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, 2022

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*)

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

5858 Horton Street, Suite 280 Emeryville, CA 94608
(*Address of principal executive offices, including zip code*)

Registrant's telephone number, including area code: (**818) 833-5000**

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	VANI	NASDAQ
Warrants	VANIW	

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). 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, 2022, computed by reference to the closing sales price on the Nasdaq Capital Market on June 30, 2022, was approximately $57.1 million.

As of March 27, 2023, the registrant had 50,735,770 shares of common stock, no par value per share and 7,680,938 warrants outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for the 2023 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, 2022.

VIVANI MEDICAL, INC.

FORM 10-K

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Below is a summary of the principal risk factors related to the Annual Report on Form 10-K ("10-K") for the fiscal year ended December 31, 2022.

Summary of Risk Factors

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 preclinical-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, and may achieve any of these objectives.
- We intend to utilize the 505(b)(2) pathway for the regulatory approval of NPM-119. Final marketing approval of 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 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.
- From time to time, we expect to release results from preclinical studies and clinical trials. Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results, and initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.
- Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We are subject to a multitude of manufacturing 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 protect our proprietary or licensed technology.
- Claims or lawsuits relating to infringement of intellectual property rights brought by or against us may adversely affect our business, financial condition, and results of operations.
- 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 Annual Report on Form 10-K, or Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Annual Report 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 initiation, timing, design, progress and results of our clinical trials, and our research and development program; and
- 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.

Any forward-looking statements in this Annual Report 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 Annual Report, 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 Annual Report 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 preclinical stage biopharmaceutical company which develops miniaturized, subdermal implants utilizing its proprietary NanoPortal™ technology to enable long-term, 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 US Centers for Disease Control and Prevention (CDC), adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. For example, approximately 50% of patients treated for type 2 diabetes are medication non-adherent, which can lead to poor clinical outcomes. We are developing a portfolio of miniature, sub-dermal 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 6 months or the life of the implant. 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 that produce side effects associated with fluctuating drug levels in the blood.

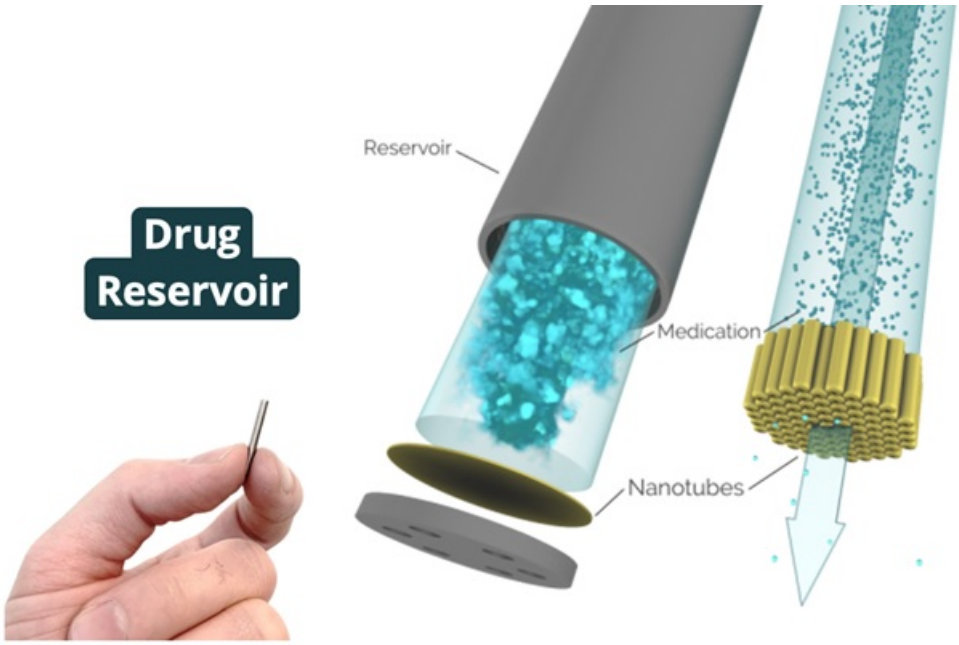
Vivani resulted from the August 2022 business combination of Second Sight Medical Products, Inc. (Second Sight) and Nano Precision Medical, Inc. (NPM). Since inception, Vivani's main priority has been the further development of the Company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes under the Company's Biopharm Division (formerly NPM). In parallel, Vivani's new management team remained committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

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, Inc. ("Cortigent"). Cortigent, currently a wholly-owned subsidiary of Vivani, was formed for the purpose of advancing the business of Vivani's neuromodulation division and is expected to continue to be majority-owned by Vivani immediately following the initial public offering.

Moving forward, Vivani's focus will be on the further development of NPM-119 and its emerging pipeline of innovative miniature, long-term drug implants to treat patients with chronic diseases and high unmet medical need. The origins of this business started while its current Vivani CEO and NPM co-founder Adam Mendelsohn and two of his graduate school colleagues at the University of California, San Francisco (UCSF) and the University of California, Berkeley (UCB), entered business school competitions leveraging their growing knowledge of chemistry, drug delivery, and nanoscale technology to propose the development of new miniature, biocompatible, drug implant prototypes capable of releasing therapeutic drug levels over an extended period of time. Based on their success and encouragement from professors and others, including medical device/pharmaceutical icon Al Mann, Dr. Mendelsohn and colleagues started Nano Precision Medical in 2009 and operations began in 2011 in an incubator on the UCB campus. Today, the company has grown to nearly 40 full-time employees and its current headquarters and operations are located at 5858 Horton Street, Emeryville, California.

Our Proprietary NanoPortal™ Implant Technology

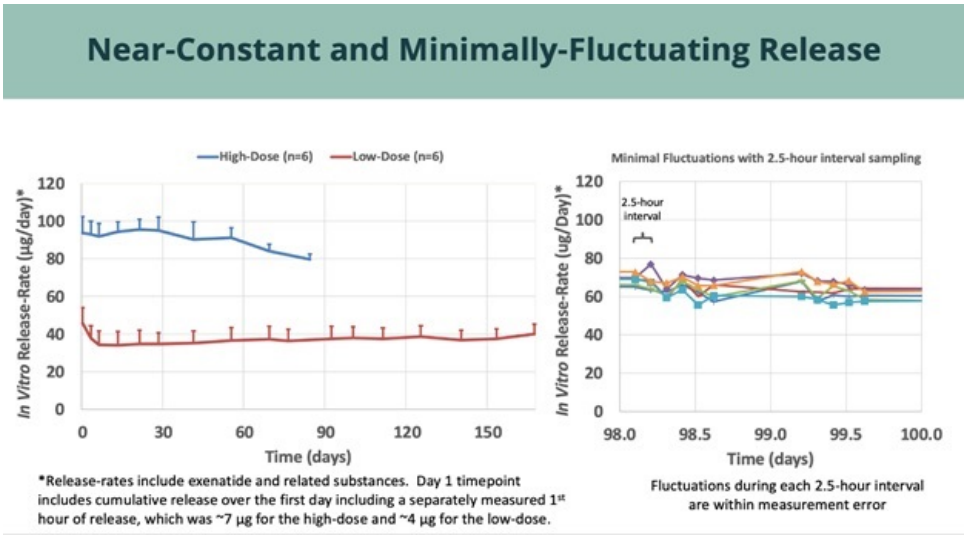
Vivani's implant technology, which we refer to as NanoPortal, utilizes a space-efficient design that allows a miniaturized implant to provide many months of therapeutic delivery of potent molecules. The technology has no moving parts, which is intended to minimize fluctuating drug delivery over the duration 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 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.

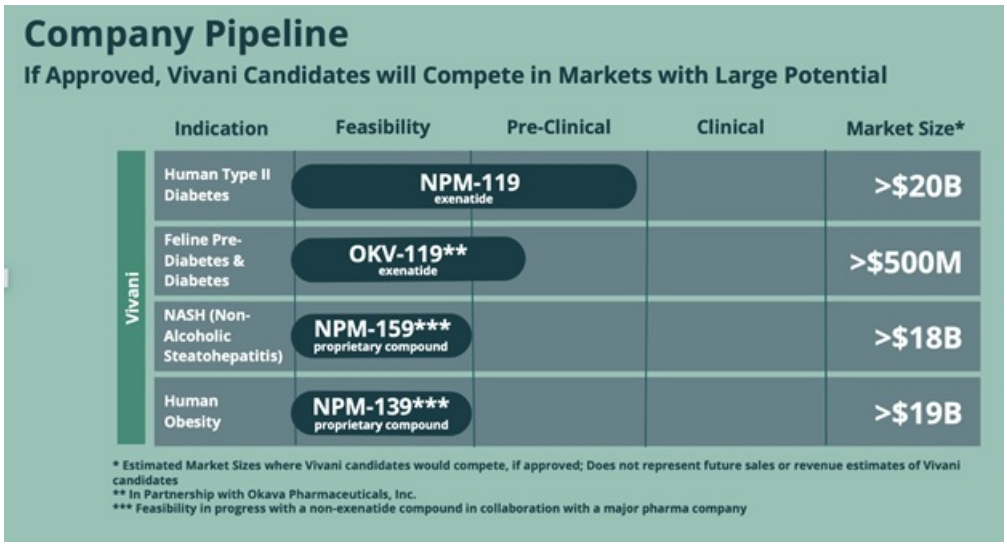
For drug molecules with adequate potency and stability, NanoPortal can allow minimization of the implant size while extending implant duration. A custom delivery profile can also be achieved by adjusting the number of accessible nanotubes, engineering changes to the implant, and/or changes in formulation 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 needs.

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 a separate chart below). 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 for individual device release rates).



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), obesity, and NASH (non-alcoholic steatohepatitis).



Below is a summary description of each pipeline program:

NPM-119: This exenatide implant candidate is in preclinical stage development for the treatment of patients with type 2 diabetes with an anticipated duration of six months. 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, approved in 2005 by the U.S. Food and Drug Administration (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. Byetta was the first GLP-1 to reach the U.S. marketplace.

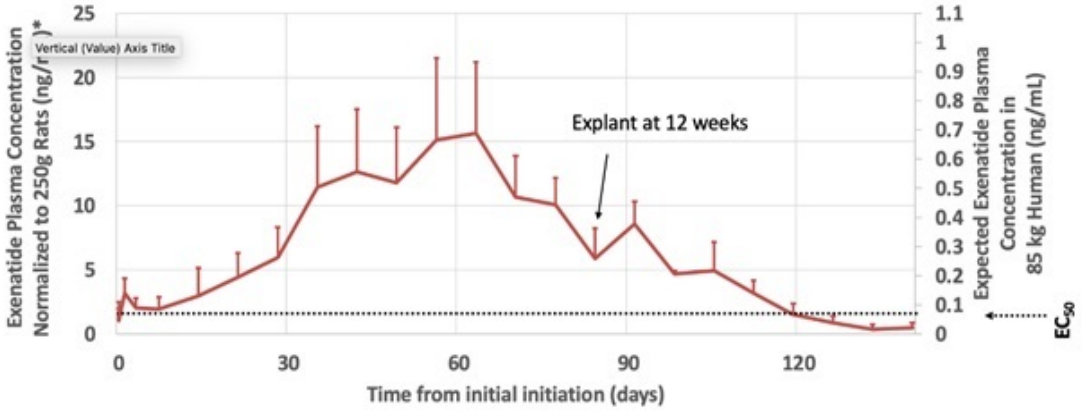
According to the CDC, more than 37 million Americans have diabetes and 90-95% have type 2 diabetes. The total number of people living worldwide with diabetes is projected to rise to 643 million by 2030 and 783 million by 2045. According to the American Diabetes Association (ADA), the total cost of diagnosed diabetes in the U.S. was $327 billion in 2017, including $237 billion for direct medical costs and $90 billion for reduced productivity. In 2022, the global sales of GLP-1 receptor agonists products was nearly $20 billion. 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. Vivani holds all commercial rights to NPM-119.

We believe NPM-119, our lead drug implant candidate, has the potential to address two important limitations of the GLP-1category, namely, poor real-world medication adherence, and a potentially undesirable gastrointestinal tolerability profile.

To address real-world medication adherence, NPM-119 is designed to provide 6 months of steady dosing from a single miniature, subdermal implant. 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. In addition, 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. NPM-119 has the potential to offer a highly differentiated 6-month dosage form to address the medication adherence challenge. Results from a small, third-party market research study funded by Vivani indicate that the majority of physicians will be highly likely to recommend a product with the NPM-119 target product profile to their type 2 diabetes patients. In the 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. These preliminary results are encouraging since 90% of type 2 diabetes patients are treated in a primary care setting.

A well-documented side effect of the GLP-1 class is poor gastrointestinal (GI) tolerability. GI intolerance can present as nausea and vomiting which can lead to volume loss (hypovolemia), 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-1class. In responding to a marketing application filed for Intarcia Therapeutics' 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 that marked increases in the dose of a GLP-1 are responsible for increased risk of GI intolerance. The establishment of marked GLP-1 dose increases being responsible for GI intolerance combined with the daily *in vitro* variability exhibited by ITCA 650 resulted in the FDA summarizing their findings as "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 acute kidney injury (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* on time scales that are even shorter than a day as exhibited by the 2.5-hour *in vitro* release rates that are shown in the 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.

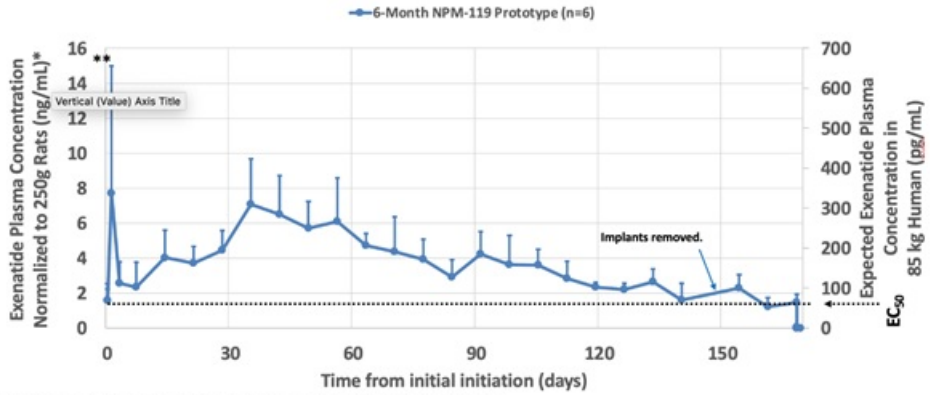
An investigational new drug application (IND) to support the initiation of clinical studies with NPM-119 is planned for submission in 2023. Vivani's initial clinical study, called LIBERATE-1, is designed as a 12-week, randomized, Phase 2 clinical study to investigate the safety, tolerability and full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes. The study will include a Bydureon BCise® (exenatide extended-release injectable suspension) comparator, will investigate glycemic control as a secondary endpoint, and will also evaluate changes in weight. The study will recruit patients on a non-exenatide GLP-1 therapy which will be discontinued prior to randomization. Conditional institutional review board (IRB) approval has been obtained pending IND clearance. The LIBERATE-1 study design was discussed in multiple FDA interactions and is planned to initiate in mid-2023, subject to IND clearance. The pharmacokinetic profile obtained in a preclinical study with the NPM-119 configuration (n=8) intended for use in LIBERATE-1 is provided in the graphic below. The left axis shows experimentally measured exenatide plasma concentrations from rats implanted with NPM-119. The right axis shows expected exenatide plasma concentrations in humans, assuming there are no NPM-119 specific translation effects, based on previously established clearance rate differences between rats and humans when exposed to steady state delivery of exenatide. Since the EC_{50} (concentration of exenatide which provides half maximal response) is 0.0835 ng/mL, this pharmacokinetic profile is expected to provide therapeutic exposure levels of exenatide in humans unless, for example, there are any device-specific pharmacokinetic translation effects from rats to humans which the results of LIBERATE-1 will determine.



*Exenatide antibody-positive animals are not included in this data set.

Vivani has also made progress towards preparing for future clinical development of NPM-119. In the second half of 2023, Vivani is planning to relocate 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 pursue 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 U.S. That said, throughout the NPM-119 development process, we also 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 pre-clinical 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.



* Exenatide antibody-positive animals are not included in this data set.
**2 of 6 implants are responsible for higher Day 1 exenatide concentrations. Additional optimization ongoing to yield consistent gradual initial PK profiles.

In addition to the NPM-119 program targeting the treatment of patients with type 2 diabetes, Vivani believes that the results of LIBERATE-1, if favorable, could support the further exploration of NPM-119 for obesity with a higher dose configuration. This would be similar to the strategy Novo Nordisk has taken with its semaglutide injection franchise, Ozempic® and Wegovy® for type 2 diabetes and obesity, respectively.

OKV-119: This exenatide implant is under development for the treatment of obese and diabetic companion cats. In 2017, there were over 90 million cats in the U.S. 20-30 million cats have obesity, and 2-4 million cats have diabetes. Over $100 billion is spent on pets in the U.S. each year, this spending is expected to triple over the next 10 years, and pet health is the fastest-growing sub-segment of this market. Since cats are difficult to medicate, we believe that a small subdermal implant administered by a veterinarian can be a welcome option for many pet owners, if approved.

The program is partnered with Okava Pharmaceuticals, Inc. (“Okava”) who is responsible for management and funding of the 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 in vivo data demonstrating a configuration that provided adequate exenatide exposure to companion felines over a 12-week duration. Vivani does not anticipate any significant Vivani focus beyond the support of product development and manufacturing activities.

NPM-139 : This implant candidate is in feasibility testing for the treatment of patients with obesity. The undisclosed compound, is the proprietary molecule of a large pharmaceutical company with whom we have entered into a material transfer agreement to conduct feasibility studies. The undisclosed compound is the drug substance in an approved product which is marketed in the U.S. for the treatment of obesity. Although the initial target product profile is under development as a six-month implant, we believe this product candidate has the potential for once-yearly administration based on preliminary results of feasibility testing to date.

The market for GLP-1 therapy in the treatment of patients with obesity is also attractive and growing rapidly. As an example, Novo Nordisk's Wegovy® (semaglutide injection) sold $336M in the fourth quarter of 2022, which represents a 111% increase quarter-over-quarter from the third quarter of 2022.

NPM-159 : This potential six-month implant candidate is in feasibility testing for the treatment of patients with non-alcoholic steatohepatitis (NASH). The undisclosed compound is the proprietary molecule of a large pharmaceutical company with whom we have entered into a material transfer agreement to conduct feasibility studies. The undisclosed compound is in a drug class that has already demonstrated, in clinical trials by a third party, signals of clinical activity for the treatment of NASH, and multiple product candidates based on that drug class are currently under development in the U.S.

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 NASH 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. Vivani develops miniaturized 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.

Vivani plans to initially test its technology and business model through the clinical and regulatory development of its lead program, NPM-119 (exenatide implant). The active drug, exenatide, is a member 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 drug treatment categories. In addition, GLP-1 receptor agonists have shown promising early clinical results in NASH and they are being evaluated in other therapeutic areas including Alzheimer's disease. Vivani intends to complete IND-enabling studies and submit an IND to permit a first-in-human (FIH) study of NPM-119 in type 2 diabetes in 2023. In addition, Vivani intends to advance its early-stage programs in obesity and NASH with two undisclosed collaborations with global pharmaceutical companies. Its business strategy includes:

- Announcing top-line results from LIBERATE-1 in the first half of 2024;
- Utilizing the 505(b)(2) abbreviated approval pathway for NPM-119 and, where applicable, for other programs whenever feasible;
- Advancing the feasibility assessments for NPM-139 and NPM-159 in 2023;
- Developing manufacturing capabilities and systems to produce materials for a future clinical development of our product candidates;
- Maintaining, expanding, and protecting its intellectual property portfolio;

- Seeking regulatory approvals for any product candidates that successfully complete clinical trials; and
- Adding operational, financial, and management information systems and personnel, including personnel to support its planned product development and commercialization efforts, as well as to support its regulatory responsibilities as a public reporting company.

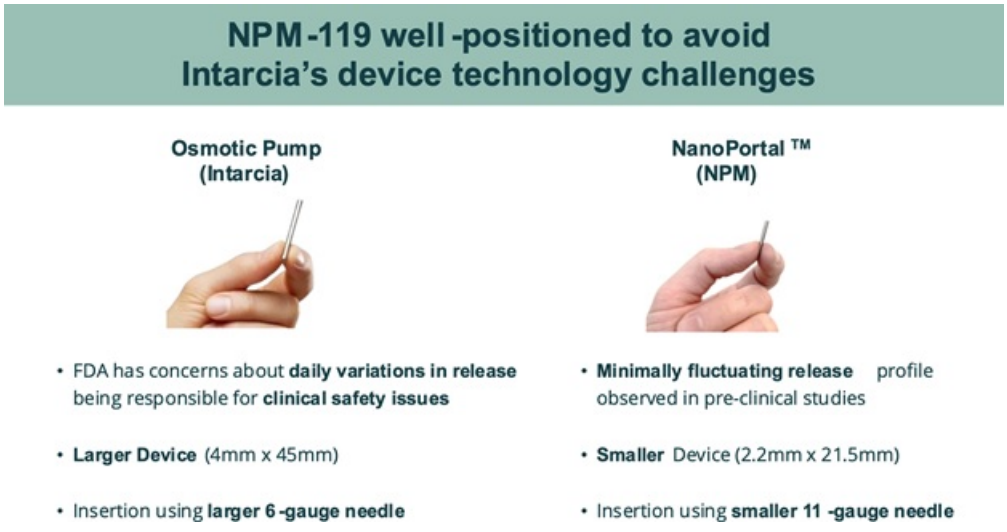
Competition

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 asset, NPM-119, the competition could be defined as any drug product/manufacturer approved for use in the treatment of patients with type 2 diabetes. However, we believe that our more direct competitors comprise other GLP-1 receptor agonist and combination products with a GLP-1 receptor agonist component approved or in development for type 2 diabetes only. 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. Manufacturers with approved GLP-1 receptor agonists include Lilly, Novo Nordisk, AstraZeneca, and Sanofi.

In addition to the marketed GLP-1 products, Intarcia Therapeutics has continued to seek approval of ITCA 650 (six-month exenatide implant) for the treatment of patients with type 2 diabetes since 2016. In public correspondence, FDA asserted that the ITCA 650 NDA did not meet criteria for approval because (i) data submitted in the application do not show that the product would be safe under the proposed conditions of use and (ii) the methods used in, and the facilities and controls used for, the manufacture, processing, or packing of the product are not shown to be adequate to preserve its identity, strength, quality, and purity. Further correspondence disclosed additional deficiencies which included, but were not limited to, data that did not demonstrate adequate device reliability in regard to dose delivery. While the ultimate fate of ITCA 650 remains unclear from a regulatory approval perspective, the information provided by FDA and Intarcia, informs our development path and regulatory strategy. In addition, the support for a six-month exenatide implant provided by patients, physicians, key opinion leaders and the American Diabetes Association provides confidence for the NPM-119 opportunity.

We believe the challenges experienced by ITCA 650 may have been related to Intarcia's proprietary implant technology. The potential differentiation between Intarcia's DUROS (osmotic pump) implant technology and Vivani's NanoPortal (no moving parts) implant technology could be a key differentiator based on recent FDA correspondence. In addition, Vivani's NanoPortal technology should also allow for a much smaller size implant and corresponding needle gauge, which may facilitate easier insertion and removal of NPM-119 compared to ITCA 650. Although no head-to-head clinical studies of NPM-119 and ITCA 650 have been conducted, there are differences in the underlying delivery technology between these two drug/device combination candidates, which may result in different release profiles, as depicted below:



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™/ GIP and dulaglutide dual agonist)
- Novo Nordisk (Victoza®/liraglutide); (Ozempic®/semaglutide); and (Rybelsus®/semaglutide)
- AstraZeneca (Bydureon BCise®/exenatide); and (Byetta®/exenatide)
- Sanofi (Adlyxin®/lixisenatide)

We believe NPM-119, our lead drug implant candidate, has the potential to address two important aspects of the GLP-1category which are associated with the above-mentioned products, namely, poor real-world medication adherence and potential undesirable gastrointestinal tolerability.

NPM-139

NPM-139 (undisclosed active pharmaceutical ingredient) is in feasibility testing for the treatment of patients with obesity. According to the World Obesity Atlas 2022, one billion adults globally will have obesity (BMI ≥30 kg/m2), or about 18% of the adult population, by 2030. In addition, it is expected that there will be 103 million children and 150 million adolescents living with obesity by 2030 as well.

Competition in the treatment of obesity includes the following:

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

NPM-159

NPM-159 (undisclosed active pharmaceutical ingredient) is in feasibility testing for the treatment of non-alcoholic steatohepatitis (NASH). According to the American Liver Foundation, approximately 5% of the U.S. adult population have NASH. About 20% of the U.S. adult population have non-alcoholic fatty liver disease (NAFLD). NASH is the more severe form of NAFLD in which patients have hepatitis or swelling or inflammation of the liver and liver cell damage.

There are no currently approved drugs for the treatment of NASH. Although the active drug in NPM-159 is undisclosed, there is encouraging preliminary clinical data from another member in this class of drugs.

Sales and Marketing

Vivani currently does not have a commercial infrastructure in any geography. As we progress our programs through development, we may build a commercial infrastructure in the United States and 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 was incorporated under the laws of California on December 17, 2009. Its operations began in 2010. Vivani's corporate office is located at 5858 Horton St. #280, Emeryville, California, 94608; its telephone number is (415) 506-8462; and its website is located at www.vivani.com. In November 2022, Vivani signed a long-term lease for a new facility 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. We plan to initiate our move into the new facility in September 2023 and have it completed by the end of 2023.

Chemistry, Manufacturing, and Controls

Vivani has developed production processes and quality systems to support the manufacture of NPM-119 clinical materials for use in the currently planned first-in-human (LIBERATE-1) clinical study. A small number of processes are continuing to be refined prior to the production of the materials to be used in the study. In addition, efforts have also been initiated to support potential subsequent clinical investigations .

Vivani has established in-house research, development, and manufacturing capabilities in its corporate headquarters in Emeryville, California, U.S. Vivani has also engaged with contract manufacturers and/or analytical laboratories for selected processes when appropriate. In general, Vivani purchases the drug substance from a third-party manufacturer and all assembly processes in which the drug substance is present, including the associated in-process testing, are intended to be performed by contract manufacturers . 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 Emeryville. 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 the NPM-119 program advances, Vivani may also engage with 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 March 27, 2023, Vivani held or controlled 14 issued U.S. patents, 8 pending U.S. patent applications, and 12 patents in various jurisdictions outside the United States. Additionally, Vivani is pursuing 22 corresponding patent applications that are pending in various foreign jurisdictions. 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 Australia, China, Germany, India, Japan, Netherlands, New Zealand, Republic of Korea, Russia 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:

- 14 patents issued in the United States (U.S. Patent Nos. 7,687,431, 9,814,867, 9,770,412, 10,479,868, 11,021,576, 10,045,943, 10,688,056, 9,511,212, 10,105,523, 10,792,481, 10,525,248, 11,129,791, 11,191,935 and 11,191,935) and 12 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 2024-2035;
- 4 patents issued in the United States (U.S. Patent Nos. 9,511,212, 10,792,481, 11,129,791 and 11,478,430), which are also directed to implantable drug delivery devices. These U.S. patents relate to exenatide and are expected to expire in 2035 and 2037;
- 3 patents issued in the United States (U.S. Patent Nos. 10,525,248, 10,105,523 and 11,191,935), which 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 2036 and 2038;
- 5 patents issued in the United States (U.S. Patent Nos. 10,479,868, 11,021,576, 10,045,943, 10,688,056 and 11,478,430) and 3 patent issued in a foreign jurisdiction which 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;
- 1 patent issued in the United States (U.S. Patent No. 9,770,412), which 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;
- 1 patent issued in the United States (U.S. Patent No. 9,814,867) and 4 patents issued in foreign jurisdictions, which 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;
- 1 patent issued in the United States (U.S. Patent No. 7,687,431) and 5 patents issued in foreign jurisdictions, which are 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
- 8 pending U.S. applications and 22 applications pending in foreign jurisdictions, which are directed to implantable drug delivery devices, methods to control release, 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 institutional review board (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 even 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 or patients 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. Involves clinical trials 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 that conduct certain clinical trials also are required to register them and post the results of completed 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 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. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. 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 a waiver of some such 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 receipt 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 addition, before approving an NDA, the FDA may also 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 clinical trials, 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 postmarket 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 applicant. NDAs 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 with the product, providing the regulatory authorities with updated safety and efficacy information, and product sampling and distribution requirements in accordance with the Prescription Drug Marketing Act, a part of the FDCA. 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 as the corresponding 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. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. 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 restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. Additionally, 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.

The FDA also may require post-marketing testing, known as Phase 4 testing, a risk evaluation and mitigation strategy (REMS) to assure the safe use of the drug, and 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.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. Alternatively, orphan drug designation may be available if the disease or the condition affects 200,000 or more individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product is the first to receive FDA approval of the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same orphan indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity, which may permit off-label use for the orphan indication. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA for the same orphan indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. 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 alternatively 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, for example 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 agent for the original 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 marketing exclusivity available in the U.S. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a Written Request from 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 that results from the MMA 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 $11,181 and $22,363 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 physician (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;

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.

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.
- 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 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.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, 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 20310. 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.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 the subject to several executive orders of the Biden Administration, including orders that address pharmaceutical pricing. In July 2021, for example, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, the Department of Health and Human Services ("HHS") has released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases, which may adversely affect our profitability. 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.

Properties

Our principal offices and facilities are located at 5858 Horton Street, Emeryville, CA 94608 and 13170 Telfair Avenue, Sylmar CA 91342 and are both leased.

In November 2022, Vivani signed a long-term lease for a new facility 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 plan to initiate our move into the new facility in September 2023 and have it completed by the end of 2023.

On February 1, 2023 our Neuromodulation division entered into a lease agreement, effective March 1, 2023, to sublease office space to replace their existing headquarters, which lease expired March 1, 2023.

Employees

As of December 31, 2022, we had 14 employees in our Neuromodulation division and 36 employees in our Biopharm Division. 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 preclinical-stage company with a limited operating history, and have no products approved for commercial sale.

We are a preclinical-stage biopharmaceutical company. In August 2022, we completed a business combination of Second Sight Medical Products, Inc. (Second Sight) and Nano Precision Medical, Inc. (Nano Precision Medical), 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-119, NPM-159, NPM-139 and OKV-119, which we have partnered with Okava Pharmaceuticals, Inc. All of our product candidates are in early-stage development and none of our product candidates have entered into clinical-stage testing, 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 initiate and conduct 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. For the years ended 2021 and 2022, we reported net losses of $12.8 million and $13.9 million, respectively, and had an accumulated deficit of $72.8 million as of December 31, 2022.

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 U.S. Food and Drug Administration (the "FDA") the European Medicines Agency (the "EMA") or comparable foreign 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 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 its 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 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, the European Medicines Agency (EMA) or other 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 shareholders 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 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, 2022, our parent which comprises the Legacy SSMP business, and our subsidiary, Nano Precision Medical, each had the following carry-forwards available to offset future taxable income and income taxes (in thousands):

	As of December 31, 2022	
	NPM	SSMP
Pre TCJA (Tax Cuts and Jobs Acts of 2017) period federal NOL carry-forward, begin expiring 2030	$ 24,647	$ 29,095
Post TCJA period federal NOL carry-forward, with no carry-forward limitation	33,113	86,412
Total federal NOL carry-forward	$ 57,760	$ 115,508
State NOL carry-forward, begin expiring 2030	$ 66,514	$ 30,439
Federal R&D tax credit carry-forward, begin expiring in 2026	$ 1,586	$ 20
State R&D carry-forward, begin expiring in 2026	$ 1,973	$ 4,989

Since Legacy SSMP and NPM file separate tax returns, the carry-forwards of one filer are not available to offset the taxable income or income taxes of the other filer.

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 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 on the licensing and development of our core assets, including NPM-119 (exenatide implant) in preclinical stage development, NPM-139 and NPM-159 (undisclosed drug molecules) in initial feasibility testing with our proprietary NanoPortal implant technology. To date, we have not commenced clinical testing of any of our product candidates. All of our product candidates will require additional development, including 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 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, the EMA 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, the EMA, and comparable foreign 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.

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, the EMA, or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign 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.

Vivani's 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, the EMA, or comparable foreign 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, or 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 advancing 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 implants 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 (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials;
- 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.

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, the EMA, 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, the EMA or comparable foreign 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;
- the willingness or availability of patients to participate in our trials, including due to any public health crisis such as the COVID-19 pandemic and the emergence of new COVID-19 variants;
- 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 sub-dermal 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 with 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 noncompetitive. 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 (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, the NPM-119 reference drug, did not demonstrate a reduction in cardiovascular morbidity and mortality, NPM-119 will 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, or 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 manufacturing risks, 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, 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-party payors 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 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, the EMA, 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 unless and until clearance is received to conduct clinical investigations under an investigational new drug application (IND) from the FDA or receive similar authorizations 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 not previously filed INDs or NDAs with the FDA or filed similar applications with other foreign regulatory agencies. 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 II 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, the EMA or comparable foreign 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, the EMA or comparable foreign 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, the EMA or comparable foreign 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, the EMA or comparable foreign 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, the EMA or comparable foreign 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, the EMA or comparable foreign 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, the EMA, or a comparable foreign authority 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, the EMA or a comparable foreign authority 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 one or more of our product candidates, including NPM-119 (exenatide implant), we plan to seek regulatory approval in the U.S. by filing an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 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 Bydureon® and/or Bydureon BCise®, AstraZeneca's exenatide extended-release injectable products. 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 intend to utilize the 505(b)(2) pathway for the regulatory approval of NPM-119 and other of our product candidates. Final marketing approval of 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 intend to pursue a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, for the approval of NPM-119 and other of our product candidates, which allows us to rely on existing 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.

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. For example, if we are unable to establish a bridge between our product candidates and the listed drug upon which we rely to demonstrate that such reliance is justified, we may be required to show safety and efficacy through one or more additional clinical trials. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. 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, including NPM-119 which is designed as a GLP-1 implant for treatment of type 2 diabetes, 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. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe. 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 current requirements on good manufacturing practices (cGMP). 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 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. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. 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, the EMA, or comparable foreign 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, the EMA, or comparable foreign 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 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, the EMA or comparable foreign 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. Such enforcement has become more common in the industry. The FDA, the EMA or comparable foreign 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. In August 2011, 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, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including (i) government budget and funding levels, (ii) the ability to hire and retain key personnel and accept the payment of user fees and (iii) statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect its business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, or otherwise impair our interactions with the agency, which could have a material adverse effect on our business.

We may be exposed to product liability, non-clinical and clinical 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 by. 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 do not currently maintain clinical trial liability insurance, although we intend to seek coverage in connection with initiating our first clinical trial of NPM-119. 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 subjects 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 damages, 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 (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 and NPM-159 both deliver active ingredients that are proprietary to another company that have been made available to us for feasibility testing under materials transfer agreements. Similarly, in the future, we may develop one or more additional product candidates that utilize active ingredients that are proprietary to another third party. Our current activities for NPM-139 and NPM-159 are limited to feasibility testing, but if we advance these programs 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 the 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 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 its 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 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, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. 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 approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, 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 following approval.

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 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, good clinical practices (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 Pharmaceuticals, Inc. with respect to OKV-119. In March 2023, we announced that our wholly owned subsidiary Cortigent, Inc., which was created to continue the historical business of Second Sight, has filed a registration statement for a potential initial public offering of common stock. 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 March 29, 2023, our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 33% 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 Medical Products (Second Sight) and Nano Precision Medical (NPM). Since inception, Vivani's main priority has been the further development of the company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes under the company's Biopharm Division (formerly NPM). In parallel, Vivani's new management team remained committed to identifying and exploring strategic options for the Neuromodulation 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, including as a result of the ongoing COVID-19 pandemic and 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 (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, 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, 2022, 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 of 2002, as amended (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, or 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 by the ongoing COVID-19 pandemic or the future outbreak of other highly infectious or contagious diseases.

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 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.

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 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal offices and facilities are located at 5858 Horton Street, Emeryville, CA 94608 and 13170 Telfair Avenue, Sylmar CA 91342.

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 us. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing our 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 our 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 9, 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 judgement, 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. The Company may appeal the decision within three months from the date of service. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022 related to this matter but plans to raise any and all legal challenges to this preliminary judgement.

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 is traded on the Nasdaq Capital Market under the symbol "VANI."

Holders

On March 24, 2023 there were approximately 123 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 Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

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, 2022 and 2021 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, Item 1A of this Form 10-K.

Business Overview

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a preclinical stage biopharmaceutical company which develops miniaturized, subdermal implants utilizing its proprietary NanoPortal™ technology to enable long-term, 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. For example, approximately 50% of patients treated for type 2 diabetes are non-adherent to their medicines, which can lead to poor clinical outcomes. We are developing a portfolio of miniature, sub-dermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing adherence by delivering therapeutic drug levels for up to 6 months or the life of the implant. In addition, the minimal fluctuations of drug levels dictated by our NanoPortal technology may improve the tolerability profiles for medicines that produce side effects associated with fluctuating drug levels.

Vivani resulted from the business combination of Second Sight Medical Products (Second Sight) and Nano Precision Medical (NPM). Since inception, Vivani's main priority has been the further development of the company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes under the company's Biopharm Division (formerly NPM). In parallel, Vivani's new management team remained committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

In February 2022, we announced the signing of a definitive merger agreement between Nano Precision Medical, Inc. ("NPM") and Second Sight Medical Products, Inc. ("Second Sight"), pursuant to which NPM became a wholly-owned subsidiary of Second Sight. On August 30, 2022, the two companies completed the merger, concurrent with which Second Sight changed its name to Vivani Medical, Inc. and now conducts the present business of the Company. In September 2022, we announced the formation of the Company's Biopharm Division to advance the assets of the former NPM which includes the further development of the Company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes. Vivani's new management team remains committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions. On December 28, 2022, the assets and liabilities of this segment were contributed to Cortigent, Inc. a newly formed wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent.

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. Vivani, is expected to continue to be majority-owned by Vivani immediately following the initial public offering.

Funding and Liquidity

Capital Funding

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

Non-Capital Funding

We were awarded a $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.

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 and receipt of grants.

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 estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2024. 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.

Recently Adopted Accounting Standards

We believe that recently issued, but not yet effective, authoritative guidance, if currently adopted, would not have a material impact on our financial statement presentation or disclosures.

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 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 Black-Scholes option pricing model. 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 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 began in November 2014 and supplemented with average historical volatilities of comparable companies in our 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.

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 the some of the cost of our development efforts. We have recorded these grants as reductions to operating expenses.

- Research and development expenses 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 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. We also expect to receive additional grants in the future that will primarily offset research and development costs.

- General and administrative expenses 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. 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, 2022 and 2021

Research and development expense. Research and development expense increased from $11.0 million in 2021 to $14.2 million in 2022, an increase of $3.2 million, or 29%. The increase from the prior year was primarily due to increased use of outside contractors associated with product design, development and manufacturing associated with our products, increased headcount and professional fees, along with inclusion of new neuromodulation division costs.

General and administrative expense. General and administrative expense increased from $2.3 million in 2021 to $7.1 million in 2022, an increase of $4.8 million, or 205%. The increase is related to a provision for a legal claim of $1.7 million and increased accounting and legal costs and other expenses related to our merger of approximately $1.5 million and the general and administrative costs of the neuromodulation division since the merger of $1.1 million.

Net loss. The net loss was $13.9 million in 2022, as compared to $12.8 million in 2021. The $1.1 million increase in net loss from 2021 to 2022 was primarily attributable to a $7.9 million increase in operating expenses offset by a $6.9 million gain on the bargain purchase and increased interest income due to rate increases on cash investments.

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 prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2024. 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.

Working capital was $40.7 million at December 31, 2022, as compared to $0.4 million at December 31, 2021.

Cash Flows from Operating Activities

During 2022, we used $18.8 million of cash in operating activities, consisting primarily of a net loss of $13.9 million, offset by $0.4 million from a net change in operating assets and liabilities and non-cash items including $5.3 million for gain on bargain purchase, depreciation and amortization of property and equipment and stock-based compensation.

During 2021, we used $11.0 million of cash in operating activities, consisting primarily of a net loss of $12.8 million, offset by a $0.4 million net change in operating assets and liabilities and non-cash charges of $1.4 million for depreciation and amortization of property and equipment, stock-based compensation and PPP loan forgiveness.

Cash Flows from Investing Activities

Investing activities in 2022 and 2021 used $0.3 million and $0.6 million, respectively, of cash for the purchase of equipment.

Cash Flows from Financing Activities

Financing activities provided $63.4 million of cash in 2022, including $55.4 million from cash acquired in merger for stock consideration and $8.0 million proceeds from SAFE note.

Financing activities provided $11.6 million of cash in 2021 from the net proceeds from the issuance of common stock and warrants.

Off-Balance Sheet Arrangements

At December 31, 2022, 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. 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, 2022 and 2021, our cash equivalents consisted solely of money market funds deposited at Merrill Lynch and restricted cash as collateral for our lease.

Exchange Rate Sensitivity

In 2022 and 2021, 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, 2022, 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 Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in this Annual Report on Form 10-K in conformity with GAAP.

This Annual Report 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 Rules 13a-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, 2022, 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 Annual Report on 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, 2022 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 constraints 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

None.

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 2023 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 2023 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 2023 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item regarding executive compensation will be included in an amendment to this Form 10-K or in our 2023 Proxy Statement and is incorporated herein by reference.

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 2023 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 2023 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 2023 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	Merger Agreement dated February 4, 2022 (incorporated by reference to the Company'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 the Company's Current Report on Form 8-K filed with the SEC on June 21, 2022).
3.1	Restated Articles of Incorporation of the Registrant as amended (incorporated by reference to Exhibit 3.1 in the Company's Registration Statement on Form S-1 filed with the SEC on September August 12, 2014)
3.1(a)	Restated Articles of Incorporation of the Registrant as amended (incorporated by reference to the registrant's registration statement on Form S-1, file no. 333-198073, originally filed with the Securities and Exchange Commission on August 12, 2014, as amended)
3.2	Amendment to Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 in the Company's Registration Statement on Form S-4 filed with the SEC on September May 13, 2022)
3.3	Second Amendment to Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K filed with the SEC on January 3, 2020)
3.4	Certificate of Amendment, filed August 25, 2022, and effective August 30, 2022 changing the name of the Company to "Vivani Medical, Inc." (incorporated by reference Exhibit 3.1 in the Company's Current Report on Form 8-K filed with the SEC on September 2, 2022)
3.5	Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 in the Company's Registration Statement on Form S-1 filed with the SEC on September August 12, 2014)
4.1	Form of the Registrant's common stock certificate (incorporated by reference to the registrant's registration statement on Form S-1, file no. 333-198073, originally filed with the Securities and Exchange Commission on August 12, 2014, as amended)
4.2	Form of Underwriter's Warrant (incorporated by reference to the registrant's registration statement on Form S-1, file no. 333-198073, originally filed with the Securities and Exchange Commission on August 12, 2014, as amended)
4.3	Form of Warrant Agreement and Form of Warrant Certificate (incorporated by reference to the registrant's registration statement on Form S-1, file no. 333-215463, originally filed with the Securities and Exchange Commission on January 9, 2017, as amended)
4.4	Form of Amendment No.1 to Warrant Agreement (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on February 22, 2019)
4.5	Description of Capital Stock (incorporated by reference to the registrant's Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 14, 2021)
10.1	Form of Lock-Up Agreement (incorporated by reference to the registrant's proxy statement/prospectus on Form S-4, file no. 333-264959, originally filed with the Securities and Exchange Commission on May 13, 2022)
10.2	Non-Employee Director Compensation Policy*
10.3	Transition funding, support and services agreement dated March 23, 2023
10.4	Employment terms- Cortigent CEO
10.5	New Alameda Lease Agreement
10.7	Cost Reimbursement Consortium Research Agreement between Registrant and Doheny Eye Institute (incorporated by reference to the registrant's registration statement on Form S-1, file no. 333-198073, originally filed with the Securities and Exchange Commission on August 12, 2014, as amended)

10.21	Merger Agreement, dated February 4, 2022, between Registrant and Nano Precision Medical, Inc. (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on February 8, 2022)
10.22	SAFE Agreement, dated February 4, 2022, between Registrant and Nano Precision Medical, Inc. (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on February 8, 2022)
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 Second Sight Medical Products, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial and Accounting Officer of Second Sight Medical Products, 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 Second Sight Medical Products, 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

* Filed or furnished herein, as applicable.
\+ Indicates management contract or compensatory plan.

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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, 2023

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 Scott Dunbar as his 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, 2023
/s/ Brigid Makes Brigid Makes	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
* Gregg Williams	Chairman of the Board	March 31, 2023
* Aaron Mendelsohn	Director	March 31, 2023
* Dean Baker	Director	March 31, 2023
* Alexandra Larson	Director	March 31, 2023

* By /s/ Scott Dunbar
Scott Dunbar
Attorney-in-fact

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Vivani Medical, Inc. and Subsidiaries

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, 2022 and 2021 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, 2022, 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, 2022 and 2021, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2022, 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 the Company's 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 Company'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 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 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 31, 2023

VIVANI MEDICAL, INC.
AND SUBSIDIARIES
Consolidated Balance Sheets
(In thousands)

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,076	$ 2,178
Prepaid expenses and other current assets	2,452	291
Total current assets	47,528	2,469
Property and equipment, net	1,182	1,173
Right-of-use asset	779	1,611
Restricted cash	1,366	—
Deposits and other assets	275	200
Total assets	$ 51,130	$ 5,453
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,177	$ 281
Accrued expenses	2,358	895
Litigation accrual	1,675	—
Accrued compensation expense	657	—
Current operating lease liabilities	955	910
Total current liabilities	6,822	2,086
Long term operating lease liabilities	—	902
Total liabilities	6,822	2,988
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 50,736 and 36,803 at December 31, 2022 and December 31, 2021, respectively	109,050	54,649
Additional paid-in capital	8,009	6,713
Accumulated other comprehensive loss	35	—
Accumulated deficit	(72,786)	(58,897)
Total stockholders' equity	44,308	2,465
Total liabilities and stockholders' equity	$ 51,130	$ 5,453

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Years Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development, net of grants	$ 14,169	$ 11,002
General and administrative, net of grants	7,072	2,321
Total operating expenses	21,241	13,323
Loss from operations	(21,241)	(13,323)
Other income	475	550
Gain on bargain purchase	6,877	—
Net loss	$ (13,889)	$ (12,773)
Net loss per common share – basic and diluted	$ (0.36)	$ (0.39)
Weighted average shares outstanding – basic and diluted	38,241	33,092

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss
(In thousands)

	Years Ended December 31,	
	2022	**2021**
Net loss	$ (13,889)	$ (12,773)
Other comprehensive income:		
Foreign currency translation adjustments	35	—
Comprehensive loss	$ (13,854)	$ (12,773)

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2020	32,197	$ 43,029	$ 5,045	$ —	$ (46,124)	$ 1,950
Issuance of shares of common stock and warrants, net of issuance costs	3,684	11,564	—	—	—	11,564
Options exercised	355	24	—	—	—	24
Warrants exercised	627	32	—	—	—	32
Repurchase of common stock	(60)	—	—	—	—	—
Stock-based compensation expense	—	—	1,668	—	—	1,668
Net loss	—	—	—	—	(12,773)	(12,773)
Balance, December 31, 2021	36,803	$ 54,649	$ 6,713	$ —	$ (58,897)	$ 2,465

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2022	36,803	$ 54,649	$ 6,713	$ —	$ (58,897)	$ 2,465
Options and warrants exercised, net of partial shares adjustment	797	16	—	—	—	16
Shares issued for SSMP net assets	13,136	54,385				54,385
Stock-based compensation expense	—	—	1,296	—	—	1,296
Net loss	—	—	—	—	(13,889)	(13,889)
Foreign currency translation adjustment	—	—	—	35	—	35
Balance, December 31, 2022	50,736	$ 109,050	$ 8,009	$ 35	$ (72,786)	$ 44,308

See accompanying notes to consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (13,889)	$ (12,773)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	381	345
Stock-based compensation	1,296	1,668
Gain on bargain purchase	(6,877)	—
PPP loan forgiveness	—	(641)
Non-cash lease expense	(36)	14
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(476)	102
Accounts payable	(1,941)	13
Accrued expenses	2,551	321
Accrued compensation expenses	204	—
Net cash used in operating activities	(18,787)	(10,951)
Cash flows from investing activities:		
Purchases of property and equipment	(338)	(572)
Net cash used in investing activities	(338)	(572)
Cash flows from financing activities:		
Cash acquired in merger for stock consideration	55,374	—
Proceeds from SAFE note	8,000	—
Net proceeds from sale of common stock and exercise of options and warrants	16	11,620
Net cash provided by financing activities	63,390	11,620
Effect of exchange rate changes on cash and cash equivalents	(1)	—
Cash, cash equivalents and restricted cash:		
Net Increase	44,264	97
Balance at beginning of year	2,178	2,081
Balance at end of year	$ 46,442	$ 2,178
Supplemental disclosure of cash flow information;		
Cash paid during the period for:		
Income taxes	$ —	$ 1
Non-cash investing and financing activities:		
Cancellation of SAFE indebtedness in merger	$ 8,000	$ —
Net liabilities acquired in merger for stock consideration	$ 2,112	$ —

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. Organization and Business Operations

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a preclinical stage biopharmaceutical company which develops miniaturized, subdermal implants utilizing its proprietary NanoPortal™ technology to enable long-term, 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. For example, approximately 50% of patients treated for type 2 diabetes are non-adherent to their medicines, which can lead to poor clinical outcomes. We are developing a portfolio of miniature, sub-dermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing adherence by delivering therapeutic drug levels for up to 6 months or the life of the implant. In addition, the minimal fluctuations of drug levels dictated by our NanoPortal technology may improve the tolerability profiles for medicines that produce side effects associated with fluctuating drug levels.

Vivani resulted from the business combination of Second Sight Medical Products (Second Sight) and Nano Precision Medical (NPM). Since inception, Vivani's main priority has been the further development of the company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes under the company's Biopharm Division (formerly NPM). In parallel, Vivani's new management team remained committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

In February 2022, we announced the signing of a definitive merger agreement between Nano Precision Medical, Inc. ("NPM") and Second Sight Medical Products, Inc. ("Second Sight"), pursuant to which NPM became a wholly-owned subsidiary of Second Sight. On August 30, 2022, the two companies completed the merger, concurrent with which Second Sight changed its name to Vivani Medical, Inc. and now conducts the present business of the Company. In September 2022, we announced the formation of the Company's Biopharm Division to advance the assets of the former NPM which includes the further development of the company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes. Vivani's new management team remains committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions. On December 28, 2022, the assets and liabilities of this segment were contributed to Cortigent, Inc. a newly formed wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent.

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. Cortigent is expected to continue to be majority-owned by Vivani immediately following the initial public offering.

Agreement and Plan of Merger with Nano Precision Medical, Inc.

On February 4, 2022, Second Sight Medical Products, Inc. ("Second Sight") entered into an agreement and plan of merger (the "Merger Agreement") with Nano Precision Medical, Inc. ("NPM"). The Merger was approved by the shareholders of Second Sight on July 27, 2022 and closed on August 30, 2022. Upon consummation of the Merger, NPM became a wholly-owned subsidiary of Second Sight. Concurrent with to the Merger, Second Sight changed its name to Vivani Medical, Inc. and changed its trading symbol from EYES to VANI, and trades under the ticker VANI on the NASDAQ market. Certain investors and members of the NPM board of directors are also investors and members of the board of directors of Second Sight.

Under the terms and conditions of the Merger Agreement, the securities of NPM converted into the right to receive shares of Second Sight's common stock representing 77.32% of the total issued and outstanding shares of common stock of Second Sight on a fully converted basis, including, without limitation, giving effect to the conversion of all options, warrants, and any and all other convertible securities assuming net settlement. Second Sight filed a Registration Statement on Form S-4 on May 13, 2022 in connection with the Merger to register the merger shares effective June 24, 2022.

On February 4, 2022, in connection with the Merger, Second Sight and NPM also entered into a Simple Agreement for Future Equity ("SAFE") whereby Second Sight provided to NPM an investment advance of $8 million. The Merger Agreement provided that the SAFE would terminate if the Merger were to be successfully completed. Under the terms of the SAFE, upon successfully completion of the Merger on August 30, 2022, the investment advance was eliminated. Under the accounting for a business combination, the $8 million adjusted the purchase consideration.

The Merger involved a change of control and was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, Second Sight was treated as the "acquired" company for financial reporting purposes with NPM as the acquirer. The assets acquired and liabilities assumed by NPM were recorded at fair value under Accounting Codification Standard ("ASC 805"), *Business* Combinations. Accordingly, on August 30, 2022 (the "Acquisition Date"), NPM (a calendar year-end entity) was deemed to have acquired 100% of the outstanding common shares and voting interest of Second Sight, Medical, Inc. The results of Second Sight's operations have been included in the consolidated financial statements since that date.

The acquisition-date fair value of consideration transferred totaled $54.4 million, which consisted of the fair value of the 13,136 common shares deemed issued to Second Sight shareholders, was determined based on the per share closing price of the Company's common shares on the acquisition date of $4.14.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date (in thousands):

At August 30, 2022

Cash	$	55,374
Property and equipment		99
Prepaid expenses		1,657
Right of use assets		140
Other assets		56
Total identifiable assets acquired		57,326
Current liabilities		(3,913)
Right of use liabilities		(151)
Total liabilities assumed		4,064
Net identifiable assets acquired	$	53,262

The SAFE loan of $8.0 million was cancelled in the Merger which adjusted the fair value of net assets acquired.

The following table summarizes the calculation of the gain on bargain purchase (in thousands):

Total consideration	$	54,385
SAFE loan forgiven		(8,000)
Less net identifiable assets acquired		(53,262)
Gain on bargain purchase	$	6,877

Because NPM purchased 100% of Second Sight and the fair value of identifiable assets acquired and liabilities assumed exceeded the fair value of the consideration, we reassessed the recognition and measurement of identifiable assets acquired and liabilities assumed and concluded that all acquired assets and assumed liabilities were properly recognized and that the valuation procedures and resulting measures were appropriate. As a result, we recognized a gain of $6.9 million.

We recognized $0.7 million of acquisition related costs that were expensed in the twelve months ended December 31, 2022. These costs are included in the consolidated income statement in the line item entitled "General and administrative costs."

Operating expenses of Second Sight included in the consolidated statements of operations from the acquisition date August 30, 2022 to the period ending December 30, 2022 were $2.1 million. Pro forma consolidated net loss as if Second Sight had been included in the consolidated results was $21.7 million for the year ended December 31, 2021, and $28.3 million for the year ended December 31, 2022.

SAFE

On February 4, 2022, in connection with the Merger, Second Sight and NPM also entered into a Simple Agreement for Future Equity ("SAFE") whereby Second Sight provided to NPM an investment advance of $8 million. The agreement provided that the SAFE would terminate if the Merger were to be successfully completed.

Under the terms of the SAFE, upon successfully completion of the Merger on August 30, 2022, the investment advance was eliminated. Under the accounting for a business combination, the $8.0 million adjusted the purchase consideration.

Liquidity and Capital Resources

From inception, our operations have been funded primarily through the sales of our common stock as well as from 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 estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2024. 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 financial statements of the Biopharm Division (formerly NPM) and the Neuromodulation Division (formerly Second Sight including Second Sight Switzerland) each of which is a reporting segment.

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 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. Actual results could differ from those estimates. 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 from those estimates.

Reclassifications

Certain items in prior period financial statements have been reclassified to conform to the presentation in the current period financial statements. Such reclassification did not impact our previously reported net loss or financial position.

Cash, Cash Equivalents and Restricted Cash

We consider all highly liquid investments with a maturity of three 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. Restricted cash of $1.4 million as of December 31, 2022 relates to the lease guarantee requirements of our new lease.

Property and Equipment

Property and equipment are recorded at historical cost less accumulated depreciation and amortization. Improvements are capitalized, while expenditures for maintenance and repairs are charged to expense as incurred. Upon disposal of depreciable property, the appropriate property accounts are reduced by the related costs and accumulated depreciation. The resulting gains and losses are reflected in the consolidated statements of operations.

Depreciation is provided for using the straight-line method in amounts sufficient to relate the cost of assets to operations over their estimated service lives. Leasehold improvements are amortized over the shorter of the life of the asset or the related lease term. Estimated useful lives of the principal classes of assets are as follows:

Lab equipment	5 – 7 years
Computer hardware and software	3 – 7 years
Leasehold improvements	2 – 5 years or the term of the lease, if shorter
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 $0.3 million for the years ended December 31, 2022 and 2021, 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 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 exempt from capitalization 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 $14.2 million, and $11.0 million net of grant revenue, for the years ended December 31, 2022 and 2021, 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 $0.4 million and $0.1 million for the years ended December 31, 2022 and 2021, 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, 2022 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 Risk

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, 2022 include assets amounting to approximately $40,000 relating to our operations in Switzerland. 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 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 Black-Scholes option pricing model. 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 began in November 2014, 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.

Comprehensive Loss

We comply with provisions of FASB ASC 220, *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 ended December 31, 2022 comprehensive loss is the total of net loss and other comprehensive income which, for us, 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, 2022.

Foreign Currency Translation and Transactions

The financial statements and transactions of the subsidiary's operations are reported in the local (functional) currency of Swiss francs (CHF) 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 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.

Product Warranties

Our policy is to warrant all shipped products against defects in materials and workmanship for up to two years by replacing failed parts. We also provide a three-year manufacturer's warranty covering implant failure by providing a functionally-equivalent replacement implant. Accruals for product warranties are estimated based on historical warranty experience and current product performance trends and are recorded at the time revenue is recognized as a component of cost of sales. The warranty liabilities are reduced by material and labor costs used to replace parts over the warranty period in the periods in which the costs are incurred. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary. The warranty liabilities are included in accrued expenses in the consolidated balance sheets and amount to $50,000 at December 31, 2022.

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 common shares 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.

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.

At December 31, 2022, and 2021, 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).

	2022	2021
Shares underlying warrants outstanding	10,311	9,074
Common stock options	5,272	4,542
Total	15,583	13,616

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 CEO, reviews financial information presented for each of our segments. We consider ourselves to have two reporting segments, specifically the Biopharm Division and the Neuromodulation Division. Neither division is revenue producing. The Neuromodulation Division and the Biopharm Division incurred $2.1 million, and $19.1 million respectively in operating expenses. The Neuromodulation Division incurred $1.5 million and the Biopharm Division $12.4 million of the $13.9 million consolidated net loss, inclusive of the $6.9 million gain on bargain purchase. The Neuromodulation Division includes $2.1 million of total assets. The Biopharm Division includes $49.0 million in total assets.

Recently Adopted Accounting Standards

We believe that any recently issued, but not yet effective, authoritative guidance, if currently adopted, would not have a material impact on our financial statement presentation or disclosures.

3. Money Market Funds

Money market funds included in cash equivalents at December 31, 2022 were $44.4 million.

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2022 and 2021 (in thousands).

	Total	Level 1	Level 2	Level 3
December 31, 2022:				
Money market funds	$ 44,417	$ 44,417	$ —	$ —
December 31, 2021:				
Money market funds	$ —	$ —	$ —	$ —

4. **Selected Balance Sheet Detail**

Property and equipment, net of accumulated depreciation and amortization

Property and equipment consisted of the following at December 31, 2022 and 2021 (in thousands):

	2022	2021
Equipment	$ 3,520	$ 3,174
Furniture	10	10
Leasehold improvements	12	12
Computer software	51	8
	3,593	3,204
Accumulated depreciation and amortization	(2,411)	(2,031)
Property and equipment, net	$ 1,182	$ 1,173

Contract Liabilities

Contract liabilities amounted to $335,000 at December 31, 2022 and are included in accrued expenses on the balance sheet.

5. 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 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, 2022 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.

6. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with 50,735,770 issued as of December 31, 2022. In addition, we are authorized to issue 10,000,000 shares of preferred stock with none issued. On August 19, 2022 the Company initiated a reverse stock split of one share for every three shares. All share numbers have been retroactively adjusted for the split. On August 30, 2022, 13,136,362 shares were deemed issued for the merger acquisition.

7. Warrants

NPM, prior to the Merger, 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, are exercisable for one share of common stock and may be exercised on a cashless basis. The warrants qualified for an exception to derivative accounting and, accordingly, their value was not bifurcated from the total purchase price. Warrants outstanding associated with these units totaled 7,747,213 as of December 31, 2022 and are not registered or tradeable.

The other adjustment for 2,563,688 warrants in the table below were outstanding Second Sight warrants exchanged as part of the Merger for Vivani warrants on a like-for-like basis. The warrants are tradeable on the open market. Under accounting standards in a business combination, these warrants were measured at fair value as of the Merger date; however, the warrants were substantially out-of-the-money and were assigned no value.

A summary of warrant activity for the years ended December 31, 2022 and 2021 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, 2020	5,402	$ 3.15	
Issued	3,672	3.15	
Exercised	—		
Forfeited or expired	—		
Warrants outstanding as of December 31, 2021	9,074	$ 3.15	
Issued	—	—	—
Exercised	(1,327)	$ 3,15	
Forfeited or expired	—		
Other adjustment	2,564	$ 35.24	1.46
Warrants outstanding as of December 31, 2022	10,311	$ 11.13	2.31
Warrants exercisable as of December 31, 2022	10,311	$ 11.13	2.31

The warrants outstanding as of December 31, 2022 have no intrinsic value.

8. Employee Benefit Plans

We have a 401(k) Savings Retirement Plan (the "Plan") that covers substantially all full-time employees who meet the Plan's eligibility requirements and provides for an employee elective contribution. The Plan provides for employer matching contributions. Employer contributions are discretionary and determined annually by the Board of Directors. For the years ended December 31, 2022 and 2021, employer contributions to the Plan totaled $0.2 million and $0.2 million, respectively.

9. Stock-Based Compensation

The Company initiated a new Incentive Plan at the time of the Merger. Under the 2022 Omnibus Plan we were authorized to issue options covering up to 20% of the outstanding shares of common stock. The maximum number of shares with respect to which options could be granted was approximately 10,147,000 shares at December 31, 2022, which is offset and reduced by options previously granted under the Plan. 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 plan provides for accelerated vesting if there is a change of control, as defined in the Plan.

We recognized stock-based compensation cost of $1.3 million and $1.7 million during 2022 and 2021, respectively. The calculated value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2022	2021
Risk-free interest rate	3.42% – 4.45%	0.7% – 0.9%
Expected dividend yield	0%	0%
Expected volatility	100%	100%
Expected term	4.25-6.08 years	5-6.08 years

A summary of stock option activity for the years ended December 31, 2022 and 2021 is presented below (in thousands, except per share and contractual life data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Options outstanding at December 31, 2020	5,888	$ 2.95	
Granted	549	3.15	
Exercised	(1,020)	0.67	
Forfeited or expired	(875)	2.82	
Options outstanding at December 31, 2021	4,542	2.89	
Granted	866	2.31	
Exercised	(73)	1.66	
Forfeited or expired	(335)	4.16	
Other adjustment	272	8.70	
Options outstanding, vested and expected to vest at December 31, 2022	5,272	$ 3.07	7.15
Options exercisable at December 31, 2022	3,819	$ 3.24	6.55

The estimated aggregate intrinsic value of stock options exercisable as of December 31, 2022 was $151,000. As of December 31, 2022, there was $2.1 million of total unrecognized compensation cost related to outstanding stock options that will be recognized over a weighted average period of 1.2 years. Other adjustment represents a prior period true-up and Second Sight options exchanged as part of the Merger for Vivani options on a like-for-like basis. Under accounting standards in a business combination, these options were measured at fair value as of the Merger date; however, the options were substantially out-of-the-money and were assigned no value.

The total stock-based compensation recognized for stock-based awards granted in the consolidated statements of operations for the years ended December 31, 2022 and 2021 is as follows (in thousands):

	2022	2021
Research and development	$ 896	$ 1,329
General and administrative	400	339
Total	$ 1,296	$ 1,668

10. Income taxes

As discussed in *Note 1, Business*, 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 (the "Legacy SSMP") since the date of the merger. Further, NPM (the major subsidiary of Vivani) and Legacy SSMP will not elect to consolidate their tax returns for income tax filing purposes. For the purposes of accounting for income taxes under GAAP, the Legacy SSMP tax provision, deferred taxes and liabilities, and various other matters such as net operation loss and R&D carry-forwards have been prepared as if it filed a separate tax return for the period from August 30, 2022 to December 31, 2022.

Due to the net losses in 2022 and 2021, 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, 2022 and 2021 are as follows (in thousands):

	As of December 31, 2022			As of December 31, 2021
	NPM	Legacy SSMP	Combined	NPM
Deferred Tax :				
Accruals/reserves	$ 725	$ 750	$ 1,475	$ 226
Capitalized R&E §174	1,997	459	2,456	
Lease ROU	48	—	48	56
Stock Compensation	1,079	420	1,499	776
Net operating loss	16,775	27,974	44,749	14,194
R&D credit	2,358	3,961	6,319	1,671
Gross Deferred Tax Assets	22,982	33,564	56,546	16,698
Investment in Sub	(1,510)	—	(1,510)	—
Accumulated depreciation/amortization	(150)	(52)	(202)	(120)
Gross deferred tax liabilities	(1,660)	(52)	(1,712)	(120)
Valuation Allowance	(21,322)	(33,512)	(54,834)	(16,804)
Total Deferred Tax Assets, Net	$ —	$ —	$ —	$ —
Change in valuation allowance for the year ended	$ 4,519	$ 461	$ 4,980	$ 4,204

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, 2022					
	NPM		Legacy SSMP		Combined	
Pre-Tax Loss [(a)]	$ (13,889)		$ (1,479)		$ (13,889)	
Federal tax (benefit) at statutory rate	$ (2,916)	21.0%	$ (311)	21.0%	$ (2,916)	21.0%
State tax (benefit), net of federal tax benefit	(970)	7.0%	(103)	7.0%	(1,073)	7.7%
R&D tax credit from current year	(687)	4.9%	(20)	0.0%	(707)	5.1%
Impact on effective rate of SSMP loss eliminated in consolidation	—		—		(311)	2.2%
Other	55	-0.4%	(27)	1.8%	28	-0.2%
Change in valuation allowance	4,519	-32.5%	462	-31.2%	4,980	-35.9%
Total provision for income taxes	$ 1	0.0%	$ 1	-0.1%	$ 2	0.0%

(a) The pre-tax losses for NPM and Legacy SSMP are presented on a stand-alone basis and do not reflect elimination of intercompany balances and transactions; specifically, the net loss recognized by NPM on its investment in Legacy SSMP. The combined pre-tax loss reflects the elimination of intercompany balances and transactions, including NPM's interest in Legacy SSMP's pre-tax loss.

	NPM
	For the year ended December 31, 2021

Pre-tax income (loss)	$ (12,773)	
Federal tax (benefit) at statutory rate	(2,682)	21.0%
State tax (benefit), net of federal tax benefit	(893)	7.0%
R&D tax credit from current year	(475)	3.7%
Other	(163)	1.3%
Change in valuation allowance	4,214	-33.0%
Total provision for income taxes	$ 1	0.0%

The pre-tax losses for NPM and Legacy SSMP in the preceding table are presented as if each entity filed separate returns; and accordingly, the information does not reflect elimination of intercompany transactions or balances. The combined pre-tax loss in the table reflects elimination of intercompany transactions and balances.

Since NPM and Legacy SSMP file as separate taxpayers, deferred tax assets and liabilities and attributes such as NOL and R&D carry-forwards of one taxpayer are not available to offset those of the other taxpayer. The combined data is presented for disclosure purposes only.

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, 2022 and 2021, 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, 2022, 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):

	As of December 31, 2022	
	NPM	Legacy SSMP
Pre TCJA (Tax Cuts and Jobs Acts of 2017) period federal NOL carry-forward, begin expiring 2030	$ 18,257	$ 29,095
Post TCJA period federal NOL carry-forward, with no carry-forward limitation	39,503	86,412
Total federal NOL carry-forward	$ 57,760	$ 115,508
State NOL carry-forward, begin expiring 2030	$ 66,514	$ 30,439
Federal R&D tax credit carry-forward, begin expiring in 2026	1,586	20
State R&D carry-forward, begin expiring in 2026	1,973	4,989
Total R&E related deferred income tax assets (net of applicable amortization) as of December 31, 2022, in the table above, was	1,997	459
Reserve for uncertain income tax positions	Nil	Nil

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 2038 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.

Our legal subsidiary, NPM experienced an "ownership change" within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended, 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.

We periodically review the uncertainties and judgments related to the application of complex income tax regulations to determine income tax liabilities in several jurisdictions. We use a "more likely than not" criterion for recognizing the income tax benefit of uncertain tax positions and establishing measurement criteria for income tax benefits. We have evaluated the impact of these positions and believe tax filing positions and deductions will more likely than not be sustained upon examination. Accordingly, no reserve for uncertain income tax positions has been recorded as of December 31, 2022.

If the cumulative unrecognized tax benefit is recognized, there will be no effect on our effective tax rate due to the full valuation allowance. Due to the nature of the unrecognized tax benefits and the existence of tax attributes, we have not accrued any interest or penalties associated with unrecognized tax benefits in the Consolidated Statement of Operations nor recognized a liability in the Consolidated Balance Sheet. We do not believe the total amount of unrecognized benefit as of December 31, 2022, will increase or decrease significantly in the next twelve months.

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, 2021, and 2020, 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.

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

We lease certain office space and equipment for our use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease costs are recognized in the income statement over the lease term on a straight-line basis. Depreciation is computed using the straight-line method over the estimated useful life of the respective assets. The depreciable life of assets and leasehold improvements are limited by the expected lease term. 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.

The Company evaluated the lease amendment under the provisions of ASC 842. Information related to the Company's right-of-use assets and related lease liabilities are as followings (in thousands, except for remaining lease term and discount rate):

Year ending December 31:	
2023	975
Total lease payments	975
Less: Imputed interest	(20)
Total lease liabilities	$ 955
Other supplemental information:	
Current operating lease liabilities	$ 955
Long term operating lease liabilities	—
Total lease liabilities	$ 955

	For the year ended December 31, 2022	**For the year ended December 31, 2021**
Cash paid for operating lease liabilities	$1.0 million	$0.9 million

Rent expense, including common area maintenance charges, was $0.9 million and $0.8 million during 2022 and 2021, respectively.

12. 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 year 2019. This requirement to collect follow-up data was halted in 2020 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 charged to expense for the year ended December 31, 2022 were $0.2 million.

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 us. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing our 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 our 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 9, 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 judgement, 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. The Company may appeal the decision within three months from the date of service. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022 related to this matter but plans to raise any and all legal challenges to this preliminary judgement.

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.

13. Subsequent Event

On February 1, 2023 Cortigent entered into a lease agreement, effective March 1, 2023, to sublease office space to replace our 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 sub-lease has a term of two years and two months. 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. As a material inducement for the lessor to execute the lease with us Vivani guaranteed the prompt payment of all rents and all other sums payable under the lease together with all other terms and conditions to be kept and performed under the lease by the lessee.

As of January 2023, Cortigent commenced to pay Mr. Adams $25,000 per month for his services to us. In March 2023 we entered into an at will letter agreement with Jonathan Adams by which we appointed him President and Chief Executive Officer of Cortigent at a base salary of $350,000 per year commencing as of March 1, 2023. He may also receive a onetime signing bonus of up to $50,000 upon Board approval. Upon Board approval following completion of the initial public offering of securities, Mr. Adams may also be issued an option to purchase 400,000 shares of our common stock at a strike price equal to the price per share at which shares initially are sold to the public in this offering. Of these, options to purchase 100,000 shares will vest on November 10, 2023 and the balance shall vest in approximately equal monthly instalments over the ensuing 36 months.

In March 2023 Cortigent entered into a Transition Funding, Support and Services Agreement with Vivani whereby Vivani will advance funds and provide or cause to be provided to the Company the services and funding that will cover salaries and related costs, rent and other overhead in order to permit the Company to operate in substantially the same manner in which business operations of the Company were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, until the earlier of December 31, 2024 or receipt of proceeds from this offering.

Vivani entered into a triple net lease agreement for a single building with 43,645 square feet of space in Alameda, California on November 21, 2022. The stated term of the lease commences on June 1, 2023 and terminates on September 30, 2033, ten years and 4 months. Payments increase annually from $2,676,311 to $3,596,784, or 124 payments less the first four which are abated, totalling approximately $31 million. Vivani will be responsible for insurance, property taxes and CAM charges. The current lease expires on September 30, 2023.

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 (333-221228, 333-255267 and 333-256904) and Form S-8 (Nos. 333-204241, 333-213184, 333-218016, 333-219737, 333-237266 and 333-267271) of our report dated March 31, 2023, relating to the consolidated financial statements of Vivani Medical, Inc. as of and for the years ended December 31, 2022 and 2021, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP

March 31, 2023
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 the 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, 2023

/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 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, 2023

/s/ Brigid Makes
Brigid 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 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, 2022, 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, 2023

/s/ Adam Mendelsohn
Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2023

/s/ Brigid Makes
Brigid Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vivani Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.