. Waivers

A waiver of any provision of this Insider Trading Policy or the Trading Procedures may be authorized in writing by the Compliance Officer and by the Chief Executive Officer if the waiver is for the Chief Financial Officer. All waivers shall be reported to the Board of Directors.

PART III. AMENDMENT

This Insider Trading Policy may be amended from time to time with the approval of the Board of Directors or a designated committee thereof.

PART IV. ACKNOWLEDGEMENT

We will deliver a copy of this Insider Trading Policy to all current employees and directors and to future employees and directors at the start of their employment or relationship with the Company. To the extent the Compliance Officer determines that consultants and/or contractors will have access to material nonpublic information, we will deliver a copy of this Insider Trading Policy to such individuals. Each of these individuals must acknowledge that they have received a copy and agree to comply with the terms of this Insider Trading Policy, and, if applicable, the Trading Procedures contained herein. The attached acknowledgment, in form provided in Exhibit B, must be completed and submitted to the Company within ten (10) days of receipt. From time to time, the recipients of this Insider Trading Policy may be required to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications thereto).

* * *

Questions regarding this Insider Trading Policy are encouraged and may be directed to the Compliance Officer.

EXHIBIT A

STOCK TRANSACTION REQUEST

Pursuant to Vivani Medical, Inc.'s Insider Trading Policy, I hereby notify Vivani Medical, Inc. (the "Company") of my intent to trade the securities of the Company as indicated below:

REQUESTER INFORMATION

Insider's Name: ________________________

INTENT TO PURCHASE

Number of shares (up to or not to exceed)________________________

Intended trade date(s): ____________________

Means of acquiring

☐ Acquisition through employee benefit plan e.g. Stock Options (please shares: specify):

____

☐ Purchase through a broker on the open market

☐ Other (please specify): _______

INTENT TO SELL

Number of shares (up to or not to exceed):___________________________

Intended trade date(s): ___________________________

Means of selling

☐ Sale through employee benefit plan e.g. Stock Options (please specify): shares:

____

☐ Sale through a broker on the open market

☐ Other (please specify): ______________________________________

RULE 144 (Not applicable if transaction requested involves a purchase)

SECTION 16

☐ I am not subject to Section 16.

☐ To the best of my knowledge, I have not (and am not deemed to have) engaged in an opposite way transaction within the previous 6 months that was not exempt from Section 16(b) of the Exchange Act.

☐ None of the above.

☐ I am not an "affiliate" of the Company and the transaction requested above does not involve the sale of "restricted securities" (as those terms are defined in Rule 144 under the Securities Act of 1933, as amended).

☐ To the best of my knowledge, the transaction requested above will meet all of the applicable conditions of Rule 144.

☐ The transaction requested will be made pursuant to an effective registration statement covering such transaction.

☐ None of the above.

CERTIFICATION

I hereby certify that I am not (1) in possession of any material nonpublic information concerning the Company, as defined in the Company's Insider Trading Policy and (2) purchasing any securities of the Company on margin in contravention of the Company's Trading Procedures. I understand that, if I trade while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties and may be subject to discipline by the Company including termination of my employment.

____________________ ____________________

Insider's Signature Date

APPROVAL

____________________ ____________________

Signature of Compliance Officer (or designee) Date

**NOTE: Multiple lots must be listed on separate forms or broken out.*

EXHIBIT B

ACKNOWLEDGEMENT

I hereby acknowledge that I have read, that I understand, and that I agree to comply with the Insider Trading Policy of Vivani Medical, Inc. (the "Company"). I further acknowledge and agree that I am responsiblefor ensuring compliance with the Insider Trading Policy and the Trading Procedures by all of my "Affiliated Persons." I also understand and agree that I will be subject to sanctions, including termination of employment, that may be imposed by the Company, in its sole discretion, for violation of the Insider Trading Policy, and that the Company may give stop-transfer and other instructions to the Company's transfer agent or any brokerage firm managing the Company's equity incentive plan(s) against the transfer of any Company securities that the Company considers to be in contravention of the Insider Trading Policy.

This acknowledgement constitutes consent for the Company to impose sanctions for violation of the Insider Trading Policy, including the Trading Procedures, and to issue any stop-transfer orders to the Company's transfer agent that the Company, in its sole discretion, deems appropriate toensure compliance.

Date: _______________ Signature: ______________________

Name: ______________________

Title: ______________________

Send signed Acknowledgement to :

Brigid Makes
Chief Financial Officer
Vivani Medical, Inc.
1350 S. Loop Road
Alameda, CA, 94502

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (333-255267 and 333-278869) and Form S-8 (No. 333-267271) of our report dated March 30, 2025, relating to the consolidated financial statements of Vivani Medical, Inc. as of and for the years ended December 31, 2024 and 2023, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP

March 30, 2025
Walnut Creek, California

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam Mendelsohn, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Vivani Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

/s/ Adam Mendelsohn
Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brigid A. Makes, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vivani Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

/s/ Brigid A. Makes
Brigid A. Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), Adam Mendelsohn, Chief Executive Officer (Principal Executive Officer) and Brigid A. Makes, Chief Financial Officer (Principal Financial and Accounting Officer) of Vivani Medical, Inc. (the "Company"), each hereby certifies that, to the best of his knowledge:

1. The Annual Report of the Company on Form 10-K (the "Report") for the fiscal year ended December 31, 2024, to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2025

/s/ Adam Mendelsohn
Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2025

/s/ Brigid A. Makes
Brigid A. Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.9

SHARE PURCHASE AGREEMENT

This Share Purchase Agreement (this "Agreement") is dated as of November 8, 2024 (the "Execution Date"), by and between Vivani Medical, Inc., a Delaware corporation (the "Company") and Gregg Williams (the "Purchaser"). The Company and the Purchaser are each hereafter referred to individually as a 'Party" and together as the "Parties."

RECITALS

WHEREAS, subject to the terms and conditions set forth in this Agreement, the Company desires to issue and sell to the Purchaser, and the Purchaser desires to purchase from the Company, shares of the Company's Common Stock (as defined below) at the Per Share Purchase Price (as defined below).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and the Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Affiliate" means, with respect to any Person, any entity that, at the relevant time (whether as of the Execution Date or thereafter), directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person, for so long as such control exists. For purposes of this definition, "control" means (a) to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) direct or indirect ownership of fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction) or more of the voting share capital or other equity interest in such entity.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed.

"Closing" means the closing of the purchase and sale of the Shares pursuant to Section 2.1.

"Closing Date" means the Business Day on which all of this Agreement has been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchaser's obligations to pay the Purchase Amount and (ii) the Company's obligations to deliver the Shares, in each case, have been satisfied or waived, but in no event later than the second (2^{nd}) Business Day following the date hereof.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Disposition" or "Dispose of" means (a) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any Common Stock, or any options, warrants or other securities or rights convertible into or exercisable or exchangeable for Common Stock, including, without limitation, any "short sale" or similar arrangement, or (b) swap, hedge, derivative instrument or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Governmental Authority" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, and any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Material Adverse Effect" means any change, event or occurrence that, individually or in the aggregate with any other changes, events or circumstances, has had or would reasonably be expected to have (a) a material adverse effect on the business, financial condition, assets or results of operations of the Company or its subsidiaries, taken as a whole, or (b) a material adverse effect on the Company's ability to perform its obligations hereunder or consummate the transactions contemplated hereby; provided, however, that in no event shall any of the following occurring after the date hereof, alone or in combination, be deemed to constitute, or be taken into account in determining whether a Material Adverse Effect has occurred: (i) changes in the Company's industry generally or in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (ii) any change, event or occurrence caused by the announcement or pendency of the transactions contemplated hereby (iii) the performance of this Agreement and the transactions contemplated hereby, or any action taken or omitted to be taken by the Company at the request or with the prior consent of the Purchaser, (iv) changes in general legal, regulatory, political, economic or business conditions occurring after the date hereof that, in each case, generally affect the biotechnology or biopharmaceutical industries, (v) acts of war, sabotage or terrorism occurring after the date hereof, or any escalation or worsening of any such acts of war, sabotage or terrorism, or (vi) earthquakes, hurricanes, floods or other natural disasters occurring after the date hereof; provided, however, that with respect to clauses (i), (iv), (v) and (vi), such effects, alone or in combination, may be deemed to constitute, or be taken intoaccount in determining whether a Material Adverse Effect has occurred, but only to the extent such effects disproportionately affect the Company compared to other companies in the biotechnology or biopharmaceutical industries.

"Material Contract" means all contracts, agreements, indentures, bonds, loans, leases, subleases, licenses, sublicenses, instruments, notes and arrangements in effect as of the Execution Date that are required to be filed as exhibits to the Company's annual report on Form 10-K filed with the Commission.

"Nasdaq" shall mean the Nasdaq Capital Market, LLC.

"Permitted Transferee" means an Affiliate of the Purchaser; provided, however, that no such Person shall be deemed a Permitted Transferee for any purpose under this Agreement unless:

(a) the Permitted Transferee shall have agreed in writing to be subject to and bound by the terms of this Agreement as though it were "the Purchaser" hereunder, and (b) the Purchaser acknowledges that it continues to be bound by the terms of this Agreement.

"Per Share Purchase Price" shall mean $1.26 per share, which is the lower of the Company's closing price of the Company's Common Stock on the Nasdaq or the 5-day average closing price of the Company's Common Stock on the Nasdaq, each immediately prior to the Closing Date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

"Purchase Amount" means, as to the Purchaser, the aggregate amount to be paid for Shares purchased hereunder in United States dollars and in immediately available funds.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Shares" means the shares of Common Stock issued or issuable to the Purchaser pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

"Subsidiary" means any subsidiary of the Company which shall include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Third Party Tender/Exchange Offer" means any tender or exchange offer made to all of the holders of Common Stock by a Third Party (other than a Third Party acting on behalf of or as part of a group or in concert with the Purchaser).

"Third Party" means any Person other than the Purchaser or the Company (or its respective Affiliates).

"Transfer Agent" means VStock Transfer, LLC, the current transfer agent of the Company, with a mailing address of 18 Lafayette Place, Woodmere, NY 11598, and any successor transfer agent of the Company.

ARTICLE II.
PURCHASE AND SALE OF SHARES

2.1 Purchase of Shares. Subject to the terms and conditions of this Agreement, at the Closing, the Company will issue and sell to the Purchaser and the Purchaser will purchase from the Company, an aggregate of 3,968,253 Shares issued and sold hereunder at the Per Share Purchase Price.

2.2 Payment. At the Closing, the Purchaser will pay the total Purchase Amount of $4,999,998.78 by wire transfer or electronic funds transfer of immediately available funds to an account designated by the Company, which account the Company shall designate to the Purchaser no less than one (1) Business Day prior to the Closing Date (or on such later date as may be permitted by the Purchaser).

2.3 Closing. On the Closing Date, subject to the satisfaction or waiver of the conditions for Closing herein, the Closing shall occur, at such time as is mutually agreed by the Parties, remotely via the exchange of documents and signatures by the Parties. At the Closing, subject to receipt by the Company of the Purchase Amount from the Purchaser as contemplated by Section 2.2, the Company shall instruct the Transfer Agent to register the Shares in book-entry in the name of the Purchaser, and the Company shall cause the Transfer Agent to deliver written confirmation of the book-entry delivery of the Shares to the Purchaser.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company hereby makes the following representations and warranties to the Purchaser:

(a) Private Sale. Subject to the accuracy of the representations and warranties made by the Purchaser in Section 3.2, the Shares will be issued and sold to the Purchaser in compliance with applicable exemptions from the registration and prospectus delivery requirements of the Securities Act and the registration and qualification requirements of all applicable securities laws of the states of the United States.

(b) Subsidiaries. All of the direct and indirect subsidiaries of the Company are set forth on the Company's filings with the Commission. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in this Agreement shall be disregarded.

(c) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite corporate power and authority to own or lease and use its properties and assets, to execute and deliver this Agreement, to carry out the provisions of this Agreement and to issue and sell the Shares. True and correct copies of the Company's organizational documents, as amended and in effect on the Effective Date, are filed or incorporated by reference as exhibits to the SEC Reports (defined below).

(d) Authorization; Enforcement. The Company has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Company, its officers, directors or shareholders is necessary for, (a) the authorization, execution and delivery of this Agreement, (b) the authorization of the performance of all obligations of the Company hereunder or thereunder, and (c) the sale, issuance and delivery of the Shares. This Agreement, upon execution and delivery by the Company, assuming due authorization, execution and delivery by the Purchaser, constitutes valid and binding obligations of the Company, enforceable in accordance with their terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights and (ii) general principles of equity that restrict the availability of equitable remedies.

(e) No Conflicts; Government Consents and Permits. (a) The execution, delivery and performance of this Agreement by the Company and the consummation by the Company of the transactions contemplated thereby (including the issuance of the Shares) will not (i) conflict with or result in a violation of any provision of the Company's organizational documents, (ii) result in any encumbrance upon any of the Shares, other than restrictions on resale pursuant to securities laws or as set forth in this Agreement, (iii) materially violate or conflict with, or result in a material breach, default, modification, acceleration of payment or termination under of any provision of, or constitute a default under, any Material Contract, or (iv) result in a material violation of any law, rule, regulation, order, judgment or decree (including United States federal and state securities laws and regulations and regulations of any self-regulatory organizations) applicable to the Company as of the Execution Date.

(f) Issuance of the Shares. When issued, the Shares will be duly and validly issued and, whenpaid for in accordance with this Agreement, will be fully paid and non-assessable, and, when delivered to the Purchaser at the Closing, shall be free and clear of all encumbrances and restrictions including, but not limited to, Liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal, purchase options, call options, subscription rights or other similar rights of shareholders of the Company, except for restrictions on transfer set forth in this Agreement or imposed by applicable securities laws. Assuming the accuracy of the representations and warranties of the Purchaser in this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws of Michigan, the state in which the Purchaser is located. No stop order or suspension of trading of the Common Stock has been imposed by Nasdaq or the SEC and remains in effect..

(g) Capitalization. The capitalization of the Company as of the date hereof is as set forthon the Company's latest Quarterly Report filed with the Commission; provided however, that since the Company's latest Quarterly Report filed with the Commission, the Company has issued certainshares under that certain Open Market Sale Agreement℠ by and between the Company and Jefferies, LLC, dated as of April 22, 2024 in an at-the-market offering. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except as a result of the purchase and sale of the Shares and set forth on the SEC Reports, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Shares will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchaser). There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Shares. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased,redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed prior to the date that this representation is made.

(j) Litigation. Other than as set forth in the SEC Reports, there is no material action, suit, Proceeding or investigation pending (of which the Company has received written notice or otherwise has knowledge) or, to the Company's knowledge, threatened, against the Company or which the Company intends to initiate.

(k) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other Governmental Authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any Governmental Authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(l) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(m) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(n) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(o) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(p) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(q) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977.

(r) Regulation M Compliance. The Company has not, and to its knowledge no one actingon its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale orresale of any of the Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

3.2 Representations and Warranties of the Purchaser. The Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and performance by the Purchaser of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. This Agreement has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. The Purchaser is acquiring the Shares as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Shares. The Purchaser is acquiring the Shares hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Shares, it was, and as of the date hereof it is, it will be an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7), (a)(8), (a)(9), (a)(12), or (a)(13) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

(e) Access to Information. The Purchaser acknowledges that it has had the opportunity to review this Agreement (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering ofthe Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received (written or oral), from the Company or any other Person representing the Company, the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Other than to other Persons party to this Agreement or to the Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(g) Non-Public Information. The Purchaser hereby represents that it, nor any other Personacting on its behalf has received or had access to information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto the Purchaser shall have consented in writing to the receipt of such information and agreed in writing with the Company to keep such information confidential.

(h) Investment Purpose; Investment Experience. The Purchaser is purchasing the Shares for its own account and not with a present view toward the public distribution thereof and has no arrangement or understanding with any other Persons regarding the distribution of the Shares. The Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Shares except in accordance with the Securities Act and to the extent permitted by this Agreement. The Purchaser has conducted its own due diligence on the Company to its satisfaction and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

(i) Reliance on Exemptions. The Purchaser has not taken any of the actions set forth in, and is not subject to, the disqualification provisions of Rule 506(d)(1) under the Securities Act and did not learn of the investment in the Shares as a result of any general solicitation or advertising. The Purchaser understands that the Company intends for the Shares to be offered and sold to it in reliance upon specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying upon the truth and accuracy of, and the Purchaser's compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Purchaser set forth herein (including in this Section 3.2(i)) in order to determine the availability of such exemptions and the eligibility of the Purchaser to acquire the Shares.

(j) Governmental Review. The Purchaser understands that no United States federal or state agency or any other Governmental Authority has passed upon or made any recommendation or endorsement of the Shares or an investment therein.

ARTICLE IV.
COVENANTS AND AGREEMENTS OF THE PARTIES

4.1 Market Listing. From the Execution Date through the Closing, the Company shall use best efforts to (a) maintain the listing and trading of the Common Stock on Nasdaq and (b) effect the listing of the Common Stock on Nasdaq.

4.2 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement.

4.3 Transfer or Resale. The Purchaser understands that:

(a) the Shares have not been and are not being registered under the Securities Act or any applicable state securities laws and, consequently, the Purchaser may have to bear the risk of owning the Shares for an indefinite period of time because the Shares may not be transferred unless (i) the resale of the Shares is registered pursuant to an effective registration statement under the Securities Act; (ii) the Purchaser has delivered to the Company an opinion of counsel (in form, substance and scope customary for opinions of counsel in comparable transactions) to the effect that the Shares to be sold or transferred may be sold or transferred pursuant to an exemption from such registration; or (iii) the Shares are sold or transferred pursuant to Rule 144 (provided, that the Purchaser provides the Company with reasonable assurances (including in the form of seller and broker representation letters) that the Shares may be sold pursuant to such rule).

(b) any sale of the Shares made in reliance on Rule 144 may be made only in accordance with the terms of Rule 144 and, if Rule 144 is not applicable, any resale of the Shares under circumstances in which the seller (or the Person through whom the sale is made) may be deemed to be an underwriter (as that term is defined in the Securities Act) may require compliance with some other exemption under the Securities Act.

(c) For as long as the Purchaser or any of its Affiliates beneficially owns any Shares, to the extent it shall be required to do so under the Exchange Act, the Company shall use reasonably best efforts to timely file the reports required to be filed by it under the Exchange Act or the Securities Act (including reports under Sections 13 and 15(d) of the Exchange Act referred to in subparagraph (c)(1) of Rule 144), and shall use reasonable efforts to take such further necessary action as the Purchaser may reasonably request in connection with the removal of any restrictive legend on the Shares being sold, all to the extent required from time to time to enable the Purchaser to sell the Shares without registration under the Securities Act within the limitations of the exemption provided by Rule 144.

4.4 Legends. The Purchaser understands that the Shares will bear restrictive legends in substantially the following form (and a stop-transfer order may be placed against transfer of the Shares):

> THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " SECURITIES ACT"), AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO VIVANI MEDICAL, INC.) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.

If such Shares are transferred pursuant to Section 4.3 of this Agreement, the Purchaser may request that the Company remove, and if so requested, the Company shall agree to authorize and instruct (including by causing any required legal opinion to be provided) the removal of any legend from the Shares, if permitted by applicable securities law, within two (2) Business Days of any such request; provided, however, each Party will be responsible for any fees it incurs in connection with such request and removal; provided, further, that such legends may only be removed (i) in connection with a sale pursuant to the Registration Statement or (ii) in connection with and pursuant to Rule 144 if the Purchaser has held the Shares for more than one (1) year.

4.5 Securities Law Disclosure; Publicity. No public release, public disclosure or announcement concerning the transactions contemplated hereby shall be made by either Party without the consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

4.6 Lockup. During the period commencing on the Closing Date and until the date that is two (2) months after the Closing Date (the "Lockup Period"), without the prior approval of the Company, the Purchaser shall not Dispose of (i) any of the Shares, together with any Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Common Stock described in clause (i) of this sentence (collectively, "Lockup Shares"); provided, however, that the foregoing shall not prohibit (A) the Purchaser from transferring any Lockup Shares to (I) a Permitted Transferee (provided, that the Permitted Transferee agrees to be bound in writing by the restrictions set forth herein), or (II) to the Company; (B) the Disposition of Lockup Shares with the prior written consent of the Company; and (C) the Disposition of Lockup Shares pursuant to a Third Party Tender/Exchange Offer, and any Disposition effected pursuant to any business combination, merger, consolidation or similar transaction consummated by the Company; provided, further, that, in the event the Company enters into any definitive agreement with a Third Party during the Lock-Up Period contemplating (x) a Third Party Tender/Exchange Offer or (y) a business combination, merger, consolidation or similar transaction to which the Company is a constituent corporation, then the restrictions on the Lock-Up Shares automatically shall be terminated and of no further force or effect.

ARTICLE V.
CONDITIONS TO CLOSING

5.1 Mutual Conditions to Closing. The obligations of the Parties to consummate the Closing are subject to the satisfaction or waiver of the following conditions at or prior to the Closing:

(d) Absence of Litigation. No Proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, will have been instituted or be pending before any Governmental Authority.

(e) No Governmental Prohibition. The sale of the Shares by the Company and the purchase of the Shares by the Purchaser will not be prohibited by any applicable law or Governmental Authority.

5.2 Conditions to Obligations of the Company to Close. The Company's obligation to complete the purchase and sale of the Shares and deliver the Shares to the Purchaser is subject to the satisfaction or waiver of the following conditions at or prior to the Closing:

(a) Receipt of Funds. The Company will have received immediately available funds in the full amount of the Purchase Amount for the Shares.

(b) Representations and Warranties. The representations and warranties made by the Purchaser in Section 3.2 will be true and correct as of the Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties will be true and correct as of such other date, except in each case where the failure of such representations and warranties to be so true and correct (without giving effect to any limitation as to "materiality" set forth therein) would not reasonably be expected to have a material adverse effect on the Purchaser's ability to perform its obligations hereunder or consummate the transactions contemplated hereby.

(c) Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Purchaser on or prior to the Closing Date shall have been performed or complied with in all material respects.

5.3 Conditions to the Purchaser's Obligations to Close. The Purchaser's obligation to complete the purchase and sale of the Shares is subject to the satisfaction or waiver of the following conditions at or prior to the Closing:

(a) Representations and Warranties. The representations and warranties made by the Company in Section 3.1 of this Agreement will be true and correct as of the Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties will be true and correct as of such other date, except in each case where the failure of such representations and warranties to be so true and correct (without giving effect to any limitation as to "materiality" set forth therein) would not reasonably be expected to have a Material Adverse Effect on the Company's ability to perform its obligations hereunder or consummate the transactions contemplated hereby.

(b) Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

(c) Nasdaq Matters.

(i) Prior to the Closing, the Company shall have taken all actions that are reasonably necessary, including providing appropriate notice to Nasdaq of the transactions contemplated by this Agreement, for the Shares to be listed on Nasdaq and shall have complied with all listing, reporting, filing and other obligations under the rules of Nasdaq and of the SEC with respect to the matters contemplated by this Agreement.

(ii) The Common Stock shall not have been suspended, as of the Closing Date, by the SEC or Nasdaq from trading on Nasdaq nor shall any such suspension by the SEC or Nasdaq have been threatened, as of the Closing Date, in writing by the SEC or Nasdaq.

(d) No Material Adverse Effect. Since the Execution Date, there shall not have been any change, development, occurrence or event that has had or would reasonably be expected to have a Material Adverse Effect on the Company.

ARTICLE VI.
MISCELLANEOUS

6.1 Termination. This Agreement may be terminated prior to the Closing by:

(a) mutual written consent of the Parties;

(b) either Party, upon written notice to the other, if the Closing does not occur by November 30, 2024 (the "Termination Date"); provided, however, that the right to terminate this Agreement under this Section 6.1(b) shall not be available to any Party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) The Company, upon written notice to the Purchaser, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 5.3(a) or (b), as applicable, could not be satisfied by the Termination Date, (i) upon a breach of any covenant or agreement on the part of the Purchaser set forth in this Agreement or (ii) if any representation or warranty of the Purchaser shall have been or become untrue, in each case such that any of the conditions set forth in Section 5.2(b) or (c), as applicable, could not be satisfied by the Termination Date; and

(d) The Purchaser, upon written notice to the Company, so long as the Purchaser is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 5.2(b) or (c), as applicable, could not be satisfied by the Termination Date, (i) upon a breach of any covenant or agreement on the part of the Company set forth in this Agreement or (ii) if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 5.3(a) or (b), as applicable, could not be satisfied by the Termination Date.

6.2 Fees and Expenses. Except as expressly set forth in this Agreement to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Shares to the Purchaser.

6.3 Entire Agreement. This Agreement, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

6.4 Notices. Any notice required or permitted to be given by this Agreement must be in writing, inEnglish. Any and all notices or other communications or deliveries required or permitted to be provided hereunder must be in writing and will be deemed given and effective if (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered or certified mail; or

(c) delivered by electronic mail, in each case, addressed as set forth on the signature pages attached hereto.

6.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, by the Company and Purchaser. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

6.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

6.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Purchaser (other than by merger). The Purchaser may assign any or all of its rights under this Agreement to any Person to whom the Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of this Agreement that apply to the "Purchaser."

6.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

6.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of this Agreement), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of this Agreement, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such Action or Proceeding shall be reimbursed by the non- prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

6.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Shares.

6.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

6.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

6.13 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchaser and the Company will be entitled to specific performance under this Agreement. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in this Agreement and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

6.14 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise this Agreement and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in this Agreement shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

6.15 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have caused this Share Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

VIVANI MEDICAL, INC.

By: /s/ Adam Mendelsohn
Name: Adam Mendelsohn
Title: Chief Executive Officer
Address: 1350 S. Loop Road, Alameda CA 94502

PURCHASER

By: /s/ Gregg Williams
Name: Gregg Williams
Address: 2000 Centerpoint Parkway Pontiac, MI 48341

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VIVANI MEDICAL, INC.

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PURCHASER

By: /s/ Gregg Williams
Name: Gregg Williams
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