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, 2021

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

Second Sight Medical Products, 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.)*
13170 Telfair Avenue,	**Sylmar**, **CA 91342**
(*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	EYES	NASDAQ
Warrants	EYESW	NASDAQ

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. ☐

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, 2021, computed by reference to the closing sales price on the Nasdaq Capital Market on June 30, 2021, was approximately $145.5 million.

As of March 23, 2022, the registrant had 39,409,176 shares of common stock, no par value per share and 7,680,938 warrants outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2022 Annual Meeting of Stockholders 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 with the Securities and Exchange Commission within 120 days after the end of registrant's fiscal year ended December 31, 2021.

SECOND SIGHT MEDICAL PRODUCTS INC.

FORM 10-K

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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 impact of the ongoing coronavirus or COVID-19, pandemic on our business and operations, results of operations and financial performance including: delays, interruptions or other adverse effects to clinical trials and patient enrollment; delays in regulatory review; manufacturing and supply chain interruptions; and the adverse effects on healthcare systems and disruption of the global economy overall;
- the initiation, timing, design, progress and results of our clinical trials, and our research and development program; and
- the completion of the business combination with Nano Precision Medical, Inc., ("NPM") on anticipated terms and timing, including unforeseen liabilities, 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 completion 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**.**

Summary of Risks Related to our Business

Some of the factors that could cause actual results to differ are identified below, as well as those discussed in the Item 1A. Risk Factors section in this Form 10-K and within MD&A. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. The occurrence of any of the risks identified below or in the Item 1A. Risk Factors section in this Form 10-K, or other risks currently unknown, could have a material adverse effect on our business, financial condition or results of operations, or we may be required to increase our accruals for contingencies. It is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties:

1. Despite promising results from the Early Feasibility Study for Orion being conducted at UCLA and Baylor we currently have no commercial products or product revenue and may never become profitable.
2. We may face substantial competition in the future and may not be able to keep pace with the rapid technological changes which may result from others discovering, developing or commercializing products before or more successfully than we do.
3. Despite early positive results in our limited initial trials at UCLA and Baylor School of Medicine our ongoing development efforts may never demonstrate the feasibility of our Orion technology.
4. We have not been profitable to date and expect our operating losses to continue for the foreseeable future; we may never be profitable.
5. There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock.
6. The COVID-19 pandemic has had an adverse effect on our business and results of operations and is expected to continue to have further adverse effects, which could be material, on our business, results of operations, financial condition, liquidity, and capital investments.
7. Any failure or delay in completing clinical trials or studies for new product candidates or next generation of our products and the expense of those trials could adversely affect our business.
8. We have lost key management and staff personnel because of Covid-19 pandemic. If we fail to recruit highly skilled personnel to replace employees who have left the Company, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.
9. We may become involved in future lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.
10. We are increasingly dependent on sophisticated information technology systems, including systems from third parties, and if we fail to properly maintain the integrity of our data or if our products do not operate as intended, our business could be materially and adversely affected.
11. We will need additional capital to support our operations and growth. Additional capital may be difficult to obtain restricting our operations and resulting in additional dilution to our stockholders.
12. Our revenue from sales of Orion, if approved, will be dependent upon the pricing and reimbursement guidelines adopted in each country and if pricing and reimbursement levels are inadequate to achieve profitability our operations will suffer.
13. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
14. We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.
15. Although we believe that our strategy to (i) leverage proven Argus II technology to develop the Orion visual cortical prosthesis and (ii) significantly expand our addressable market to include a portion of the almost six million patients who are blind from eye trauma, optic nerve disease and injury, diabetic retinopathy, glaucoma and other currently untreatable causes is more likely to address a better and faster way to treat many causes of blindness, including the Retinitis Pigmentosa population, we will continue to incur material near term losses, market uncertainty and our stock may experience significant fluctuations as we continue to focus exclusively on Orion.

16. If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

17. Although we are currently in compliance with Nasdaq listing standards in the past we have received notices of deficiencies. If our common stock is delisted, the market price and liquidity of our common stock and our ability to raise additional capital would be adversely impacted.

18. Entities controlled by Gregg Williams, our Chairman of the Board, have the ability to influence or control the outcome of matters submitted for stockholder approval, may limit your ability to influence outcomes of director elections and may have interests that differ from those of our other stockholders.

19. We have the right to issue shares of preferred stock. If we were to issue preferred stock, it is likely to have rights, preferences and privileges that may adversely affect the common stock.

20. Should any of the various conditions to our proposed Merger transaction with Nano Precision Medical Inc. fail to be timely satisfied or if the Merger does not close for any other reason we may be required to pay a termination fee in certain instances, incur substantial cost with no attendant benefit, and experience other adverse effects on our business, financial results, and/or operations. Even if the Merger is completed we may experience additional risks associated with the combined company and its ability to develop its products, finance operations and continue the businesses on an integrated basis.

PART I

Item 1. Business

Our Company

Overview

Second Sight Medical Products, Inc. ("Second Sight," the "Company," "we," "us," "our" or similar terms) has developed, manufactured and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. We are a recognized global leader in neuromodulation devices for blindness, and are committed to developing new technologies to treat the broadest population of sight-impaired individuals.

Leveraging our 20 years of experience in neuromodulation for vision, we are developing the Orion® Visual Cortical Prosthesis System ("Orion"), an implanted cortical stimulation device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes, including glaucoma, diabetic retinopathy, optic nerve injury or disease and eye injury. Orion is intended to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses. The device is designed to bypass diseased or injured eye anatomy and to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the brain's visual cortex, where it is intended to provide the perception of patterns of light. We are conducting a six-subject Early Feasibility Study of the Orion device at the Ronald Reagan UCLA Medical Center in Los Angeles ("UCLA") and Baylor College of Medicine in Houston ("Baylor"). Regularly scheduled visits at both sites were paused in mid-March 2020 due to the coronavirus outbreak, however visits at UCLA resumed mid-September 2020 and Baylor resumed in December 2020. Our 36 month results, all of which were measured after the study resumed, indicate to us that:

- We have a good safety profile. Five subjects experienced a total of fourteen adverse events (AEs) related to the device or to the surgery, through February 2022. One was considered a serious adverse event (SAE), and all of the adverse events were in the expected category. The one SAE occurred at about three months post-implant, was resolved quickly, and did not require a hospital stay. There have been no serious adverse events due to the device or surgery since June 2018.

- The efficacy data is encouraging. We measure efficacy by looking at three measures of visual function: The first is square localization, where Orion subjects sit in front of a touch screen and are asked to touch within the boundaries of a square when it appears. The second is direction of motion, where subjects are asked to identify the direction and motion of lines on a screen. The third is grating visual acuity, a measure of visual acuity that is adapted for very low vision. Five subjects have completed these tests at 36-months. For these 36-month results, on square localization, five of five subjects tested in our feasibility study performed significantly better with the system on than off. On direction of motion, five of five performed better with the system on than off. On grating visual acuity, two of five tested had measurable visual acuity on the scale of this test (versus none who can do it with the device off). Another efficacy measurement of day-to-day functionality and benefit is FLORA, an acronym for Functional Low-Vision Observer Rated Assessment. FLORA is an assessment performed by an independent, third-party low vision orientation and mobility specialist who spends time with each of the subjects in their homes. The specialist asks each of the subjects a series of questions and also observes them performing 15 or more daily living tasks, such as finding light sources, following a sidewalk, or sorting laundry. The specialist then determines if the system is providing a benefit, if it is neutral, or if it is actually hurting the abilities of subjects to perform these tasks. FLORA results to date show that 4 out of 4 completing the FLORA at 36 months had positive or mild positive results indicating the Orion system is providing benefit. We reached agreement with the FDA in the fourth quarter of 2019 to utilize a revised version of FLORA as our primary efficacy endpoint in our pivotal trial for Orion, pending successful validation of the instrument.

No peer-reviewed data is available yet for the Orion system. We are currently negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

Product and Clinical Development Plans

By further developing our visual cortical prosthesis, Orion, we believe we may be able to significantly expand our market to include nearly all profoundly blind individuals. The principal notable exceptions for potential use of the Orion are those who are blind due to otherwise currently treatable diseases, individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare. However, of the estimated 36 million blind people worldwide, there are approximately 5.8 million people who are legally blind due to causes that are not otherwise treatable. We continue to develop and refine our estimates of the potential addressable market size as we evaluate the commercial prospects for Orion using a combination of published sources, third party market research, and physician feedback. We currently estimate over 500,000 individuals in the US are legally blind due to retinitis pigmentosa, glaucoma, diabetic retinopathy, optic nerve disease and eye injury. Of this population, we estimate the potential US addressable market is between 50,000 and 100,000 individuals with bi-lateral blindness at the light-perception level or worse. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Our objective in designing and developing the Orion visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for human vision. A six-subject Early Feasibility Study of the Orion device is currently underway at UCLA and Baylor. Our 36 month results indicate a good safety profile with encouraging efficacy data and benefits in helping subjects perform their daily living tasks. We believe these data results are encouraging and support advancement of Orion into a larger pivotal clinical study. Early promising results are not necessarily indicative of results which may be obtained in our larger Orion clinical trials.

In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion. This designation is given to a few select medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review.

On February 26, 2021, the U.S. Food and Drug Administration (FDA) approved the Argus 2s Retinal Prosthesis System, a redesigned set of external hardware (glasses and video processing unit) initially for use in combination with previously implanted Argus II systems for the treatment of retinitis pigmentosa (RP). The Company expects that the Argus 2s will be adapted to be the external system for the next generation Orion Visual Cortical Prosthesis System currently under development. In addition to ergonomic improvements, the Argus 2s system offers significantly more processing power, potentially allowing for improved video processing.

Our principal offices are located in Los Angeles, California.

Our first commercially approved product, the Argus® II Retinal Prosthesis System ("Argus II"), treats outer retinal degenerations, such as retinitis pigmentosa, also referred to as RP. The Argus II was the only retinal prosthesis approved in the United States by the Food and Drug Administration ("FDA"), and was the first approved retinal prosthesis in the world. RP is a hereditary disease, affecting an estimated 1.5 million people worldwide including about 100,000 people in the United States, that causes a progressive degeneration of the light-sensitive cells of the retina, leading to significant visual impairment and ultimately blindness. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

We began selling the Argus II System in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. Given the limited addressable market of Argus II, we no longer market the Argus II and have focused all of our resources on the development of Orion.

We are also researching multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Orion user experience. In most cases, we collaborate with 3rd party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that we believe will be complimentary to our products include: eye tracking, object recognition and localization, thermal imaging and depth-based decluttering.

In early March 2020, we commenced clinical validation activities for the FLORA-20 instrument, the primary efficacy endpoint we have selected for our future pivotal clinical trial of Orion. In mid-March 2020, our validation activities were suspended as a result of public health concerns and related social distancing due to COVID-19. We are in the process of evaluating when activities related to the validation study can be resumed.

In May 2020, we completed an underwritten public offering of 7,500,000 shares of common stock at an offering price of $1.00 per share for aggregate gross proceeds of $7.5 million, and net proceeds of approximately $6.7 million after deducting underwriting discounts, commissions and other offering expenses.

In May 2020, we entered into a Letter Agreement with Sylmar Biomedical Park, LLC (the “Landlord”) to terminate our facility leases in which we agreed to vacate the premises by June 18, 2020 and pay $210,730 to bring our leases current and pay a one-time early termination fee of $150,000. Prior to the early termination, we were obligated to pay aggregate base rent of approximately $0.9 million and common area maintenance expenses for the respective remaining terms of our leases in February 2022 and April 2023.

We completed our offer to rescind certain purchases of shares under our ESPP plan on May 27, 2020. We voluntarily offered to rescind the sale of shares of our common stock to employees who purchased those shares under the ESPP and to reimburse any losses upon the sale of our shares of our common stock for certain purchase periods because these shares may not have been exempt from registration under the Securities Act of 1933. The rescission of these share purchases resulted in the repurchase and cancelation of 39,467 shares of our common stock. The total cost for the repurchase of these shares and the reimbursement of any losses from the sale of such shares totaled approximately $270,000.

In June 2020, we commenced a process to dissolve our Swiss subsidiary which is still in process.

On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest of $135,000 during the quarter ended June 30, 2021.

On January 22, 2021, we entered into a lease agreement, effective February 1, 2021, to sub-lease office space to replace our existing headquarters. We will pay $17,000 per month, increasing to $17,500 per month on February 1, 2022, plus operating expenses, to lease 17,290 square feet of office space at 13170 Telfair Avenue, Sylmar CA 91342. Additionally, we received full rent abatement for March 2021, and will receive half rent abatement for March 2022. The sub-lease is for two years and two months. We are not affiliates with, or related to, or otherwise have any other relationship with the other parties, other than the lease.

On March 23, 2021, we closed our private placement to seven institutional investors of 4,650,000 shares of common stock at a price of $6.00 per share for aggregate net proceeds of approximately $24.5 million.

On March 26, 2021, the Board of Directors appointed Scott Dunbar to replace Matthew Pfeffer, as acting Chief Executive Officer. Mr. Pfeffer resumed his role as a director at such date.

On June 25, 2021, we closed an underwritten public offering of 11,500,000 shares of common stock at a price of $5.00 per share for aggregate net proceeds of $53.3 million.

On February 4, 2022, we entered into an agreement and plan of merger with Nano Precision Medical, Inc., a California corporation, and, upon and subject to the execution of a joinder, NPM Acquisition Corp., a California corporation and a wholly-owned subsidiary of the Company (“Merger Sub”). Pursuant to the agreement and subject to the terms and conditions set forth therein, NPM will merge with and into Merger Sub (the “Merger”), and upon consummation of the merger, Merger Sub will cease to exist and NPM will become a wholly-owned subsidiary of the Company. Upon completion of the merger and subject to shareholder approval, the Company will change its name as agreed in the future and may change its trading symbol as NPM requests in writing following consultation with Nasdaq.

Our Technology

Orion works by converting video images captured by a miniature camera housed in a user's glasses into a series of small electrical pulses that are transmitted wirelessly to an array of electrodes. The Orion array is implanted on the surface of the visual cortex of the brain, bypassing the eye and optic nerve and directly stimulating the region of the brain responsible for vision. The pulses generated are intended to create a perception of patterns of light in the brain. Following the implant surgery, users learn to interpret these visual patterns as artificial vision, allowing them to detect shapes of people and objects in their surroundings.

We believe Orion possesses several unique technological advancements compared to other neurostimulation devices, including a hermetic package with the smallest size and largest number of individually programmable electrodes, and a patented electrode material that allows for high charge densities and small electrode size. Several other engineering challenges, including device reliability, extended lifetime, and a safe and effective bio-interface, were overcome during the development of the products and these solutions have been protected both by patents and by trade secrets. Much of the technology developed for Argus II is also used in Orion. As of December 31, 2021, we have more than 300 issued patents and over 15 pending patent applications worldwide.

We have demonstrated the ability to design products with long-term reliability. The Argus I retinal prosthesis, a proof of concept device that was a predecessor to the Argus II, was implanted in six patients in the United States. Argus I patients were implanted an average of almost seven years, with one patient having used the device for over 10 years. The Argus II system has been implanted in over 350 patients. The average implant duration for these patients is nearly five years with several users continuing to use the system 10 years following implantation.

In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion. This designation is given to a select number of medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review. With this designation, we believe the Orion will have the following advantages during the FDA review process:

- more interactive review both for the Investigational Device Exemption (IDE) and Premarket Approval application;
- greater reliance on post-market data collection and greater acceptance of uncertainty in the benefit-risk profile at the time of approval;
- priority review (i.e., review of the submission is placed at the top of the review queue and receives additional review resources); and
- senior FDA management involvement and assignment of a cross-disciplinary case manager.

We expect that inclusion in the Breakthrough Devices Program may shorten the timeline required to bring the Orion to market as a commercial product. We also are currently evaluating our pivotal trial design for Orion and hope to reach consensus with the FDA on design specifics. Major elements of our clinical trial design include the number of patients, study duration, and the endpoints suitable for assessing visual function, functional vision and quality of life. We have reached agreement with FDA on the primary effectiveness endpoint, pending validation of an assessment we have developed for the purpose. We are currently working with FDA on alignment on a primary safety endpoint and confirmation of a statistical sample size which will drive the number of subjects to be enrolled in the pivotal study. While negotiations with the FDA are ongoing, we believe the study design will require a minimum pre-market sample population of at least 45 subjects (plus additional post-market subjects) with at least 12 months of follow-up data for each patient prior to submittal of a premarket approval (PMA) application.

Our Markets

According to the World Health Organization (WHO)1, 253 million people suffer from moderate to severe vision impairment worldwide. Of these, 36 million people are considered legally blind. The WHO further estimates that 80% of legal blindness is avoidable, leaving 7.8 million legally blind individuals. We continue to develop and refine our estimates of the potential addressable market size as we evaluate the commercial prospects for Orion using a combination of published sources, third-party market research, and physician feedback.

In the U.S., 1.3 million people are legally blind3. We commissioned third-party market research for the potential market for Orion and we currently estimate over 500,000 individuals in the U.S. are legally blind. Of this population, we estimate the potential U.S. addressable market is between 50,000 and 100,000 individuals with bi-lateral blindness at the light-perception level or worse. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Many other diseases can also cause blindness. Many of the largest causes of visual impairment (i.e. refractive error and cataracts) are avoidable or curable, and their prolonged or untreated impact on vision is largely observed in developing nations and are not part of our target market. Some other causes of blindness, such as brain trauma to the visual cortex, may also not be suitable for treatment by a cortical stimulator. However, the remaining causes of severe vision loss which include glaucoma, diabetic retinopathy, eye trauma, optic nerve disease or injury and many others can result in severe visual impairment that could potentially be treatable by an Orion visual prosthesis system.

We believe that, if approved by the FDA, the Orion will initially treat a subset of these legally blind individuals, likely starting with the ones who are completely blind. If this is the case, we anticipate that if we are further able to collect additional clinical data demonstrating the efficacy of the Orion for patients with better vision, we will be able to expand the approved indications and addressable market of the Orion to include a larger subset of these 5.8 million individuals for whom no effective treatment currently exists.

By further developing our visual cortical prosthesis, Orion, we believe we will significantly expand our market to include nearly all profoundly blind individuals. The only notable exceptions for potential use of the Orion are those who are blind due to otherwise currently treatable diseases, individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare.

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1 WHO Fact Sheet, updated October 11, 2018.
2 Congdon N, O'Colmain B, Klaver CC, et al. Causes and prevalence of visual impairment among adults in the United States. *Arch Ophthalmol*. Apr 2004;122(4):477-485. This percent amount was derived from the rates of different causes of blindness by different races and racial demographic data from 2010 U.S. Census data.
3 National Eye Institute (http://www.nei.nih.gov/eyedata/blind.asp).

Our Strategy

Our strategy can be summarized as follows:

- Leverage proven Argus technology to develop the Orion visual cortical prosthesis and significantly expand our addressable market to include a portion of the almost 6 million patients who are blind from eye trauma, optic nerve disease and injury, diabetic retinopathy, glaucoma and other untreatable causes.

- Invest in research and development of technologies intended to enhance the Orion user experience, including eye tracking, distance filtering/decluttering, object and facial recognition and thermal imaging.

- Continue to provide limited product support for Argus II patients while expanding our overall investment in Orion.

Global Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the price of the Orion system, our future sales would be limited without the availability of third-party reimbursement. In the U.S., coding, coverage, and payment are necessary for the surgical procedure and Orion system to be reimbursed by payors. Coding will need to be established for the device and the surgical procedure. Coverage and payment vary by payor. The majority of Argus II patients were eligible for Medicare, and coverage was primarily provided through traditional Medicare, sometimes referred to as Medicare Fee-for-Service ("FFS") or Medicare Advantage. A small percentage of patients were covered by commercial insurers.

- **Medicare FFS patients** – Coverage is determined by Medicare Administrative Contractors (MACs) that administer various geographic regions of the U.S.

- **Medicare Advantage patients** – Medicare Advantage plans are required to cover the same benefits as those covered by the MAC in that jurisdiction. For example, if a MAC in a jurisdiction has favorable coverage for Orion, then typically Medicare Advantage plans in that MAC jurisdiction offer the same coverage. Individual hospitals and ASCs may negotiate contracts specific to that individual facility. In addition, procedural payment is variable and can be based on a percentage of billed charges, payment groupings or other individually negotiated payment methodologies. Medicare Advantage plans also allow providers to confirm coverage and payment for the procedure in advance of implantation.

- **Commercial insurer patients** – Commercial insurance plans make coverage and payment rate decisions independent of Medicare, and contracts are individually negotiated with facility and physician providers.

Currently, we are in the process of evaluating potential reimbursement pathways for Orion in the U.S. market. Compared to Argus II, which was largely catering to the Medicare patient population, Orion is expected to address a patient population with a more diverse and balanced payor mix due to our potential indications profile and expected younger patient population, on average. As Orion is a part of the FDA's Breakthrough Devices program, we are closely evaluating a variety of fast-track reimbursement programs, including recent encouraging announcements from CMS proposing modernization of payment policies for medical devices that meet FDA's Breakthrough Devices designation. We have also approached some commercial payors and CMS to get their feedback to ensure our overall reimbursement strategy for Orion therapy will cater to their key data requirements.

Market Development Plans

Orion. By further developing our visual cortical prosthesis, Orion, we believe we may be able to significantly expand our market to include nearly all profoundly blind individuals. The only notable exceptions for potential use of the Orion are those who are blind due to otherwise currently treatable diseases, individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare. However, of the estimated 36 million blind people worldwide, there are approximately 5.8 million people who are legally blind due to causes that are not otherwise treatable. We continue to develop and refine our estimates of the potential addressable market size as we evaluate the commercial prospects for Orion using a combination of published sources, third party market research, and physician feedback. We currently estimate over 500,000 individuals in the US are legally blind due to retinitis pigmentosa, glaucoma, diabetic retinopathy, optic nerve disease and eye injury. Of this population, we estimate the potential US addressable market is between 50,000 and 100,000 individuals with bi-lateral blindness at the light-perception level or worse. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Our objective in designing and developing the Orion visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for human vision. A six-subject Early Feasibility Study of the Orion device is currently underway at UCLA and Baylor. Regularly scheduled visits at both sites were placed on hold in mid-March due to Covid-19, however visits at UCLA resumed mid-September 2020 and Baylor resumed in December 2020. Our 36 month results for the six subjects indicate a good safety profile with encouraging efficacy data and benefits in helping subjects perform their daily living tasks. We believe these data are encouraging and support advancement of Orion into a larger pivotal clinical study. Early promising results are not necessarily indicative of results which may be obtained in large clinical trials. No assurance can be given that we will achieve similar results in our larger Orion clinical trials. No peer-reviewed data is available yet for the Orion system.

In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion. This designation is given to a few select medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review.

COVID-19 Pandemic

In accordance with local and state guidelines regarding the COVID-19 pandemic, we are requiring all of our employees to wear masks in the office and use their best judgement to work remotely or work in the office. While many of our employees are accustomed to working remotely, much of our workforce has not historically been remote. Although we continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available, restricting the ability to do business in person may create operational or other challenges, any of which could harm our business, financial condition and results of operations.

In addition, our clinical trials have been affected by the COVID-19 outbreak. Patient visits in ongoing clinical trials were delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, some of our suppliers of certain materials used in the development of our product candidates are located in areas impacted by COVID-19 which could limit our ability to obtain sufficient materials for our product candidates. COVID-19 has and will continue to adversely affect global economies and financial markets, and may result in an economic downturn that could affect demand for our product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. See the Risk Factors section for further discussion of the possible impact of the COVID-19 pandemic on our business.

Commercial efforts to develop retinal implants by others include:

- Pixium: A publicly held French company that is developing the PRIMA (sub-retinal implant) for Dry-AMD patients. In 2017, Pixium announced approval for two feasibility studies of PRIMA in Dry-AMD patients. One study reportedly is in Paris with five subjects, and a second Early Feasibility Study in the U.S. of five patients is underway at two sites – Pittsburgh, Pennsylvania and Miami, Florida. To date, Pixium has announced the successful implantation and activation of five devices in Paris and two devices in the U.S. with limited performance data reported.

- NanoRetina Inc., a company based in Israel, and several other early stage companies are reported to have developed intellectual property or technology that may improve retinal prostheses in the future. A clinical trial is underway in Europe and an unknown number of patients have been implanted.

- Academic entities are also working on vision restoring implants. These include Bionic Vision Australia (an early prototype device has been developed and to our knowledge implanted in three human subjects), Boston Retinal Implant project (preclinical phase), Monash Vision Group (preclinical phase), and the Illinois Institute of Technology (clinical phase). Of these projects, we believe most have not yet demonstrated a working implant, only one has reportedly begun long-term clinical work in humans, and to our knowledge only the Illinois Institute of Technology has received FDA approval to begin clinical trials in the U.S.

Our Competition

The U.S. life sciences industry is highly competitive. The treatment of blindness is a significant clinically unmet need and others continue to make progress. There are several approaches to treating blindness including other visual prostheses and non-electrical stimulation treatments. Visual prosthesis approach include:

- Retinal Prostheses: The retina is the first nerve tissue in the visual network that generates electrical signals. A retinal prosthesis implant stimulates the retina with electrodes. We are aware of three primary approaches to this: 1) Subretinal Prosthesis, which is placed beneath the retina and between the retina and choroid, 2) Epiretinal Prosthesis, which is placed on the surface of the retina, and 3) Suprachoridal prosthesis, which is placed outside the choroid (behind the eye). Active retinal prosthesis companies and research groups include:

    - Pixium Vision: A publicly held French company that is developing the PRIMA (sub-retinal implant) for Dry-AMD patients. In 2017, Pixium announced approval for two feasibility studies of PRIMA in Dry-AMD patients. One study reportedly was in Paris with five subjects, and a second Early Feasibility Study in the U.S. of five patients is underway at two sites – Pittsburgh, Pennsylvania and Miami, Florida. A pivotal study of PRIMA is underway in Europe (France, Germany, and UK) with read-out of results expected in 2023. However, no plans for a pivotal study in the US have been announced.

    - The Boston Retinal Implant project is developing a subretinal prosthesis system, but has not advanced to clinical trials.

    - Nano Retina Inc., a company based in Israel, and several other early stage companies are reported to have developed intellectual property or technology that may improve retinal prostheses in the future. A Nano Retina clinical trial is underway in Europe and Israel, and 5 subjects reportedly have been implanted to date.

    - Bionic Vision Technologies, based in Australia, was recently granted Breakthrough Device status for its Bionic Eye Visual Prosthesis System, a suprachoroidal device. The company has completed a two-year feasibility study and has partnered with Cirtec Medical in the US. It is in the planning stages for a global pivotal study.

- Optic Nerve Implant: Moving down the visual network path, some are developing a cuff electrode array that is placed around the optic nerve just behind the eye. We believe these are in early research phase.

- Visual Cortical Prosthesis: To our knowledge, we are the only commercially focused organization developing a visual cortical prosthesis (Orion), which is placed beneath the skull and on the surface of the visual cortex. A few other groups worldwide are developing an intracortical visual prosthesis with electrodes that penetrate the brain, including:.

    - Illinois Institute of Technology’s Intracortical Visual Prosthesis (ICVP), a system of wireless, penetrating electrode arrays, has been designated a Breakthrough Device and has advanced to early feasibility study in the US. One subject of 5 has been implanted.

    - Monash Vision Group’s Gennaris system is also composed of wireless penetrating arrays. To our knowledge, this project is still in a preclinical phase.

    - Neuralink is developing a brain implant with penetrating electrodes that it has demonstrated in animal models. Vision restoration is one of Neuralink’s many stated goals.

As we continue to demonstrate the potential benefits and safety profile of Orion, we may face competition from other entities seeking to develop a visual cortical prosthesis. While we are currently precluded by the exclusion criteria in our Early Feasibility Study from testing Orion in any indication where a current therapeutic option exists, such as with RP using Argus, we or others may ultimately seek to demonstrate the potential benefits and safety profile of a visual cortical prosthesis for RP.

Other approaches not involving electrical stimulation include:

- Transplants: transplanting retinal tissue to stimulate remaining retinal cells.

- Stem Cells: generally, involves implanting immature retinal support cells aimed at slowing retinal degeneration. A single patient in London, England with wet AMD was reportedly implanted in 2015 with an embryonic stem cell line in a study sponsored by Pfizer. This study has been suspended. Patients with dry AMD were recruited in several countries (US, UK, and South Korea) for similar small studies. Data from these early-stage studies are encouraging with regard to safety and potential therapeutic benefit, but these have been described as Phase ½ clinical trials, with the likely next step of ongoing in vitro cell optimization and small clinical validation studies prior to larger pivotal studies . A few other study groups are investigating different human embryonic stem cell and induced pluripotent stem cell lines for retinal diseases, but to our knowledge, they are all in early stages.

- Genetics and Gene Therapy: involves identifying a specific gene that is causing retinal problems (there are over 120 for retinitis pigmentosa alone) resulting in visual impairments and blindness and inserting healthy genes into an individual's cells using a virus as a delivery mechanism to treat the diseases. A company (Spark Therapeutics) completed a phase 3 study in 21 patients with a median age of 11 for a gene that affects a very small percentage of retinitis pigmentosa patients, RPE65. That company applied for and received FDA approval for Luxturna in 2018. Pricing for these injections is reported to be approximately $850,000 for both eyes. We believe that there is virtually no overlap with our current market since our patients generally are adults (Orion was studied in adults 22-74 years old). Luxturna also treats better sighted patients since it is aimed at improving or preserving residual vision. In contrast, Orion seeks to create artificial vision where vision is completely lost.

- Optogenetics Therapy: aimed at slowing down, reversing, and/or eliminating the process by which photoreceptors in the eye are compromised. This therapy requires using the patient's cells with a virus as a delivery mechanism intended to cause cells within the eye to become light sensitive. Animal work has shown that these cells are not sensitive enough to respond to ambient light, so this approach currently also requires a light amplifier outside the body to increase light delivered to the retina. Several phase 1/2a and 2b/3 trials of optogenetic treatments for RP or related diseases are active in the US, but none of these treatments have been approved for marketing in any markets, to our knowledge.

- Nutritional Therapy: involves diets or supplements that are thought to prevent or slow the progress of vision loss.

- Implantable Telescope: VisionCare Ophthalmic Technologies, Inc. offers an FDA approved implantable miniature telescope for AMD, a magnifying device that is implanted in the eye. The VisionCare telescope is approved for use in patients with severe to profound vision impairment (best corrected visual acuity of 20/160 to 20/800) due to dry AMD.

- Wicab's The BrainPort® V100 includes a video camera mounted on a pair of sunglasses, a hand-held controller, and tongue array. The tongue array contains 400 electrodes and is connected to the glasses via a flexible cable. White pixels from the camera are felt on the tongue as strong stimulation, black pixels as no stimulation, and gray levels as medium levels of stimulation. This device is indicated for the profoundly blind.

- There are currently no known treatments for dry AMD after the disease has caused severe to profound vision loss nor are there any established treatments that delay or reverse the progression of dry AMD other than supplements.

- Therapies exist for Wet AMD that delay the progression of visual impairment or slightly improve the vision, rather than completely curing or reversing its course. These therapies are approved in many regions throughout the world, including the U.S. and European Union ("EU").

Warranty

We generally provide a standard limited warranty for the Argus II system covering replacement over the following periods after implant:

- three years on implanted epiretinal prosthesis
- two years on wearable components other than batteries and chargers
- three months on batteries and chargers

Based on our experience to date, the Argus II system has proven to be a reliable device generally performing as intended. We have accrued warranty expense of $50,000 as of December 31, 2021, which is based upon our historical experience rate.

Our Research Development and Quality Assurance

We have a single facility, located at our principal office in Los Angeles, California.

We rely on many suppliers to provide the materials and services necessary to produce and test our products. Many of these materials or services are currently provided by sole source suppliers. In a number of instances we maintain sole source suppliers because our current purchasing volumes do not warrant developing more than one supplier. We expect to secure additional providers as our production volumes increase. If we experience a loss of a sole supplier before confirming an alternative, we risk possible disruptions in our operations. We attempt to mitigate the sole source risk by, among other things, increasing parts inventory as a partial hedge against interruptions in parts supply and by actively seeking to develop alternative supplier sources before experiencing any such disruptions.

Employees

As of December 31, 2021, we had 15 employees, including 10 in clinical, regulatory and research and development; and 5 in administration. 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.

Properties

Our principal office and facilities are located at 13170 Telfair Avenue, Sylmar CA 91342, which consists of approximately 17,290 rentable square feet at a current base rent of about $17,000 per month. Our sub-lease expires in March 2023. We believe that these premises are adequate for our foreseeable needs.

Available Information

Our website address is www.secondsight.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

Risks Related to Dependence on Our Commercial Products

Despite promising results from the Early Feasibility Study for Orion being conducted at UCLA and Baylor we currently have no commercial products or product revenue and may never become profitable.

To date, we have not generated profit from sales of our now discontinued Argus II product and will not generate revenues until we complete the development and attain the marketing approval for Orion. We have relied principally on financing from the sale of equity securities and the receipt of government and other grants to fund our operations. We expect that our future financial results will depend primarily on our success in further developing the Orion, conducting FDA approved clinical trials and obtaining clearance or approval for, launching, selling and supporting our Orion technology. To establish these operations we will need to expend significant resources on hiring additional personnel, conducting continued scientific and product research and development, engaging in further pre-clinical and clinical investigation, giving expanded attention to intellectual property development and prosecution, seeking domestic and international regulatory approvals, marketing and promotion, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives and other operational personnel, and the continued development of relationships with potential partners as we continue to seek regulatory clearance or approval for our products. As a pre-revenue company we continue to incur significant operating losses, and we expect to continue to incur additional losses for at least the next several years. We cannot assure you that we will generate revenue or be profitable in the future. Our future or updated Orion products may never be cleared or approved or become commercially viable or accepted for use.

Investment in medical device technology entails material uncertainty and is highly speculative. It entails substantial upfront capital expenditures over time and significant risk that any potential product will fail to demonstrate adequate safety, efficacy, clinical utility or acceptance by physicians and blind individuals. Investors should evaluate an investment in us in light of the uncertainties encountered by developing medical technology companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to implement our business plan.

Our commercial and financial success depends on our products being accepted in the market, and if not achieved will result in our not being able to generate revenues to support our operations.

Even if we are able to obtain favorable reimbursement within the markets that we serve, commercial success of our products will depend, among other things, on their acceptance by retinal specialists, ophthalmologists, brain surgeons, general practitioners, low vision therapists and mobility experts, hospital purchasing and controlling departments, patients, and other members of the medical community. The degree of market acceptance of any of our product candidates will depend on factors that include:

- cost of treatment;
- pricing and availability of future alternative products;
- the extent of available third-party coverage or reimbursement;
- perceived efficacy of the Orion system relative to other future products and medical solutions; and
- prevalence and severity of adverse side effects associated with treatment.

The activities of competitive medical device companies, or others, may limit our revenue from the sale of the Orion system.

Our commercial opportunities for the Orion system may be reduced if our competitors develop or market products that are more effective, are better tolerated, receive better reimbursement terms, achieve greater acceptance by physicians, have better distribution channels, or are less costly.

Currently, to our knowledge, no other medical devices comparable to the Orion system have been approved by regulatory agencies, in the U.S. or Europe, to restore some functional vision in persons who have become blind due to unpreventable causes. Other visual prosthesis companies such as Pixium are developing retinal implant technologies to partially restore some vision in blind patients mainly from age related macular degeneration. Pixium's initial RP prosthesis product was withdrawn from the market. A previous competitor, Retina Implant, has withdrawn from the market. Neither Retina Implant nor Pixium has filed for market approval with the FDA. To our knowledge Pixium has obtained an IDE for a feasibility study in the U.S. for its PRIMA product, which is directed toward age related macular degeneration or AMD, and is conducting a pivotal trial of PRIMA in several countries in Europe. The Illinois Institute of Technology's Intracortical Visual Prosthesis group is currently recruiting participants for a US early feasibility study of a visual cortical prosthesis, and has recently implanted one subject. Neuralink has recently demonstrated a cortical implant in animal models. Vision restoration is one of Neuralink's stated goals. These and other potentially competitive therapies, if or when developed or brought to market, may result in pricing and market access pressure even if the Orion system is otherwise viewed as a preferable therapy.

Many privately and publicly funded universities and other organizations are engaged in research and development of potentially competitive products and therapies, such as stem cell and gene therapies, some of which may target multiple indications of our product candidates. These organizations include pharmaceutical companies, biotechnology companies, public and private universities, hospital centers, government agencies and research organizations. Our competitors include large and small medical device and biotechnology companies that may have significant access to capital resources, competitive product pipelines, substantial research and development staff and facilities, and substantial experience in medical device development.

We may face substantial competition in the future and may not be able to keep pace with the rapid technological changes which may result from others discovering, developing or commercializing products before or more successfully than we do.

In general, the development and commercialization of new medical devices is highly competitive and is characterized by extensive research and development and rapid technological change. Physicians and persons who may be suitable for the Orion implant likely will consider many factors including product reliability, clinical outcomes, product availability, price, and product and patient support services that we may be able to provide. Market share as it develops can shift as a result of technological innovation and other business factors. Major shifts in industry market share have occurred in connection with product problems, physician advisories and safety alerts, reflecting the importance of product quality and reliability in the medical device industry, and any quality problems with our processes, goods and services could harm our reputation for producing high-quality products and would erode our competitive advantage, sales and market share. Our competitors may develop products or other novel approaches and technologies to deal with treating blindness that are more effective, safer or less costly than any that we are developing, and if those products gain market acceptance our revenue and financial results could be adversely affected.

If we fail to develop new products or enhance existing products, our leadership in the markets we serve could erode, and our business, financial condition and results of operations may be adversely affected.

Despite early positive results in our limited initial trials at UCLA and Baylor School of Medicine our ongoing development efforts may never demonstrate the feasibility of our Orion technology.

Our research and development efforts remain subject to all of the risks associated with the development of new technology. Our Orion technology, though based on our FDA approved Argus II retinal prosthesis, is not yet fully developed. Development of the underlying technology, including the further development and refinement of our Orion technology, may be affected by unanticipated technical or other problems, among other development and research issues, and the possible insufficiency of funds needed in order to complete development of these products or devices. Regulatory and clinical hurdles, adverse reactions experienced in trials, or other operational or regulatory challenges also may result in delays and cause us to incur additional expenses that may increase our need for capital and result in additional losses. For example, three of the six subjects implanted in the Early Feasibility Study have been explanted by the subjects' request. While all had been implanted at least three years, the explants represent a limit in the long-term data that can be collected in the current study. If we cannot complete, or if we experience significant delays in developing our technology, applications or products for use by those patients who can benefit from vision restoration, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

Since we have had an operating history of losses and have no current revenue producing operations, the future of our business is difficult to evaluate.

To date, our operations on a consolidated basis have consisted of the continued development and clinical studies of our Orion-focused technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we will continue to incur additional losses for the next several years. In addition, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. This operating history makes it difficult to evaluate our technology or prospective operations and business prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and initial trials may not be predictive of future trial results.

Clinical testing is expensive and can take several or more years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in nonclinical studies and early feasibility clinical studies does not ensure that expanded clinical trials that will be used to support regulatory submissions will be successful. These setbacks may be caused by, among other things, nonclinical findings made while clinical trials were underway, and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates.

Interim "top-line" and preliminary results 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 publish interim top-line or preliminary results from our clinical trials. Interim results 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. Preliminary or top-line results 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, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Risks Related to Our Common Stock

We have not been profitable to date and expect our operating losses to continue for the foreseeable future; we may never be profitable.

We have incurred operating losses and generated negative cash flows since our inception and have financed our operations principally through equity investments and borrowings. Our ability to generate sufficient revenues to fund operations is uncertain. For the fiscal year ended December 31, 2020, we generated no revenue from operations and incurred a net loss of $14.9 million. For the fiscal year ended December 31, 2021, we generated no revenue from operations and incurred a net loss of $8.9 million. Our total accumulated deficit through December 31, 2021, was $328.6 million.

As a result of our limited commercial operating history, revenue is difficult to forecast. We expect expenses to increase in the future as we expand our activities in connection with the further development of Orion. We cannot assure you that we will be profitable in the future. Accordingly, the extent of our future losses and the time required to achieve profitability, if ever, is uncertain. Failure to achieve profitability could materially and adversely affect the value of our common stock and our ability to effect additional financings. The success of the business depends on our ability to increase revenues to offset expenses. If we do not achieve profitability, or otherwise fall short of projections, our business, financial condition and operating results will be materially adversely affected.

Sales, or the availability for sale, of substantial amounts of our common stock could adversely affect the value of our common stock.

We cannot predict the effect, if any, that future sales of our common stock, or the availability of our common stock for future sales, will have on the market price of our common stock. Sales of substantial amounts of our common stock in the public market and the availability of shares for future sale could adversely affect the prevailing market price of our common stock. This in turn could impair our future ability to raise capital through an offering of our equity securities.

There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock.

We are not restricted from issuing additional shares of common stock. The market price of our common stock could decline as a result of sales of our common stock and warrants or the perception that such sales could occur. We may issue and sell additional shares of our common stock in private placements or registered offerings in the future. We also may conduct additional registered rights offerings in the future pursuant to which we may issue shares of our common stock or other securities.

Risks Relating to Our Operations

The COVID-19 pandemic has had an adverse effect on our business and results of operations and is expected to continue to have further adverse effects, which could be material, on our business, results of operations, financial condition, liquidity, and capital investments.

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) originated in Wuhan, China and has since spread globally. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. In addition, most states in the U.S., including California, where we are headquartered, have declared a state of emergency. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

In accordance with local and state guidelines regarding the COVID-19 pandemic, we are requiring all of our employees to wear masks in the office and use their best judgement to work remotely or work in the office. While many of our employees are accustomed to working remotely, much of our workforce has not historically been remote. Although we continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available, restricting the ability to do business in person may create operational or other challenges, any of which could harm our business, financial condition and results of operations.

In addition, our clinical trials have been affected by the COVID-19 outbreak. Patient visits in ongoing clinical trials have been delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. For example, scheduled patient visits to our clinical sites at UCLA and Baylor were temporarily put on hold due to COVID-19. Visits have now resumed at both sites. In addition, the validation study for the revised FLORA assessment was paused due to travel requirements for its completion. Also, some of our suppliers of certain materials used in the development of our product candidates are located in areas impacted by COVID-19 which could limit our ability to obtain sufficient materials for our product candidates. COVID-19 has and will continue to adversely affect global economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We could experience further harm to our business and we cannot anticipate all of the ways in which health epidemics such as COVID-19 and its variants could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change.

COVID-19 has directly and indirectly adversely affected Second Sight and will likely continue to do so for an uncertain period of time. In March and April 2020 we laid off the majority of our employees as a result of COVID-19 and an inability to obtain financing. We retain approximately fifteen of our employees to oversee current operations, including some that were re-hired once our financial situation improved and the future of the company became clearer. The cumulative effects of COVID-19 and its variants on the Company cannot be predicted at this time, but could include, without limitation:

- reputational damages of the Company and its products;
- inability to raise additional funds to finance and continue our operations;
- inability to maintain adequate office laboratory facilities;
- inability to retain and hire experienced personnel;
- diminished ability, or inability, to enroll patients or complete clinical trials and other activities required to achieve regulatory clearance of our products under development
- inability to finalize our plan for and enroll patients into our proposed pivotal clinical trial;
- material delays or inability to complete development and commercialization of Orion;
- inability to satisfy Nasdaq's continued listing requirements and possible delisting; and
- other uncertain events that may have negative impact on our operations.

Materials necessary to manufacture Orion may not be available on commercially reasonable terms, or at all, which may delay development, manufacturing and commercialization of our products.

We rely on numerous suppliers to provide materials, components and services necessary to produce the Orion system and next generation product candidates. Certain suppliers are currently sole source because of our low manufacturing volumes and our need for specialty technical or other engineering expertise. Our suppliers may be unable or unwilling to deliver these materials and services to us timely as needed or on commercially reasonable terms. Should this occur, we would seek to qualify alternative suppliers or develop in-house manufacturing capability but may be unable to do so. Substantial design or manufacturing process modifications and regulatory approval might be required to facilitate or qualify an alternate supplier. Even where we could qualify alternative suppliers the substitution of suppliers may be at a higher cost and cause time delays including delays associated with additional possible FDA review, that could impede the production of the Orion system, reduce gross profit margins and impact our ability to deliver our products as may be timely required to meet demand.

Any failure or delay in completing clinical trials or studies for new product candidates or next generation of our products and the expense of those trials could adversely affect our business.

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of incremental changes, including new wearables and software enhancements and for new product candidates such as Orion are time consuming and expensive. If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we have contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for those product candidates, we may not be able to obtain marketing approval or we may obtain approval for indications that are not as broad as intended. Our product development costs also will increase if we experience delays in testing or approvals.

The completion of clinical trials for our product candidates could be delayed because of our inability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials; delays in patient enrollment and variability in the number and types of patients available for clinical trials; difficulty in maintaining contact with patients after treatment, resulting in incomplete data; poor effectiveness of product candidates during clinical trials; unforeseen safety issues or side effects; and governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we incur significant delays in our clinical trials, our competitors may be able to bring their products to market before we do which could result in harming our ability to commercialize our products or potential products. If we experience any of these occurrences our business will be materially harmed.

We have lost key management and staff personnel because of Covid-19 pandemic. If we fail to recruit highly skilled personnel to replace employees who have left the Company, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We have laid off the majority of our employees including key members of our executive management team because Covid-19 outbreak affected our ability to fund our operations. Our existing employees could leave our company with little or no prior notice. The loss of any management executive or any other principal member of our management team or our inability to attract and retain skilled employees could impair our ability to identify, develop and market new products or effectively deal with regulatory and reimbursement matters. Will McGuire, our President and Chief Executive Officer, tendered his resignation effective March 27, 2020 and our Board appointed Matthew Pfeffer, a member of our Board of Directors, as acting chief executive officer, and Edward Sedo, our Controller, as Principal Accounting and Financial Officer. On March 26, 2021 Matthew Pfeffer relinquished his position as acting chief executive officer and the Board appointed Scott Dunbar, our Senior Patent Counsel and Compliance Officer, as acting chief executive officer. To the extent that we lose experienced personnel, it is critical that we develop other employees, hire new qualified personnel and successfully manage the transfer of critical knowledge. No assurance can be given that we will be able to do so.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We intend to adopt policies for compliance with these anti-bribery laws, which often carry substantial penalties. We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Risks Related to Intellectual Property and Other Legal Matters

If we or our licensors are unable to protect our/their intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Patents and other proprietary rights are essential to our business, and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Two patents licensed from the John Hopkins University (the JHU Patents) expired in 2018, along with our License Agreement with the Johns Hopkins University. The expiration of the JHU Patents removes a barrier to entry for competitors who may be interested in selling a product competitive with Argus II. The JHU Patents are specific to retinal stimulation and have no effect on Orion technology.

Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our technology and may prevent or delay the development, regulatory approval or commercialization Orion system or new product candidates. Further, the validity of some of our patents has been challenged.

Pixium has three currently pending oppositions in the European Patent Office (EPO) challenging the validity of European patents owned by Second Sight. The EPO proceedings involving Pixium and Second Sight are:

- EP1937352 *Sub-Threshold Stimulation to Precondition Neurons for Supra-Threshold Stimulation* – cancelled in the Opposition Division, appeal pending.

- EP2061549 – *Package for an Implantable Neural Stimulation Device* - Cancelled in the Opposition Division, appeal pending.

- EP2185236 – *Implantable Device for the Brain* – Upheld in the Opposition Division, appeal pending.

If we are the target of claims by third parties asserting that our products or intellectual property infringe upon the rights of others we may be forced to incur substantial expenses or divert substantial employee resources from our business and, if successful, those claims could result in our having to pay substantial damages or prevent us from developing one or more product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

The validity of some of our patents has been challenged. If we experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

We hold an exclusive license from the Doheny Eye Institute (DEI) to intellectual property relating to the Argus II visual prosthesis and Orion cortical visual prosthesis. This license imposes various commercialization, milestone payment, profit sharing, insurance and other obligations on us. If we fail to comply with any material obligations, DEI will have the right to terminate the license, which covers part of the Argus and Orion systems. The existing or future patents to which we have rights based on our agreements with DEI may be too narrow to prevent third parties from developing or designing around these patents. Additionally, we may lose our exclusive rights to the patents and patent applications we license in the event of a breach or termination of the license agreement. The license expires with the expiration of the last of the licensed patents on August 8, 2033. The royalty in the agreement is 0.5% of the patented portion of Argus II system sales. All of the patents in the DEI agreement are co-owned by Second Sight and DEI. We license DEI's interest in the patents to maintain our exclusive use on that intellectual property. Should the license terminate, we retain the right to utilize the intellectual property, but may not be able to prevent others from doing so, in which case we may lose a competitive advantage.

If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets.

The strength of our patents involves complex legal and scientific questions and can be uncertain. We have over 300 issued patents and over 15 pending patent applications worldwide as of December 31, 2021. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around our intellectual property and in that event we may lose competitive advantage and our business may suffer.

Further, the patent applications that we license or have filed may fail to result in issued patents. The claims may need to be amended. Even after amendment, a patent may not issue and in that event we may not obtain the exclusive use of the intellectual property that we seek and may lose competitive advantage which could result in harm to our business.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization activities for Orion.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to the Argus II or Orion systems, the medical device industry is characterized by many litigation cases regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our product, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product.

In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

We may become involved in future lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

The U.S. Patent and Trademark Office may initiate interference proceedings to determine the priority of inventions described in or otherwise affecting our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

We are increasingly dependent on sophisticated information technology systems, including systems from third parties, and if we fail to properly maintain the integrity of our data or if our products do not operate as intended, our business could be materially and adversely affected.

We are increasingly dependent on sophisticated information technology systems for our products and infrastructure, and we rely on these information technology systems, including technology from third-party vendors, to process, transmit and store electronic information in our day-to-day operations. We continuously monitor, upgrade and expand the systems we operate to improve information systems capabilities. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop or contract new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, and the increasing need to protect patient and customer information. In addition, third parties may attempt to hack into our products or systems and may obtain data relating to patients with our products or proprietary information. If we fail to maintain or protect our information systems and data integrity with cyber security effectively, we could lose existing customers, have difficulty attracting new customers, have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, physicians, and other health care professionals, have regulatory sanctions, fines, or penalties imposed, have increases in operating expenses, incur expenses or lose revenue as a result of a data privacy breach, or suffer other adverse consequences. There can be no assurance that our process of upgrading and expanding our information systems capabilities, protecting and enhancing our systems including cyber security methods, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future. Our products contain hardware and software protections which are intended to prevent unauthorized access or control of our implanted device. However, if an unauthorized user is able to breach our controls and gain access to one of our devices implanted in a patient, serious harm, injury and/or death may result. Any significant breakdown, intrusion, interruption, corruption, or destruction of these systems, as well as any data breaches, could have a material adverse effect on our business.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

We face a risk of product liability claims arising from the prosthesis being implanted, and it is possible that we may be held liable for injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. We maintain product liability insurance relating to our clinical trials and commercial sales, with an aggregate coverage limit under these insurance policies of $10 million, and while we believe this amount of insurance currently is sufficient to cover our product liability exposure, these limits may not prove adequate to fully cover potential liabilities. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products. If the use of our products harm or are alleged to harm people, we may be subject to costly and damaging product liability claims that exceed our policy limits and cause us significant losses that could seriously harm our financial condition or reputation.

Legislative or regulatory reform of the health care system in the U.S. and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In March 2010, the Patient Protection and Affordable Care Act, and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the medical device industry and other healthcare related industries by imposing additional costs and changes to business practices.

Moreover, in some foreign countries, including countries in Europe and Canada, the pricing of approved medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments appear likely, and we expect ongoing initiatives in the U.S. and Europe. These reforms could have an adverse effect on our ability to obtain timely regulatory approval for new products and on anticipated revenues from product candidates, both of which may affect our overall financial condition.

We are a "non-accelerated filer" and a "smaller reporting company" for SEC filing purposes and we cannot be certain if the reduced disclosure requirements applicable will make our common stock less attractive to investors.

For so long as we remain a 'non-accelerated filer" we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not 'non-accelerated filers," including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may find our common stock less attractive because we 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 or may decline.

In addition, Section 107 of the JOBS Act also provides that a "smaller reporting company" can take advantage of an extended transition period for complying with new or revised accounting standards. However, we chose to "opt out" of this extended transition period, and as a result, we intend to comply with new or revised accounting standards on the relevant dates that adoption of those standards may be required. Our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

Risks Relating to Our Financial Results and Need for Financing

Fluctuations in our quarterly operating results and cash flows could adversely affect the price of our common stock.

Our operating results will be affected by numerous factors such as:

- materially reduced revenue we receive as a result of refocusing our business and resources to the Orion II as we discontinued the production of the Argus II systems, and eliminated our marketing and implants of the Argus II;

- the status of our preclinical and clinical development programs;

- continued clinical results from our Early Feasibility Study of six subjects currently under way at UCLA and Baylor;
- the filing and acceptance of an IDE with the FDA to initiate a larger pivotal trial for regulatory approval;
- clinical results from conducting our larger pivotal trial(s):
- three of our six patient EFS study have had the devices explanted which could cause us to have difficulty recruiting future subjects for implantation;
- our ability to obtain regulatory approval of the Orion system in the U.S. and other additional jurisdictions;
- the emergence of products that compete with our product candidates;
- our ability to leverage Argus II technology for cortical stimulation using Orion;
- the status of our preclinical and clinical development programs, variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- any intellectual property infringement lawsuits to which we may become a party; and
- our ability to obtain reimbursement from government or private payors at levels we deem adequate to sustain our operations.

If our quarterly operating results fall below the expectations of investors or securities analysts, or if we experience delays in reaching commercialization of the Orion system the price of our common stock could decline substantially. Any quarterly fluctuations in our operating results and cash flows may cause the price of our stock to fluctuate substantially. We believe that, in the near term, quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We need additional capital to support our operations and growth. Additional capital may be difficult to obtain restricting our operations and resulting in additional dilution to our stockholders.

Our business requires additional capital for implementation of our long term business plan. We currently estimate that our existing cash and cash equivalents can sustain our operations for at least 24 months. The actual amount of funds that we will need for our business will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include:

- the amount of our future operating losses;
- legal, accounting and other costs associated with the proposed merger with NPM;
- expenses relating to the Early Feasibility Study of the Orion;
- ongoing commercialization planning for the Orion system;
- the amount of our research and development, including research and development for the Orion visual prosthesis, marketing and general and administrative expenses; and
- regulatory changes and technological developments in our markets.

In November 2017, we entered into an At-the-Market sales agreement (the “Sales Agreement”) with B. Riley FBR Inc. and H.C. Wainwright & Co., LLC, as agents (“Agents”) pursuant to which we may offer and sell, from time to time through either of the Agents, shares of our common stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the Securities and Exchange Commission. We agreed to pay the Agents a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. During January and February 2018, we sold approximately 278,000 shares of common stock for net proceeds of $4.0 million. During December 2019 we sold approximately 17,000 shares of common stock under this agreement for net proceeds of $0.1 million. During 2018 we also sold privately in at the market transactions an aggregate of approximately 1,966,000 shares of common stock for gross proceeds of approximately $22.0 million.

In a rights offering completed on February 22, 2019 we sold approximately 5,976,000 units, each priced at $5.792 for net cash proceeds of approximately $34.4 million. Each unit consisted of one share and one immediately exercisable warrant having an exercise price of $11.76 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 5,180,000 units in the offering for an aggregate investment of approximately $30 million.

In May 2020, March 2021 and June 2021we sold 7.5 million shares, 4.65 million shares and 11.5 million shares for net proceeds of $6.7 million, $24.5 million and $53.3 million, respectively. On December 8, 2020 we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors and $1.2 million from two unaffiliated shareholders. These loan obligations were unsecured, bore interest at 12% per year and were repaid during 2021.

As we require additional funds, we may seek to fund our operations through the sale of additional equity securities, debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or business units or to merge all or a portion of our business with another entity.

Our ability to utilize and benefit from our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2021, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $124.3 million and $76.8 million, respectively. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until these unused losses expire. However, we may be unable to use these losses to offset taxable income before our unused losses expire at various dates that range from 2035 through 2037 for federal net operating losses generated before 2018. Federal net operating losses generated for year 2018 and forward do not expire. State net operating losses expire from 2033 through 2041. 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, carryforwards 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.

We experienced an "ownership change" within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended, during the second quarter of 2017. The ownership change will subject our net operating loss carryforwards to an annual limitation, which will significantly restrict our 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 our stock at the time of the ownership change multiplied by a tax-exempt interest rate specified by the Internal Revenue Service. We have analyzed the available information to determine the amount of the annual limitation. Based on information available to us, the 2017 limitation is estimated to range between $1.4 million and $3.7 million annually. In total, we estimate that the 2017 ownership change will result in approximately $120 million and $56 million of federal and state net operating loss carryforwards expiring unused.

Risks Related to Our Business and Industry

We have incurred operating losses since inception and may continue to incur losses for the foreseeable future.

We have had a history of operating losses and we expect that operating losses will continue into the near term. Although we have had sales of the Argus II product, these limited sales were insufficient to cover our operating expenses. Given the limited addressable market of Argus II, we no longer market the Argus II and have focused all of our resources on the development of Orion. Our ability to generate positive cash flow will hinge on our ability to develop the Orion visual prosthesis, correctly price our product to our markets, and obtain government and private insurance reimbursement. As of December 31, 2021 we had stockholders' equity of $68.4 million and an accumulated deficit of $328.6 million. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Our business is subject to international economic, political and other risks that could negatively affect our results of operations or financial position.

We anticipate that revenue from Europe and other countries outside the U.S. may be material to our future long-term success. Accordingly, our operations are subject to risks associated with doing business internationally, including:

- currency exchange variations;
- extended collection timelines for accounts receivable;
- greater working capital requirements;
- multiple legal frameworks and unexpected changes in legal and regulatory requirements;
- the need to ensure compliance with the numerous regulatory and legal requirements applicable to our business in each of these jurisdictions and to maintain an effective compliance program to ensure compliance with these requirements;
- political changes in the foreign governments impacting health policy and trade;
- tariffs, export restrictions, trade barriers and other regulatory or contractual limitations that could impact our ability to sell or develop our products in certain foreign markets;
- trade laws and business practices favoring local competition; and
- adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations and the healthcare expenditure of domestic or foreign nations.

The realization of any of these or other risks associated with operating in Europe or other non-U.S. countries could have a material adverse effect on our business, results of operations or financial condition.

We are subject to stringent domestic and foreign medical device regulation and any unfavorable regulatory action may materially and adversely affect our financial condition and business operations.

Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical devices. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;
- result in product shortages due to regulatory delays;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing, and possibly post-market surveillance;
- involve modifications, repairs or replacements of our products;
- require design changes of our products;
- result in limitations on the indicated uses of our products; and
- result in our never being granted the regulatory approval we seek.

Any of these occurrences that we might experience will cause our operations to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition.

We have ongoing responsibilities under FDA and international regulations, both before and after a product is commercially released. For example, we are required to comply with the FDA's Quality System Regulation (QSR), which mandates that manufacturers of medical devices adhere to certain quality assurance requirements pertaining, among other things, to validation of manufacturing processes, controls for purchasing product components, and documentation practices. As another example, the Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury, or that a malfunction occurred which would be likely to cause or contribute to a death or serious injury upon recurrence. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize such medical devices, order a recall, repair, replacement, or refund of such devices, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA has been increasing its scrutiny of the medical device industry and the government is expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions by the FDA or other agencies. Additionally, the FDA may restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the disease or condition to be treated, the jurisdiction in which we are seeking approval and the regulations applicable to that particular medical device. Regulatory agencies, including those in the U.S., Canada, Europe and other countries where medical devices are regulated, can delay, limit or deny approval of a product for many reasons. For example,

- a medical device may not be safe or effective;
- regulatory agencies may interpret data from preclinical and clinical testing differently than we do;
- regulatory agencies may not approve our manufacturing processes;
- regulatory agencies may conclude that our device does not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, electrical safety; and
- regulatory agencies may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the U.S. Any of these occurrences could prove materially harmful to our operations and business.

Any revenue from sales of Orion will be dependent upon the pricing and reimbursement guidelines adopted in each country and if pricing and reimbursement levels are inadequate to achieve profitability our operations will suffer.

Our financial success is dependent on our ability to price our products in a manner acceptable to government and private payors while still maintaining our profit margins. Numerous factors that may be beyond our control may ultimately impact our pricing of Orion and determine whether we are able to obtain reimbursement or reimbursement at adequate levels from governmental programs and private insurance. If we are unable to obtain reimbursement or our product is not adequately reimbursed, we will experience reduced sales, our revenues likely will be adversely affected, and we may not become profitable.

Obtaining reimbursement approvals is time consuming, requires substantial management attention, and is expensive. Our business will be materially adversely affected if we do not receive approval for reimbursement of Orion under government programs and from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare Administrative Contractor level or by fiscal intermediaries in the U.S., and by regional or national funding agencies in Europe. Our business could be materially adversely affected if the Medicare program, local Medicare Administrative Contractors or fiscal intermediaries were to make such a determination and deny, restrict or limit the reimbursement of Orion. Similarly in Europe, these governmental and other agencies could deny, restrict or limit the reimbursement of Orion at the hospital, regional or national level. Our business also could be adversely affected if surgeons and the facilities within which they operate are not adequately reimbursed by Medicare and other funding agencies for the cost of the procedure in which they implant the Orion on a basis satisfactory to the administering surgeons and their facilities. If the local contractors that administer the Medicare program and other funding agencies are slow to reimburse surgeons or provider facilities for the Orion system, the surgeons and facilities may delay their payments to us, which would adversely affect our working capital requirements. Also, if the funding agencies delay reimbursement payments to the hospitals, any increase to their working capital requirements could reduce their willingness to treat blind patients who wish to have our Orion devices implanted. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business will be materially harmed.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

In order to obtain marketing approval for Orion we must demonstrate the safety and efficacy of Orion through clinical trials as well as additional supporting data. If Orion is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon Orion's development, cause it to have reduced functionality, or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We are conducting an initial feasibility clinical study of Orion at UCLA and Baylor, but we cannot guarantee that any positive results in this limited trial will successfully translate to a pivotal clinical trial. It is not uncommon to observe results in human clinical trials that are unexpected based on limited trials testing, and many product candidates fail in large clinical trials despite promising limited clinical trial results. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain marketing approval for their products. No assurance can be given that we will not encounter similar results in our Orion trials.

Human subjects in our clinical trials may suffer significant adverse events, tolerability issues or other side effects associated with the surgical implantation, chronic implantation, and chronic use of the Orion device. These events include, but are not limited to, the following (events that are also anticipated during or following explanation of the Orion device are identified with an asterisk (*)): intracranial hemorrhage*; subcutaneous hematoma*; vascular injury causing stroke or hemorrhage (e.g. injury to the superior sagittal sinus or posterior cerebral artery perforators)*; hydrocephalus*; intracranial hypotension or cerebrospinal fluid (CSF) leak*; headache or pain in the head, including deep pain*; tingling at the implant site*; brain edema*; infection*; meningitis*; implant site pain, swelling, discharge or effusion*; suture-related complications or stitch abscess*; skin erosion on and/or around the implant site; adverse tissue reaction to the implant; tissue damage at the implant/explant site*; cranial defect/bone damage*; decline in residual vision*; dizziness/syncope*; foreign body sensation at the implant site*; activation of motor or sensory neurons (e.g., muscle twitch); clinically symptomatic seizure*; development of epilepsy; coma*; death*; psychiatric events, including but not limited to mood changes, depression, suicidality, and psychosis*; neurological deficit, including but not limited to language (dysphemia), dysesthesias, paresis, paresthesia, visual field, motor deficit (including apraxia), and memory impairment*; drug hypersensitivity, adverse drug reaction, or therapeutic agent toxicity*; events related to any surgery and general anesthesia including cardiac risks, including stroke/transient ischemic attack, arrhythmia, cardiac arrest, and myocardial infarction*, venous thromboembolic (VTE) disease*; pneumonia*, urinary tract infection*, post-operative delirium*, postoperative constipation*, post-operative vomiting or nausea*, or post-operative fever*; injuries due to falls or bumps; skin irritation or burns; Orion system failure or malfunction; array migration; damage to the Orion electronics case; device interaction including the Orion device may interfere with the proper functioning of other electronic devices and emissions from other electronic equipment may interfere with the proper functioning of the Orion device; and (explant only) inability to remove all or part of the Orion device due to fibrosis or other reason.

No assurance can be given that we will not encounter adverse events in our Orion trials. The observed efficacy and extent of light perception and vision restoration for subjects implanted with Orion in our feasibility study may not be maintained over the long term, or may not be observed in a larger pivotal clinical trial. If general clinical trials of Orion fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of Orion.

For example, in June 2018, one subject in our Early Feasibility Study for Orion ("EFS") experienced a seizure while in the clinic when we were evaluating a specific video stimulation algorithm. The seizure resolved quickly with medication and the subject was released from the clinic without need for hospitalization or further treatment. The subject was allowed to continue using the Orion device after the serious adverse event was reviewed by a safety committee for the study and clinicians at the implanting institution.

In addition, in January 2019 we observed higher impedance levels on 11 of 60 electrodes with the first EFS subject implanted with the Orion device in January 2018. As a result, some of these electrodes no longer generated a phosphene, or observable spot of light, for the subject. Mechanical and software safeguards are built into the device to avoid excessive electrical stimulation and, as a result, the higher impedance levels do not pose any known safety risks to the subject. Given the pattern of high impedances, we took the precaution of disabling half of the electrodes on the array to ensure that other potentially affected electrodes were not used. The subject continued to use the device and participate in the clinical study. This subject was explanted (electively, to be able to undergo an MRI for an unrelated issue) after having been implanted for 42 months. Analysis of the explanted device indicated that it was still functional, and there were no signs of corrosion or material damage to the electrodes. There was visible damage to the cable, likely due to stresses in silicone attributable to the manufacturing process of the first batch of implants. The manufacturing process was changed for later implants. We currently have no indication that the issue exists with any of the Orion devices implanted in each of the other three current EFS subjects, each of whom has been implanted about 4 years. Prior to initiation of EFS, we subjected six Orion implants to accelerated aging tests and had no failures for what was the equivalent of up to 6.5 years.

In October 2019, we also observed changes to impedances (higher and lower) on most electrodes with the sixth EFS subject implanted with the device in January 2019. These impedance changes were coincident with a loss of most perception from the device, though there is no indication of a medical adverse event or a device defect. When examined again in November 2019, this sixth EFS subject showed improved perception and more normal impedances including performance on the 12-month visual function and functional vision assessments that was similar to pre-incident performance. We are currently investigating the possible root cause(s) for these changes, which may or may not be device related (that is, the possible root causes may be subject related). This subject was explanted (also electively) after having been implanted for 36 months. Analysis of this explanted device has not been completed.

In March 2022, a third EFS subject underwent elective explant after having been implanted for 46 months. Analysis of this explanted device has not been completed.

We cannot provide any assurance that we will not experience similar or other issues with any of the implanted Orion devices, be able to determine the root cause of the issue or to ascertain whether the issue is isolated or systemic in nature. Additional testing, investigation, design changes or mitigation activities may delay our plans to conduct additional clinical studies for Orion and/or our marketing approval and may have a material adverse effect on our business.

If device defects, significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting subjects to the clinical trial, subjects may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities may suspend clinical trials of Orion at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks. Devices developed in the prosthesis industry that initially showed promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude Orion from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its actual or perceived safety and tolerability profile. Any of these developments could materially harm our business, financial condition and prospects.

Should Orion obtain marketing approval, adverse effects associated with it may also develop after such approval and could lead to requirements for conducting additional clinical safety trials, placing additional warnings in the labeling, imposing significant restrictions on Orion, or withdrawing the Orion from the market while further incurring attendant costs of explants and exposure to litigation. We cannot predict whether Orion will cause significant adverse effects in humans that would preclude or lead to the revocation of regulatory approval. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

We are also subject to stringent government regulation in European and other foreign countries, which could delay or prevent our ability to sell our products in those jurisdictions.

We intend to pursue market authorizations for the Orion system and other product candidates in additional jurisdictions and undergo additional audits. For us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time and costs required to obtain approval may differ from that required to obtain an approval by the FDA. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. Violations of foreign laws governing use of medical devices may lead to actions against us by the FDA as well as by foreign authorities. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain all the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required for marketing our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, we must reestablish our ISO 13485:2016 certification and CE mark certification that have lapsed, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to maintain the ISO 13485:2016 certification or CE mark certification or other international regulatory approvals would prevent us from selling in some countries in Europe and elsewhere. The failure to obtain these approvals could harm our business materially

Even if we obtain clearance or approval to sell our products, we are subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential collaborative partners such as distributors, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

We have no large-scale manufacturing experience, which could limit our growth.

Our limited manufacturing experience may not enable us or any outside suppliers to make our products in the volumes that would be necessary for us to achieve a significant amount of commercial sales. Our product involves new and technologically complex materials and processes. As we move from making product for clinical trials to larger quantities for greater commercial distribution, we must develop new internal or external manufacturing techniques and processes that allow us to scale production. We may not be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and maintain our or outside manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. To date, our manufacturing activities have largely been to provide units for clinical testing and commercial sales of the now discontinued Argus II system. We may face substantial difficulties in reestablishing and maintaining manufacturing and obtaining the manufacturing from outside suppliers for our products at a larger commercial scale and those difficulties may impact the quality of our products and adversely affect our ability to increase sales.

To establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience delays or other difficulties in managing this growth.

As our development and commercialization plans and strategies evolve, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Our management team may have to use a substantial amount of time to manage these growth activities. Our future financial performance and our ability to commercialize the Orion system and our other product candidates and compete effectively will depend, in part, on our ability to timely and effectively manage any future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our proposed Orion development activity and business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

Risks Related to the Securities Market, and Ownership of Our Common Stock

Although we believe that our strategy to (i) leverage proven Argus II technology to develop the Orion visual cortical prosthesis and (ii) significantly expand our addressable market to include a portion of the almost six million patients who are blind from eye trauma, optic nerve disease and injury, diabetic retinopathy, glaucoma and other untreatable causes is more likely to address a better and faster way to treat many causes of blindness, we will incur material near term losses, market uncertainty and our stock may experience significant fluctuations as we continue to focus exclusively on Orion.

Based on assessments of the development of our Orion technology and the positive results in our Early Feasibility Study of the six subjects implanted with the Orion at UCLA Medical Center and at Baylor College of Medicine, in May 2019 our Board approved an acceleration of our transition from the Argus II to the Orion platform so we may more rapidly implement our strategy of treating blindness domestically and worldwide. As a result, we will or have:

- accelerated the changeover to, and upgrades of, our supply chain, manufacturing and quality assurance processes, as well as our facilities and talent pool to the Orion program and suspended production of Argus II system;

- manufacture Orion devices that we will require to support FDA approval of the Orion commercial product;

- seek to conduct a larger feasibility study or a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;

- terminated our commercial activities and other costs associated with expanding or maintaining Argus II sales;

- incurred non-cash impairment charges of approximately $1.2 million of which $0.5 million related to Argus II inventory and $0.7 million to write-down our fixed assets that were not directly related to the development of Orion in the year ended December 31, 2020;

- incurred cash severance and related expenses of approximately $800,000 in the year ended December 31, 2020 affecting employees primarily associated with Argus II operations and $0.2 million in material and overhead costs associated with Argus II; and

- reduce and assess our current level of support of the Argus II patient population.

As a result of this transition from Argus II, our future success will depend on the further development, regulatory approval and commercialization of the Orion product. Although we believe this more rapid changeover and implementation of our long-term strategy for treating blindness by Orion will provide us a sizable, commercially sustainable domestic and worldwide market for our products, in the near term we will incur significant losses, market volatility and regulatory uncertainty, including uncertainty associated with pricing and reimbursement coverage with no current assurance of market acceptance. No assurance can be given that this strategy will achieve domestic and regulatory approvals or result in commercial viability of our products or our company.

If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

We have experienced operating losses, and we may continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no revenue and do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital.

We will need to raise additional capital in order to continue to execute our business plan in the future however there is no assurance that we will be successful, or that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us. If we are unable to raise sufficient additional funds, we will need to further scale back our operations. The ongoing COVID-19 pandemic and resulting negative impact on the global macroeconomic environment and capital markets may make it more difficult for us to raise additional funds.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop our technologies and planned products to the stage of FDA approvals and a commercial launch. We have pursued and may pursue additional funding through various financing sources, including the private sale of our equity and debt securities, licensing fees for our technology and joint ventures with capital partners and project type financing. If we raise funds by issuing equity or equity-linked securities, dilution to some or all our stockholders will result. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish, or license to a third party on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our Orion features updated products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

If our development activity, regulatory efforts and substantial investments related to Orion do not result in a commercial product or if our company never achieves profitability or positive free cash flow, our stock price will decline, we will not be able to sustain operations and our stockholders may incur a complete loss of their investment in our company. The price of our common stock has been and may continue to be volatile and the value of your investment could decline.

Medical technology stocks have historically experienced high levels of volatility. The trading prices of our common stock have fluctuated and may continue to fluctuate substantially. The market price of our common stock may be higher or lower than the price you pay, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose substantially all or part of your investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include:

- announcements of new offerings, products, services, therapies, treatments or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- challenges to our patents and the patents and intellectual property that we license;
- United States and European approvals or denials of our products;
- price and volume fluctuations in the overall stock market from time to time;
- significant volatility in the market price and trading volume of medical device or technology companies in general;
- fluctuations in the trading volume of our shares or the size of our public float;
- actual or anticipated changes or fluctuations in our results of operations;
- whether our results of operations meet the expectations of securities analysts or investors;
- actual or anticipated changes in the expectations of investors or securities analysts;
- litigation involving us, our industry, or both;
- regulatory developments in the United States, foreign countries, or both;
- general economic conditions and trends;
- major catastrophic events;
- sales of large blocks of our common stock;
- departures of key employees; and
- an adverse impact on our business from any of the other risks cited herein.

In addition, if the market for medical technology stocks or the stock market, in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations and financial condition.

If shares of our common stock cease to be listed on a national exchange we will not be subject to compliance with rules requiring the adoption of certain corporate governance measures and as a result our stockholders may experience reduced protections.

Each of the New York Stock Exchange and the Nasdaq Stock Market LLC require the implementation of various measures relating to corporate governance for listed companies. These quantitative and qualitative measures are designed to enhance the integrity of corporate management and the securities markets and apply to securities which are listed on those stock exchanges. While we have adopted these measures, we will not be required to comply with many of the corporate governance provisions if our common stock is not listed on a national securities exchange. As a result, if we cease to be listed on national exchange and elect to cease compliance with any of the corporate governance measures required by national exchanges, our stockholders may lose protections afforded to listed companies.

If shares of our common stock cease to be listed on a national exchange they could become subject to the "penny stock" rules of the SEC and the trading market in our securities may become limited, which will make transactions in our stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Exchange Act establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that is no longer trading on a national exchange and has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (a) that a broker or dealer approve a person's account for transactions in penny stocks; and (b) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (a) obtain financial information and investment experience objectives of the person and (b) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form: (a) sets forth the basis on which the broker or dealer made the suitability determination; and (b) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

If shares of our common stock cease to be listed on a national exchange our securities will not be eligible for federal preemption rights and be subject to state "blue sky" laws which may affect our capabilities of raising capital.

Each state has its own securities laws, often called "blue sky" laws, which (i) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state. We do not know whether securities will be registered or exempt from registration under the laws of any state. If our securities cease to be listed on the national exchange, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our common stock. Registering or qualifying shares with states can be time consuming. Compliance and regulatory costs may vary from state to state and may adversely affect future financings and our ability to raise capital.

If our common stock is delisted from national exchange some institutional investors may not be allowed to purchase our shares and may be required to liquidate their current positions in our stock which could negatively affect the price and volatility of our shares.

Institutional investors may be restricted by their investment policies from investing in shares of companies that are not listed on a national exchange and may be required to liquidate their positions if our securities are delisted from a national exchange. Liquidations, should they occur, may increase volatility and cause wide fluctuations and further declines in the prices of our securities.

Delisting of our common stock from a national exchange can cause material dilution of our stock in future financings which can erode shareholder value.

If we are not able to maintain listing of our securities on Nasdaq the trading prices of our securities may decline and we may need to sell larger amounts of our securities to obtain needed operating capital, possibly at prices which are at further discounts to the market or upon other terms that are less favorable to us, subjecting our shareholders to material dilution and losses to their investment.

Sales of substantial amounts of our common stock in the public or private markets could reduce the price of our common stock and may dilute your voting power and ownership interest in us.

Sales of a substantial number of shares of our common stock in the public or private markets, or the perception that these sales could occur, as well as sales of shares by directors or officers, which have occurred or which may occur from time to time, could adversely affect the market price of our common stock and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Entities controlled by Gregg Williams, our Chairman of the Board, have the ability to influence or materially affect the outcome of matters submitted for stockholder approval, may limit your ability to influence outcomes of director elections and may have interests that differ from those of our other stockholders.

As of March 1, 2022, entities controlled and beneficially owned by Gregg Williams, our Chairman of the Board, own of record an aggregate of approximately 25.1% of the outstanding shares of our common stock (or 35.1% after giving effect to Mr. Williams' right to acquire beneficial ownership of 6,055,532 shares of common stock upon exercise of options or warrants). As a result, Mr. Williams is able to exercise substantial influence over all matters requiring stockholder approval, including

- electing or defeating the election of our directors;
- amending or preventing amendment of our articles of incorporation or bylaws;
- effecting or preventing a merger, sale of assets or other corporate transaction; and
- materially affecting the outcome of any other matter submitted to our stockholders for vote.

Mr. Williams may also have interests that differ from other stockholders and he may vote in a manner that is or could be deemed as adverse to interests of other stockholders. His significant stock ownership could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. This concentration of voting power may have the effect of deterring, delaying or impeding actions that could be beneficial to other stockholders. See also "*Risk Relating to the Proposed Merger*" below.

We do not intend to pay dividends for the foreseeable future and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any dividends on our common stock. We intend to retain any earnings to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the future. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to our equity incentive plans, would result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

The public market for our common stock has been volatile since completion of our initial public offering in November 2014. This volatility may affect the ability of our investors to sell their shares as well as the price at which they sell their shares.

We completed our initial public offering in November 2014. Since that time, our per share and day-to-day trading prices have often been volatile. This volatility may continue or increase in the future. The market price for the shares may be significantly affected by factors such as progress in the development of our technology, progress in our pre-clinical and clinical trials, agreements with research facilities or co-development partners, commercialization of our technology, coverage by third-party payors, variations in quarterly and yearly operating results, general trends in the medical device industry, and changes in FDA and foreign regulations affecting us and our industry. Furthermore, in recent years the stock market has experienced extreme price and volume fluctuations that are unrelated or disproportionate to the operating performance of the affected companies. Those broad market fluctuations may adversely affect the market price of our common stock.

Substantial future sales of shares of our common stock in the public market could cause our stock price to fall.

If our common stockholders (including those persons who may become common stockholders upon exercise of our options or warrants or upon completion of our acquisition of Nano Precision Medical Inc. as noted below) sell substantial amounts of our common stock, or the public market perceives that stockholders might sell substantial amounts of our common stock, the market price of our common stock could decline significantly. Such sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that our management deems appropriate.

We have the right to issue shares of preferred stock. If we were to issue preferred stock, it is likely to have rights, preferences and privileges that may adversely affect the common stock.

We are authorized to issue 10 million shares of "blank check" preferred stock, with such rights, preferences and privileges as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue preferred stock in one or more series, and to fix for any series the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights, and other rights, preferences and privileges for the preferred stock. No shares of preferred stock are presently issued and outstanding and we have no immediate plans to issue shares of preferred stock. The issuance of shares of preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could adversely reduce the voting rights and powers of the common stock and the portion of our assets allocated for distribution to common stockholders in a liquidation event, and could also result in dilution in the book value per share of our common stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of our Company, to the detriment of the holders of our common stock. We cannot assure you that we will not, under certain circumstances, issue shares of our preferred stock.

We may be assessed penalties and fines under California's board gender diversity statutes which require all publicly held companies based in California to meet the minimum requirements for female directors and directors from underrepresented communities on their boards of directors as of January 1, 2021.

As of January 1, 2021, all publicly held domestic or foreign corporations whose principal executive offices are located in California must meet the minimum requirements for female directors and for directors from underrepresented communities on their boards as required respectively by Women on Boards (SB 826) and Underrepresented Communities on Boards (AB 979). California law authorizes the California Secretary of State to impose fines to enforce compliance of SB 826 including a $100,000 fine for "failure to timely file board member information with the Secretary of State"; a $100,000 fine for a first violation, defined as "each director seat required by this section to be held by a female, which is not held by a female during at least a portion of a calendar year"; and a $300,000 fine for subsequent violations. We currently have one female director and under California's staggered compliance schedule as of December 31, 2021 we are required to have to have a minimum of three female directors. To date we have not filed board information with the Secretary of State. To our knowledge the Secretary of State has not to date imposed any fines. California has also instituted a parallel Board diversity compliance and reporting framework focused on directors "from an underrepresented community," which is defined to mean "an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender." Under the law's staggered compliance schedule a publicly held corporation whose principal executive offices are located in California must have at least one director from an underrepresented community on its board as of December 31, 2021. Companies that fail to timely comply with AB 979 will be fined $100,000 for the first violation and $300,000 for subsequent violations. We are not in compliance with these provisions.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, a novel strain of coronavirus, may materially and adversely affect our business and our financial results.

Public health epidemics or widespread outbreaks of contagious diseases could adversely impact our business. Any outbreak of contagious diseases, and other adverse public health developments, such as the recent novel strain of coronavirus (COVID-19), initially limited to a region in China and now affecting the global community, could impact our operations depending on future developments, which are highly uncertain, largely beyond our control and cannot be predicted with certainty. These uncertain factors include the duration of the outbreak, potential impact to our employees who may contract the disease or be subject to quarantine, new information which may emerge concerning the severity of the disease and the actions to contain or treat its impact, such as the temporary closure of facilities or diversion of healthcare resources, including clinical trial sites, the flow of goods in our supply chains and the ability for third-party service providers to fulfill their contractual obligations to us. These factors may disrupt our ability to conduct our existing and future clinical trials in the U.S., cause disruptions or restrictions on our employees' ability to work and have a material adverse effect on our overall productivity.

We may also experience a more challenging fundraising environment that may restrict our access to capital both publicly and privately amid the recent escalated volatility of the U.S. and global financial markets, increases in travel restrictions, quarantines, business shutdowns or warnings and from potential disruptions or delays of trade, scientific, and investor conferences. Should we experience any of these or other currently unforeseen consequences of a health epidemic, pandemic or other outbreak, including the current COVID-19 outbreak, our business, financial condition, and results of operations could be materially and adversely affected.

Risks Relating to the Proposed Merger.

The Proposed Merger is subject to the approval of our shareholders and certain other conditions, some or all of which may not be satisfied, or completed on a timely basis, if at all. Failure to complete, or unexpected delays in completing the proposed Merger could have material adverse effects on us.

Completion of the proposed Merger is subject to a number of closing conditions, including obtaining approval of our shareholders. We can provide no assurance that all required consents and approvals will be obtained or that all closing conditions will otherwise be satisfied (or waived, if applicable), and, even if all required consents and approvals can be obtained and all closing conditions are satisfied (or waived, if applicable), we can provide no assurance as to the terms, conditions, and timing of such consents and approvals or the timing of the completion of the proposed Merger. Many of the conditions to completion of the proposed Merger are not within our control, and we cannot predict when or if these conditions will be satisfied (or waived, if applicable).

Each party's obligation to consummate the proposed Merger is also subject to the accuracy of the representations and warranties of the other party (subject to customary materiality qualifications) and compliance in all material respects with the covenants and agreements contained in the Merger Agreement as of the closing of the proposed Merger, including, with respect to us, covenants regarding conducting our business in the ordinary course and to not engage in certain kinds of material transactions prior to closing. In addition, the Merger Agreement may be terminated under certain specified circumstances. As a result, we cannot assure you that the proposed Merger will be completed, even if our shareholders approve the proposed Merger, or that, if completed, it will be exactly on the terms set forth in the Merger Agreement or within the expected time frame.

We may not complete the proposed Merger within the time frame we anticipate or at all, which could have an adverse effect on our business, financial results, or operations.

If the proposed merger is not completed for any reason, including as a result of our shareholders or NPM shareholders failing to approve the proposed Merger, there may be various adverse consequences and Second Sight may experience negative reactions from the financial markets and from its customers and employees. For example, Second Sight's business may have been impacted adversely by the failure to pursue other beneficial opportunities due to the focus of management on the proposed Merger, without realizing any of the anticipated benefits of completing the proposed Merger. Further, if the Merger Agreement is terminated, the market price of Second Sight's common stock could decline to the extent that current market prices reflect a market assumption that the proposed Merger will be beneficial and will be completed.

Additionally, Second Sight has incurred and will incur substantial expenses in connection with the negotiation and completion of the transactions contemplated by the Merger Agreement, as well as the costs and expenses of preparing, filing, printing and mailing of a proxy statement/prospectus in connection with the proposed Merger, and all filing and other fees paid in connection with the preparation of the pertinent registration statement. Many of these fees and costs will be payable by us even if the proposed Merger is not completed and may relate to activities that we would not have undertaken other than to complete the proposed Merger. If the proposed Merger is not completed, Second Sight would have to pay these expenses without realizing the expected benefits of the proposed Merger.

In certain instances, the Merger Agreement requires us to pay a termination fee, which could affect the decisions of a third party considering making an alternative acquisition proposal.

If the Merger Agreement is terminated under certain circumstances, Second Sight may be required to pay a termination fee of $1 million or $5 million to NPM, depending on the reason for the termination. These liquidated damages limit our ability to consider alternative proposals and could affect the structure, pricing, and terms proposed by a third party seeking to acquire or merge with us and could discourage a third party from making a competing acquisition proposal, including a proposal that would be more favorable to our shareholders than the proposed Merger.

In the event the proposed Merger does not occur, the Company may not achieve the expected effects of the SAFE and could incur losses.

On February 4, 2022, the Company and NPM entered into an agreement ("SAFE") whereby we provided NPM pending closing of the proposed Merger an investment advance of $8 million. The SAFE provides that effective upon the termination date of the Merger Agreement, without completion of the proposed Merger, NPM will be required to issue the Company that number of shares of NPM capital stock which following that issuance will equal not less than 2.133% of the issued and outstanding shares of NPM Capital Stock on a fully diluted basis. In the event NPM completes an equity financing at a lower valuation, the Company may be eligible to receive additional shares of NPM Capital Stock as set forth in the SAFE. If the proposed Merger is completed, the SAFE will terminate.

The SAFE was entered pending closing of the proposed Merger and based on the expectation of the Company that the proposed Merger is more likely to occur than not. In the event the proposed Merger is not consummated, the Company may end up with illiquid assets in the form of future equity rights in NPM, a private, pre-revenue company. Future equity financings of NPM are beyond the Company's control and may never take place in the future. In the event the proposed Merger is not consummated, no assurance can be given that the Company will recover its investment or that or that the SAFE will not result in significant losses for the Company. A copy of the SAFE is attached as Exhibit 10.1 to our Form 8-K filed with the SEC on February 8, 2002 and is incorporated herein by this reference.

Certain of our directors have material interests in NPM. There is no assurance that the efforts of our Board, and of the special committee of our Board, to evaluate the fairness and effects of the proposed Merger were sufficient.

Three of our directors, Gregg Williams, Dean Baker, and Aaron Mendelsohn, are also directors of NPM and as to Gregg Williams and Aaron Mendelsohn have substantial investments and financial interests in NPM. Additionally, NPM was founded by Adam Mendelsohn, the son of Aaron Mendelsohn, a member of the Board. As a result, a special committee of the Board, consisting of members having no affiliation with NPM, was created for the purpose of evaluating the proposed Merger and determining whether the Merger Agreement and the proposed Merger are in the best interests of the Company. Following multiple consultations with financial and legal advisers, the special committee issued its recommendation for the Board to approve the proposed Merger on the terms of the Merger Agreement and the concurrently entered SAFE agreement. Notwithstanding the foregoing, there can be no assurance that the efforts of the special committee in connection with the proposed Merger were sufficient, nor can there be an assurance that the special committee was aware of and considered all the relevant facts and circumstances surrounding the proposed Merger. The opinion of the special committee was based on then-available information as the case may be, as of the date of each such opinion and does not reflect any subsequent events. Therefore, there can be no assurance that the terms of the proposed Merger are fair and in the best interest of the Company despite the opinion of the special committee.

Litigation challenging the Merger Agreement may prevent the proposed Merger from being consummated at all or within the expected timeframe.

Second Sight could be subject to litigation related to the proposed Merger or any failure to complete the proposed Merger or to proceedings commenced against Second Sight to perform its obligations under the proposed Merger Agreement. One of the conditions to the consummation of the proposed Merger is that the consummation of the proposed Merger is not restrained, made illegal, enjoined or prohibited by any order or legal or regulatory restraint or prohibition of a court of competent jurisdiction or any governmental entity. As such, if the plaintiffs in such potential lawsuits are successful in obtaining an injunction prohibiting the defendants from completing the proposed Merger on the agreed upon terms, then such injunction may prevent the proposed Merger from becoming effective, or from becoming effective within the expected timeframe.

We will be subject to various uncertainties while the proposed Merger is pending that may cause disruption and may make it more difficult to maintain relationships with business partners and continue our operations.

We are a relatively small company with limited personnel. Our efforts to complete the proposed Merger could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. A substantial amount of our management's and employees' attention is being directed toward the completion of the proposed Merger and, thus, is being diverted from our day-to-day operations. These adverse effects of the pendency of the proposed Merger could be exacerbated by any delays in completion of the proposed Merger or termination of the Merger Agreement.

The Merger Agreement subjects us to restrictions on our business activities prior to the consummation of the proposed Merger.

The Merger Agreement subjects us to restrictions on our business activities. It obligates us to generally conduct our businesses in the ordinary course (as more particularly defined in the Merger Agreement) until the proposed Merger is consummated or the Merger Agreement is terminated and to generally use our reasonable best efforts to (i) preserve our assets and business organization, (ii) maintain our existing relationships and goodwill with material customers, suppliers, distributors, governmental authorities and business partners, and (iii) to keep available the services of our officers and key employees. These restrictions could prevent us from pursuing certain business opportunities that arise prior to the consummation of the proposed Merger or the termination of the Merger Agreement .

We expect to incur substantial expenses related to the completion of the proposed Merger and the integration of our business with that of NPM.

We expect to incur substantial expenses in connection with the completion of the merger and the integration of a large number of processes, policies, procedures, operations, technologies and systems of NPM and Second Sight in connection with the proposed Merger. The management of the combined company may face significant challenges in implementing such integration, many of which may be beyond the control of management and which may result in increased costs and diversion of management's time and energy, as well as materially adversely impact the anticipated synergies of the merger and the business, financial condition and results of operations of the combined company. The integration process and other disruptions resulting from the proposed Merger may also adversely affect the combined company's relationships with employees, suppliers, and others with whom Second Sight and NPM have business or other dealings, and difficulties in integrating the businesses of Second Sight and NPM could harm the reputation of the combined company.

The combined company will continue to be subject to multiple risks and uncertainties.

Even if consummated, the proposed Merger entails significant risks for the combined company. The success of the proposed Merger will depend in part on the combined company's ability to retain the talent and dedication of key employees currently employed by Second Sight and NPM and integrate the businesses. We will list the material risk factors associated with the operations of the combined company following the proposed Merger in the pertinent registration statement of the Company filed in connection with the proposed Merger, if and when any of such registration statement is filed with the Securities and Exchange Commission.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal office and facilities are located at 13170 Telfair Avenue Sylmar, California 91342, which consists of approximately 17,290 rentable square feet at a base rent of approximately $17,000 per month. The sub-lease expires in March 2023. We believe that these premises are adequate for our foreseeable needs.

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 Form 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 claims damages of €5.1 million, about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000.

In November 2020, we and Pixium retained Oppenheimer & Co. Inc. as placement agent for a proposed private placement of securities in connection with the Business Combination. On April 1, 2021, we received an invoice from Oppenheimer for more than $1.86 million. This amount includes a requested commission of 6.5% on $27.9 million raised in our March 2021 private placement. We believe that claims for payment presented by this invoice are without merit.

On or about July 19, 2021, Martin Sumichrast filed a complaint with the Superior Court of the State of California, County of Los Angeles—Central District, claiming that he is entitled to compensation for services, as well as exemplary and other damages in an amount to be determined at trial but not less than $2 million, which arise from his allegedly arranging and securing financing that the Company obtained in May 2020 via a registered underwritten public offering of common stock. The complaint was dismissed by the court on January 18, 2022. Mr. Sumichrast appealed the dismissal, but the appeal was abandoned March 1, 2022.

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

(a) Market Price, Dividends and Related Matters

Second Sight's common stock is traded on the Nasdaq Capital Market under the symbol "EYES."

	High	Low
Fiscal Year Ended December 31, 2021		
First quarter	$ 15.48	$ 1.43
Second quarter	$ 9.43	$ 4.94
Third quarter	$ 4.75	$ 3.11
Fourth quarter	$ 3.41	$ 1.69
Fiscal Year Ended December 31, 2020		
First quarter	$ 6.05	$ 0.99
Second quarter	$ 2.10	$ 0.81
Third quarter	$ 1.04	$ 0.73
Fourth quarter	$ 3.22	$ 0.73

On March 17, 2022 there were approximately 77 shareholders of record.

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

Use of Proceeds from Financings

On June 25, 2021, we closed an underwritten public offering of 11,500,000 shares of common stock at a price of $5.00 per share for aggregate net proceeds of $53.3 million. We applied proceeds to further develop and enhance our products, support operations and for general corporate purposes.

On March 23, 2021, we closed our private placement to seven institutional investors of 4,650,000 shares of common stock at a price of $6.00 per share for aggregate net proceeds of approximately $24.5 million. We applied proceeds to further develop and enhance our products, support operations and for general corporate purposes.

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, 2021 and 2020 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

Second Sight Medical Products, Inc. (NASDAQ: EYES) has developed, manufactured and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. We are a recognized global leader in neuromodulation devices for blindness and are committed to developing new technologies to treat the broadest population of sight-impaired individuals.

Leveraging our 20 years of experience in neuromodulation for vision, we are developing the Orion® Visual Cortical Prosthesis System ("Orion"), an implanted cortical stimulation device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes, including glaucoma, diabetic retinopathy, optic nerve injury or disease and eye injury. Orion is intended to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses. The device is designed to bypass diseased or injured eye anatomy and to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the brain's visual cortex, where it is intended to provide the perception of patterns of light. We are conducting an Early Feasibility Study of the Orion device at the Ronald Reagan UCLA Medical Center in Los Angeles ("UCLA") and Baylor College of Medicine in Houston ("Baylor"). Regularly scheduled visits at both sites were paused in mid-March 2020 due to the coronavirus outbreak, however visits at UCLA resumed mid-September 2020 and Baylor resumed in December 2020. Our 36 month results, all of which were measured after the study resumed, indicate to us that:

- We have a good safety profile. Five subjects experienced a total of fourteen adverse events (AEs) related to the device or to the surgery, through February 2022. One was considered a serious adverse event (SAE), and all of the adverse events were in the expected category. The one SAE occurred at about three months post-implant, was resolved quickly, and did not require a hospital stay. There have been no serious adverse events due to the device or surgery since June 2018.

- The efficacy data is encouraging. We measure efficacy by looking at three measures of visual function: The first is square localization, where Orion subjects sit in front of a touch screen and are asked to touch within the boundaries of a square when it appears. The second is direction of motion, where subjects are asked to identify the direction and motion of lines on a screen. The third is grating visual acuity, a measure of visual acuity that is adapted for very low vision. Five subjects have completed these tests at 36-months. For these 36-month results, on square localization, five of five subjects tested in our feasibility study performed significantly better with the system on than off. On direction of motion, five of five performed better with the system on than off. On grating visual acuity, two of five tested had measurable visual acuity on the scale of this test (versus none who can do it with the device off). Another efficacy measurement of day-to-day functionality and benefit is FLORA, an acronym for Functional Low-Vision Observer Rated Assessment. FLORA is an assessment performed by an independent, third-party low vision orientation and mobility specialist who spends time with each of the subjects in their homes. The specialist asks each of the subjects a series of questions and also observes them performing 15 or more daily living tasks, such as finding light sources, following a sidewalk, or sorting laundry. The specialist then determines if the system is providing a benefit, if it is neutral, or if it is actually hurting the abilities of subjects to perform these tasks. FLORA results to date show that 4 out of 4 completing the FLORA at 36 months had positive or mild positive results indicating the Orion system is providing benefit. We reached agreement with the FDA in the fourth quarter of 2019 to utilize a revised version of FLORA as our primary efficacy endpoint in our pivotal trial for Orion, pending successful validation of the instrument.

No peer-reviewed data is available yet for the Orion system. We are currently negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

Our principal offices are located in Los Angeles, California.

Our first commercially approved product, the Argus® II Retinal Prosthesis System ("Argus II"), treats outer retinal degenerations, such as retinitis pigmentosa, also referred to as RP. The Argus II was the only retinal prosthesis approved in the United States by the Food and Drug Administration ("FDA"), and was the first approved retinal prosthesis in the world. RP is a hereditary disease, affecting an estimated 1.5 million people worldwide including about 100,000 people in the United States, that causes a progressive degeneration of the light-sensitive cells of the retina, leading to significant visual impairment and ultimately blindness. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

We conducted a qualitative patient preference information (PPI) study in 2021. In the study, an independent third party conducted guided interviews with 30 people who would potentially qualify for an implant such as the Orion System. Subjects were 18 – 74 with acquired bare light or no light perception bilaterally. They included balanced subsamples of sex, age, sudden vs. gradual vision loss, and time since vision loss. The one-hour semi-structured interviews were centered on a hypothetical device similar to Orion. The performance description was based on feedback from our Early Feasibility Study (EFS) participants implanted with Orion. The interviews also included a description of known risks for Orion, including the serious adverse event rate from the EFS. Throughout the interview, participants were asked for feedback on all aspects the hypothetical system; they also rated their interest in being implanted multiple times after each presentation of new information. These results created a valuable dataset for future device design and marketing. When asked at the end of the interview if they would be interested in being implanted with the hypothetical device, 33.3% replied with a strong yes, 10.0% a weak yes, 23.3% a weak no, and 33.3% a strong no.

Our prior market research found that there are 50,000 to 80,000 individuals in the United States with no light perception or bare light perception due to currently untreatable causes. Calculating 30% of 50,000 yields a minimum US market for Orion of 15,000 individuals, which does not include new cases each year.

We began selling the Argus II System in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. Given the limited addressable market of Argus II, we no longer market the Argus II and have focused all of our resources on the development of Orion.

We are also researching multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Orion user experience. In most cases, we collaborate with 3rd party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that we believe will be complimentary to our products include: eye tracking, object recognition and localization, thermal imaging and depth-based decluttering.

In March 2020, we were severely adversely impacted by the unprecedented economic shock caused by the COVID-19 pandemic and its related effects on our ability to secure financing for our planned activities. As a result, we significantly reduced our staff and expenses and conserved liquidity as we continued operations and explored our strategic options. These options included securing additional funding and exploring business alternatives that included partnering, acquiring, investing in or combining with businesses that may or may not be in a related industry. We were actively seeking opportunities to develop partnerships or collaborations with others to advance further Orion development, conduct pivotal trials and bring the product to market for the treatment of blindness. No assurances can be given that any of these initiatives will occur.

In early March 2020, we commenced clinical validation activities for the FLORA-20 instrument, the primary efficacy endpoint we have selected for our future pivotal clinical trial of Orion. In mid-March 2020, our validation activities were suspended as a result of public health concerns and related social distancing due to COVID-19. We are in the process of evaluating when activities related to the validation study can be resumed.

On March 27, 2020, the Board of Directors appointed Matthew Pfeffer, a member of our Board and Chairman of the Audit Committee of the Board, as acting Chief Executive Officer. On March 26, 2021, Scott Dunbar replaced Matthew Pfeffer, as acting Chief Executive Officer. Mr. Pfeffer resumed his role as director at such date.

In furtherance of our decision to withdraw Argus II from the market, we have terminated two post-market studies for Argus II in Germany and the U.S., terminated an extended non-significant risk study in the U.S. for Argus 2s, and suspended our technical support of Argus II worldwide.

In May 2020, we completed an underwritten public offering of 7,500,000 shares of common stock at an offering price of $1.00 per share for aggregate gross proceeds of $7.5 million, and net proceeds of approximately $6.7 million after deducting underwriting discounts, commissions and other offering expenses. Based on our current plans, existing cash and cash equivalents can sustain our operations into June 2021.

In May 2020, we entered into a Letter Agreement with Sylmar Biomedical Park, LLC (the “Landlord”) to terminate our facility leases in which we agreed to vacate the premises by June 18, 2020 and pay $210,730 to bring our leases current and pay a one-time early termination fee of $150,000. Prior to the early termination, we were obligated to pay aggregate base rent of approximately $0.9 million and common area maintenance expenses for the respective remaining terms of our leases in February 2022 and April 2023.

We completed our offer to rescind certain purchases of shares under our ESPP plan on May 27, 2020. We voluntarily offered to rescind the sale of shares of our common stock to employees who purchased those shares under the ESPP and to reimburse any losses upon the sale of our shares of our common stock for certain purchase periods because these shares may not have been exempt from registration under the Securities Act of 1933. The rescission of these share purchases resulted in the repurchase and cancelation of 39,467 shares of our common stock. The total cost for the repurchase of these shares and the reimbursement of any losses from the sale of such shares totaled approximately $270,000.

In June 2020, we commenced a process to dissolve our Swiss subsidiary which is ongoing.

On July 7, 2020, we entered into a lease with Sylmar Biomedical Park, LLC, to lease a smaller portion of our present facility. The new lease allowed us to significantly reduce our rent while maintaining operations and the current address. The term of the lease was from June 16, 2020 until December 31, 2020. We have terminated this lease and moved effective February 1, 2021.

On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest of $135,000 during the quarter ended June 30, 2021.

Effective February 1, 2021, we entered into a sub-lease to replace our existing headquarters and leased 17,290 square feet of office space at 13170 Telfair Avenue, Sylmar California 91342. Rent paid was $17,000 per month, until February 1, 2022 when it increased to $17,500 per month, plus operating expenses. We received full rent abatement for March 2021, and half rent abatement for March 2022. The sub-lease is for two years and two months. Neither we nor any affiliates are related to, or otherwise have any other relationship with, the other parties, other than the lease.

By letter dated February 26, 2021, the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) approved the Argus 2s Retinal Prosthesis System developed by Second Sight Medical Products, Inc. Argus 2s is a redesigned set of external hardware (glasses and video processing unit) to be used in combination with previously implanted Argus II systems for the treatment of retinitis pigmentosa (RP). We issued a press release on March 5, 2021 entitled *Second Sight Medical Products, Inc. Receives FDA Approval for the Argus 2s Retinal Prosthesis System.* Argus II, and now Argus 2s, are approved under a humanitarian device exemption (HDE). The approval is contingent upon the Company filing periodic reports with CDRH, use only under prescription, under the supervision of an institutional review board (IRB), and taking all other required actions under FDA rules. We expect that the Argus 2s will be adapted to be the external system for the next generation Orion Visual Cortical Prosthesis System currently under development

We are researching multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Orion user experience. In most cases, we collaborate with third-party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that we are currently researching include: eye tracking, object recognition and localization, thermal imaging and depth-based image decluttering.

We are subject to the risks and uncertainties associated with a business without revenues, including limitations on our operating capital resources and uncertain future demand for our product. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future. Based on our current plans, we do not have sufficient funds to continue operating our business at current levels for at least twelve months from the date of issuance of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity offerings, debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, or we may be unable to expand our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Capital Funding

Capital Funding

From inception, our operations have been funded primarily through the sales of our common stock and warrants, as well as from the issuance of convertible debt, research and clinical grants, and limited product revenue generated from the sale of our Argus II product. We have funded our business since 2019 has been primarily through the following transactions:

- On June 25, 2021, we closed an underwritten public offering of 11,500,000 shares of common stock at a price of $5.00 per share for aggregate net proceeds of $53.3 million

- On March 23, 2021, we closed our private placement to seven institutional investors of 4,650,000 shares of common stock at a price of $6.00 per share for aggregate net proceeds of approximately $24.5 million

- On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest of $135,000 during the quarter ended June 30, 2021

- On May 5, 2020, we closed our underwritten public offering of 7,500,000 shares of common stock at an offering price of $1.00 per share for aggregate net proceeds of approximately $6.7 million

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. Our second year grant of $1.4 million was approved on April 6, 2021 and our third year grant of $1.4 million was approved on May 12, 2021. As of December 31, 2021 we recorded $0.3 million of grant costs receivable, included in prepaid expenses and other current assets.

On September 17, 2019, we received a $2.4 million, four-year grant from the National Institutes of Health (NIH) to develop spatial localization and mapping technology (“SLAM”). This grant involves a joint collaboration with the Johns Hopkins University Applied Physics Laboratory and is intended to speed the integration of SLAM into future generations of Orion. The goal is to give Orion users the ability to localize objects and navigate landmarks in unfamiliar surroundings in real time. APL is the primary recipient of the grant. We have suspended our activities on the project until we clarify our future plans.

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 in both public and private offerings.

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 for at least twenty-four months. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

Insurance Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the price of the Orion system, our future sales would be limited without the availability of third-party reimbursement. In the U.S., coding, coverage, and payment are necessary for the surgical procedure and Orion system to be reimbursed by payors. Coding will need to be established for the device and the surgical procedure. Coverage and payment vary by payor. The majority of Argus II were patients are eligible for Medicare, and coverage is primarily provided through traditional Medicare, sometimes referred to as Medicare Fee-for-Service ("FFS") or Medicare Advantage. A small percentage of patients are covered by commercial insurers.

- **Medicare FFS patients** – Coverage is determined by Medicare Administrative Contractors (MACs) that administer various geographic regions of the U.S.

- **Medicare Advantage patients** – Medicare Advantage plans are required to cover the same benefits as those covered by the MAC in that jurisdiction. For example, if a MAC in a jurisdiction has favorable coverage for Orion, then typically Medicare Advantage plans in that MAC jurisdiction offer the same coverage. Individual hospitals and ASCs may negotiate contracts specific to that individual facility. In addition, procedural payment is variable and can be based on a percentage of billed charges, payment groupings or other individually negotiated payment methodologies. Medicare Advantage plans also allow providers to confirm coverage and payment for the procedure in advance of implantation.

- **Commercial insurer patients** – Commercial insurance plans make coverage and payment rate decisions independent of Medicare, and contracts are individually negotiated with facility and physician providers.

Currently, we are in the process of evaluating potential reimbursement pathways for Orion in the U.S. market. Compared to Argus II, which was largely catering to the Medicare patient population, Orion is expected to address a patient population with a more diverse and balanced payor mix due to our potential indications profile and expected younger patient population, on average. As Orion is a part of the FDA's Breakthrough Devices Program, we are closely evaluating a variety of fast-track reimbursement programs, including recent encouraging announcements from CMS proposing modernization of payment policies for medical devices that meet FDA's Breakthrough Devices designation. We have also approached some commercial payors and CMS to get their feedback to ensure our overall reimbursement strategy for Orion therapy will cater to their key data requirements.

Product and Clinical Development Plans

Orion. By further developing our visual cortical prosthesis, Orion, we believe we may be able to significantly expand our market to include nearly all profoundly blind individuals. The principle notable exceptions for potential use of the Orion are those who are blind due to otherwise currently treatable diseases, individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare. However, of the estimated 36 million blind people worldwide, there are approximately 5.8 million people who are legally blind due to causes that are not otherwise treatable (including RP) or age-related macular degeneration ("AMD"). We continue to develop and refine our estimates of the potential addressable market size as we evaluate the commercial prospects for Orion using a combination of published sources, third party market research, and physician feedback. We currently estimate over 500,000 individuals in the US are legally blind due to retinitis pigmentosa, glaucoma, diabetic retinopathy, optic nerve disease and eye injury. Of this population, we estimate the potential US addressable market is between 50,000 and 100,000 individuals with bi-lateral blindness at the light-perception level or worse. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Our objective in designing and developing the Orion visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for human vision. An Early Feasibility Study of the Orion device is currently underway at UCLA and Baylor. Regularly scheduled visits at both sites were placed on hold in mid-March due to Covid-19, however visits at UCLA resumed mid-September 2020 and Baylor resumed in December 2020. Our 36 month results for the five subjects indicate a good safety profile with encouraging efficacy data and benefits in helping subjects perform their daily living tasks. We believe these data are encouraging and support advancement of Orion into a larger pivotal clinical study. Early promising results are not necessarily indicative of results which may be obtained in large clinical trials. No assurance can be given that we will achieve similar results in our larger Orion clinical trials. No peer-reviewed data is available yet for the Orion system.

In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion. This designation is given to a few select medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review.

COVID-19 Pandemic

In accordance with local and state guidelines regarding the COVID-19 pandemic, we are requiring all of our employees to wear masks in the office and use their best judgement to work remotely or work in the office. While many of our employees are accustomed to working remotely, much of our workforce has not historically been remote. Although we continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available, restricting the ability to do business in person may create operational or other challenges, any of which could harm our business, financial condition and results of operations.

In addition, our clinical trials have been affected by the COVID-19 outbreak. Patient visits in ongoing clinical trials have been delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, some of our suppliers of certain materials used in the development of our product candidates are located in areas impacted by COVID-19 which could limit our ability to obtain sufficient materials for our product candidates. COVID-19 has and will continue to adversely affect global economies and financial markets and may result in an economic downturn that could affect demand for our product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 or its variants could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. See the Risk Factors for further discussion of the possible impact of the COVID-19 pandemic on our business.

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.

Patent Costs. We have over 300 domestic and foreign patents. 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 are included in general and administrative expenses in the consolidated statements of operations.

Results of Operations

Cost of sales. Cost of sales includes adjustments related to prior sales of our Argus II system. Our product involves technologically complex materials and processes.

Operating Expenses. We generally recognize our operating expenses as incurred in four general operational categories: research and development, clinical and regulatory, sales and marketing, 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, clinical and regulatory, sales and marketing 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, 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, such as the Orion Visual Cortical Prosthesis. We also expect to receive additional grants in the future that will be offset primarily against research and development costs.

- Clinical and regulatory expenses consist primarily of salaries, travel and related expenses for personnel engaged in clinical and regulatory functions, as well as internal and external costs associated with conducting clinical trials and maintaining relationships with regulatory agencies. We expect clinical and regulatory expenses to increase as we conduct clinical studies of potential future products such as the Orion Visual Cortical Prosthesis.

- Sales and marketing expenses consist primarily of salaries, commissions, travel and related expenses for personnel engaged in sales, marketing and business development functions, as well as costs associated with promotional and other marketing activities, including the cost of units consumed as demos or samples. We have suspended sales activities until such time as we are ready to market Orion.

- 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, 2021 and 2020

Cost of sales. Cost of sales were a negative $0.1 million in 2021 and a negative $0.5 million in 2020. In 2020, we ceased sales of Argus II, thus a significant portion of our manufacturing activity related to Orion prototypes were reported in our research and development expenses. In addition, we revised our expected warranty expenses due to our cessation of Argus II production and the related peripherals which resulted in a reduction of our warranty liability of $0.5 million in 2020 and $0.1 million in 2021.

Research and development expense. Research and development expense decreased from $4.8 million in 2020 to $2.4 million in 2021, a decrease of $2.4 million, or 51%. The decrease from the prior year was primarily due to decreased headcount and outside services.

Clinical and regulatory expense. Clinical and regulatory expense decreased from $1.7 million in 2020 to $0.4 million in 2021, a decrease of $1.3 million, or 78%. The decrease primarily related to costs associated with the Orion feasibility study which were reduced due to the pandemic restricting our patient access. We expect clinical and regulatory costs to increase in the future as we conduct additional clinical trials, such as the future pivotal study with Orion and if we enroll additional subjects.

Selling and marketing expense. Selling and marketing expense decreased from $0.7 million in 2020 to zero in 2021. This decrease in spending is the result of our cancelation of our commercial activities associated with the Argus II until such time as we produce a commercial product from our Orion platform.

General and administrative expense. General and administrative expense increased from $5.9 million in 2020 to $6.3 million in 2021, an increase of $0.4 million, or 6%. The increase is primarily related to increased legal costs and termination costs related to our terminated merger.

Restructuring charges. We recorded non-cash restructuring charges of $1.2 million in 2020 comprised of $0.5 million to fully reserve our inventory in connection with our decision to no longer market Argus II and $0.7 million to write-down our fixed assets that are not directly involved in the development of Orion. We recorded a cash charge of $0.2 million in material and overhead costs associated with Argus II and a $0.8 million for severance compensation and other associated costs all of which was substantially settled by December 31, 2020.

Net loss. The net loss was $8.9 million in 2021, as compared to $14.9 million in 2020. The $6.0 million decrease in net loss from 2020 to 2021 was primarily attributable to a $6.4 million decrease in operating expenses due to cessation of Argus II commercial activities.

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 in both public and private offerings.

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 for at least twenty-four months. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

On June 25, 2021, we closed an underwritten public offering of 11,500,000 shares of common stock at a price of $5.00 per share for aggregate net proceeds of $53.3 million.

On March 23, 2021, we closed our private placement to seven institutional investors of 4,650,000 shares of common stock at a price of $6.00 per share for aggregate net proceeds of approximately $24.5 million

On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest of $135,000 during the quarter ended June 30, 2021.

On May 5, 2020, we closed our underwritten public offering of 7,500,000 shares of common stock at an offering price of $1.00 per share for aggregate net proceeds of approximately $6.7 million.

Working capital was $68.0 million at December 31, 2021, as compared to a negative $0.9 million at December 31, 2020.

Cash Flows from Operating Activities

During 2021, we used $9.2 million of cash in operating activities, consisting primarily of a net loss of $8.9 million, and $0.5 million from a net change in operating assets and liabilities, offset by non-cash charges of $0.2 million for depreciation and amortization of property and equipment and stock-based compensation.

During 2020, we used $16.8 million of cash in operating activities, consisting primarily of a net loss of $14.9 million, and $3.7 million from a net change in operating assets and liabilities, offset by non-cash charges of $1.8 million for depreciation and amortization of property and equipment, stock-based compensation and restructuring charges for inventory impairment.

Cash Flows from Investing Activities

Investing activities in 2021 and 2020 used $14,000 and $0.3 million, respectively, of cash for the purchase of equipment. In 2020 the sale of assets held for sale provided cash of $0.4 million.

Cash Flows from Financing Activities

Financing activities provided $75.6 million of cash in 2021, including $77.8 million from the net proceeds from the issuance of common stock and warrants exercises reduced by the repayment of debt of $2.2 million.

Financing activities provided $8.6 million of cash in 2020, including $6.7 million from the net proceeds from the issuance of common stock and warrants and $2.2 million from the issuance of debt offset by the repurchase of ESPP shares and fractional shares of $0.3 million.

Off-Balance Sheet Arrangements

At December 31, 2021, 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, 2021 and 2020, our cash equivalents consisted solely of money market funds.

Exchange Rate Sensitivity

In 2021 and 2020, 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, 2021, 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 CAO, 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, 2021, 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, 2021 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 2022 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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
1.1	Form of Underwriting Agreement (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)
1.2	Form of Underwriting Agreement, dated June 22, 2021, between Registrant and ThinkEquity LLC (incorporated by reference to the registrant's Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on June 28, 2021)
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	Amended and Restated Bylaws of the Registrant, as currently in effect (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.)
4.1	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 Indemnification Agreement between Registrant and each of its directors and officers (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)+
10.2	2003 Equity Incentive Plan (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)+
10.3	2003 Form of Employee Option Agreement (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)+
10.4	2011 Equity Incentive Plan, as amended (incorporated by reference to registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 15, 2016)+
10.5	2011 Form of Employee Option Agreement (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)+
10.6	Sub-Sublease for Multiple Tenants, dated January 7, 2021, between Registrant and Triscenic Production Services, Inc. (incorporated by reference to the Current Report on Form 8-K, originally filed with the Securities and Exchange Commission on January 27, 2021)
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)
10.8	Second Sight Medical Product, Inc. 2015 Employee Stock Purchase Plan (incorporated by reference to registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 16, 2015)+
10.9	Executive Employment Agreement between Registrant and Will McGuire (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 25, 2015)+
10.10	Executive Employment Agreement between Registrant and John Blake (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2018)(+)
10.11	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated May 3, 2018 (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2018)
10.12	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated August 14, 2018 (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2018)
10.13	Executive Employment Agreement between Registrant and William Patrick Ryan(incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on September 4, 2018)(+)
10.14	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated October 18, 2018 (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 22, 2018)
10.15	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated December 12, 2018 (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2018)
10.16	Form of Securities Purchase Agreement, dated March 23, 2021, between Registrant and purchasers (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 26, 2021)
10.17	Registration Rights Agreement, dated March 23, 2021, between Registrant and purchasers(incorporated by reference to registrant's current report on Form 8-K filed with the(incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 26, 2021)
10.18	Placement Agency Agreement, dated March 23, 2021, between Registrant and ThinkEquity LLC (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 26, 2021)
10.19	Termination Agreement, dated March 23, 2021, between Registrant and Hudson Bay Capital Management (incorporated by reference to

	registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 26, 2021)
10.20	Form of Lock Up Agreement (incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 28, 2021)
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)
21.1	List of subsidiaries of the Registrant.(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)
23.1*	Consent of BPM LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Gumbiner Savett Inc., 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 28, 2022

Second Sight Medical Products, Inc.

/s/ Scott Dunbar
Scott Dunbar
Acting Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

The undersigned officers and directors of Second Sight Medical Products, 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/ Scott Dunbar Scott Dunbar	Acting Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2022
/s/ Edward Sedo Edward Sedo	Acting Chief Accounting Officer (Principal Financial and Accounting Officer)	March 28, 2022
/s/ Gregg Williams Gregg Williams	Chairman of the Board	March 28, 2022
/s/ Matthew Pfeffer Matthew Pfeffer	Director	March 28, 2022
/s/ Jonathan Will McGuire Jonathan Will McGuire	Director	March 28, 2022
/s/ Aaron Mendelsohn Aaron Mendelsohn	Director	March 28, 2022
/s/ Dean Baker Dean Baker	Director	March 28, 2022
/s/ Alexandra Larson Alexandra Larson	Director	March 28, 2022

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Second Sight Medical Products, Inc. and Subsidiary

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Second Sight Medical Products, Inc. and Subsidiary (the "Company") as of December 31, 2021, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows, for the year ended December 31, 2021, 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, 2021, and the results of their operations and their cash flows for the year ended December 31, 2021, 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.

/s/ BPM LLP
We have served as the Company's auditor since 2014.
Santa Monica, California
March 28, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Second Sight Medical Products, Inc. and Subsidiary

Opinion on the Consolidated Financial Statements

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Going Concern

The consolidated financial statements as of and for the year ended December 31, 2020 have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 1 to the financial statements included in the Form 10-K filed on March 16, 2021, the Company is subject to the risks and uncertainties associated with a business with one product line and limited revenues. The Company has incurred significant operating losses and negative operating cash flows from operations since inception. The Company's continued operations are dependent upon its ability to raise additional funds through equity or debt financing. There can be no assurances that the Company will be able to secure any such additional financing on acceptable terms and conditions, or at all. These conditions raised substantial doubt about the Company's ability to continue as a going concern as of December 31, 2020. Management's plans in regard to these matters are also described in Note 1 to the financial statements included in the Form 10-K filed on March 16, 2021. The consolidated financial statements as of and for the year ended December 31, 2020 do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Gumbiner Savett Inc.
We have served as the Company's auditor since 2014
Santa Monica, California
March 16, 2021

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY
Consolidated Balance Sheets
(In thousands)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,593	$ 3,177
Prepaid expenses and other current assets	914	1,092
Total current assets	70,507	4,269
Property and equipment, net	117	174
Right-of-use asset	228	—
Deposits and other assets	27	17
Total assets	$ 70,879	$ 4,460
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 519	$ 486
Accrued expenses	548	1,210
Accrued compensation expense	748	173
Accrued clinical trial and grant expenses	462	1,063
Current operating lease liabilities	185	—
Current debt	—	2,200
Total current liabilities	2,462	5,132
Long term operating lease liabilities	52	—
Total liabilities	2,514	5,132
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 39,409 and 23,214 at December 31, 2021 and December 31, 2020, respectively	347,940	270,126
Additional paid-in capital	49,389	49,314
Accumulated other comprehensive loss	(379)	(448)
Accumulated deficit	(328,585)	(319,664)
Total stockholders' equity (deficit)	68,365	(672)
Total liabilities and stockholders' equity (deficit)	$ 70,879	$ 4,460

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Years Ended December 31,	
	2021	**2020**
Net sales	$ —	$ —
Cost of sales	(130)	(500)
Gross profit	130	500
Operating expenses:		
Research and development, net of grants	2,370	4,836
Clinical and regulatory, net of grants	378	1,687
Selling and marketing	—	701
General and administrative	6,315	5,943
Restructuring charges	—	2,229
Total operating expenses	9,063	15,396
Loss from operations	(8,933)	(14,896)
Interest income	12	16
Net loss	$ (8,921)	$ (14,880)
Net loss per common share – basic and diluted	$ (0.27)	$ (0.72)
Weighted average shares outstanding – basic and diluted	32,817	20,575

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Consolidated Statements of Comprehensive Loss
(In thousands)

	Years Ended December 31,	
	2021	**2020**
Net loss	$ (8,921)	$ (14,880)
Other comprehensive income:		
Foreign currency translation adjustments	69	114
Comprehensive loss	$ (8,852)	$ (14,766)

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity(Deficit)
	Shares	Amount				
Balance, December 31, 2019	15,643	$ 264,008	$ 48,613	$ (562)	$ (304,784)	$ 7,275
Repurchase of fractional shares in connection with reverse stock split	(2)	(11)	—	—	—	(11)
Issuance of common stock and warrants in connection with rights offering, net of issuance costs	7,500	6,393	280	—	—	6,673
Issuance of common stock in connection with ATM	1	6	—	—	—	6
Stock-based compensation expense	—	—	421	—	—	421
Repurchase of ESPP shares as part of a rescission offer	(39)	(270)	—	—	—	(270)
Cash-less exercise of underwriter's warrants	96	—	—	—	—	—
Release of restricted stock units	15	—	—	—	—	—
Comprehensive loss:						
Net loss	—	—	—	—	(14,880)	(14,880)
Foreign currency translation adjustment	—	—	—	114	—	114
Comprehensive loss	—	—	—	114	(14,880)	(14,766)
Balance, December 31, 2020	23,214	270,126	49,314	(448)	(319,664)	(672)
Issuance of common stock, net of issuance costs	16,150	77,789	—	—	—	77,789
Stock-based compensation expense	—	—	75	—	—	75
Exercise of underwriter's warrants	45	25	—	—	—	25
Comprehensive loss:						
Net loss	—	—	—	—	(8,921)	(8,921)
Foreign currency translation adjustment	—	—	—	69	—	69
Comprehensive loss	—	—	—	69	(8,921)	(8,852)
Balance, December 31, 2021	39,409	$ 347,940	$ 49,389	$ (379)	$ (328,585)	$ 68,365

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (8,921)	$ (14,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	70	164
Stock-based compensation	75	421
Non-cash lease expense	9	3
Restructuring charges-inventory impairment	—	1,214
Changes in operating assets and liabilities:		
Accounts receivable	—	461
Inventories	—	529
Prepaid expenses and other assets	168	(785)
Accounts payable	63	(1,051)
Accrued expenses	(625)	(731)
Accrued compensation expenses	574	(2,524)
Accrued clinical trial and grant expenses	(601)	357
Net cash used in operating activities	(9,188)	(16,822)
Cash flows from investing activities:		
Purchases of property and equipment	(14)	(330)
Sale of assets held for sale	—	398
Net cash provided by (used) in investing activities	(14)	68
Cash flows from financing activities:		
Net proceeds from sale of common stock	77,789	6,679
Repurchase of ESPP shares and fractional shares in connection with reverse stock split	—	(281)
Debt financing (repayment)	(2,200)	2,200
Proceeds from exercise of options, warrants and employee stock purchase plan options	25	—
Net cash provided by financing activities	75,616	8,598
Effect of exchange rate changes on cash and cash equivalents	2	6
Cash and cash equivalents:		
Net Increase (decrease)	66,416	(8,150)
Balance at beginning of year	3,177	11,327
Balance at end of year	$ 69,593	$ 3,177
Supplemental disclosure of cash flow information;		
Cash paid during the period for:		
Interest	$ 135	$ -
Non-cash financing activities:		
Fair value of warrants issued in connection with issuance of common stock	$ -	$ 280

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Notes to Consolidated Financial Statements

1. Organization and Business Operations

Second Sight Medical Products, Inc. ("Second Sight," the "Company," "we," "us," "our" or similar terms), was incorporated in the State of California in 2003. We develop, manufacture and market implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. We are a recognized global leader in neuromodulation devices for blindness and are committed to developing new technologies to treat the broadest population of sight-impaired individuals.

In 2007, Second Sight formed Second Sight (Switzerland) Sàrl, initially to manage clinical trials for its products in Europe, and later to manage sales and marketing in Europe, the Middle East and Asia Pacific. As the laws of Switzerland require at least two corporate stockholders, Second Sight (Switzerland) Sàrl is 99.5% owned directly by us and 0.5% owned by an executive of Second Sight, who is acting as our nominee. Accordingly, Second Sight (Switzerland) Sàrl, is considered 100% owned for financial statement purposes and is consolidated with Second Sight for all periods presented.

We are currently developing the Orion® Visual Cortical Prosthesis System ("Orion"), an implanted cortical stimulation device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes, including glaucoma, diabetic retinopathy, optic nerve injury or disease, or forms of cancer and trauma. A feasibility study of the Orion device is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles ("UCLA") and Baylor College of Medicine in Houston ("Baylor").

Our commercially approved product, the Argus® II retinal prosthesis system ("Argus II"), entered clinical trials in 2006, received CE Mark approval for marketing and sales in the European Union ("EU") in 2011, and received approval by the United States Food and Drug Administration ("FDA") for marketing and sales in the United States in 2013. We began selling the Argus II in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. Given the limited addressable market of Argus II, we have made the decision to maximize capital efficiency by ceasing the production and sales of our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs.

Liquidity and Capital Resources

From inception, our operations have been funded primarily through the sales of our common stock as well as from research and clinical grants. Funding of our business since 2020 has been primarily provided by:

- On June 25, 2021, we closed an underwritten public offering of 11,500,000 shares of common stock at a price of $5.00 per share for aggregate net proceeds of $53.3 million
- On March 23, 2021, we closed our private placement to seven institutional investors of 4,650,000 shares of common stock at a price of $6.00 per share for aggregate net proceeds of approximately $24.5 million
- On May 5, 2020, we closed our underwritten public offering of 7,500,000 shares of common stock at an offering price of $1.00 per share for aggregate net proceeds of approximately $6.7 million
- On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest during the quarter ended June 30, 2021.

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 for at least twenty-four months. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

2. Summary of Significant Accounting

Policies Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of Second Sight and Second Sight Switzerland. 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 on financial position.

Cash and Cash Equivalents

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.

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. As a result of our decision to cease marketing of Argus II we recorded an impairment of $0.7 million related to our property and equipment used primarily for Argus activities. We sold a substantial number of our property and equipment for net proceeds of $0.4 million in July 2020.

Depreciation and amortization of property and equipment amounted to $0.1 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

Research and Development

Research and development costs are charged to operations in the period incurred and amounted to $2.4 million, and $4.8 million net of grant revenue, for the years ended December 31, 2021 and 2020, 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 $0.2 million for the years ended December 31, 2021 and 2020, 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 years ended December 31, 2021 and 2020 grants offset against operating expenses were $1.4 million and $1.3 million, respectively.

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, 2021 and 2020 include assets amounting to approximately $30,000 and $18,000, respectively, 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 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 Income or 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 and other comprehensive income (loss) is reported on the face of the financial statements. For the years ended December 31, 2021 and 2020 comprehensive income (loss) is the total of net income (loss) and other comprehensive income (loss) 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 years ended December 31, 2021 and 2020.

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 (loss). 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 carryforwards.

As of December 31, 2021, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $124.3 million and $76.8 million, respectively. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until these unused losses expire. However, we may be unable to use these losses to offset taxable income before our unused losses expire at various dates that range from 2035 through 2037 for federal net operating losses generated before 2018. Federal net operating losses generated for year 2018 and forward do not expire. State net operating losses expire from 2033 through 2041. 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, carryforwards 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.

We experienced an "ownership change" within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended, during the second quarter of 2017. The ownership change will subject our net operating loss carryforwards to an annual limitation, which will significantly restrict our 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 our stock at the time of the ownership change multiplied by a tax-exempt interest rate specified by the Internal Revenue Service. We have analyzed the available information to determine the amount of the annual limitation. Based on information available us, the 2017 limitation is estimated to range between be $1.4 million and $3.7 million annually. In total, we estimate that the 2017 ownership change will result in approximately $120 million and $56 million of federal and state net operating loss carryforwards expiring unused.

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. During 2021 and 2020, we reduced our warranty expense by $0.1 million and $0.5 million, respectively due to the discontinued sales of Argus II and the resultant end of the product warranty periods. The warranty liabilities are included in accrued expenses in the consolidated balance sheets.

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, 2021, and 2020, 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).

	2021	2020
Underwriter's warrants	10	77
Warrants issued with rights offerings	7,681	7,682
Common stock options	182	196
Total	7,873	7,955

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 reviews financial information presented on a consolidated basis. Accordingly, we consider ourselves to be in a single reporting segment, specifically the discovery, development and commercialization of visual prosthetics for profoundly blind individuals. We historically managed our Argus II and Orion programs on a consolidated basis within this single operating segment and do not assess the performance of our product lines or geographic regions on other measures of income or expense, such as program expense, operating income or net income. Our underlying technology consists of hardware components (implanted and wearable) and software. A vast majority of this underlying technology is shared between our Argus II and Orion branded systems. While we have ceased production and marketing the Argus II product indicated for individuals with retinitis pigmentosa, we are developing Orion as a next generation product with potential to treat a broader market of blind individuals, including the retinitis pigmentosa market.

Restructuring Charge

On March 31, 2020, due to the COVID-19 pandemic and related inability to secure additional funding, we laid off the majority of our employees and reduced our operating expenses significantly to allow for our continuing business operations. Due to our focus on Orion and wind down of selling and marketing activities related to Argus II, we recorded further impairment charges to our inventory of $0.5 million and $0.7 million to our fixed assets used primarily for Argus activities. We also incurred $1.0 million in severance payments and other costs associated with the wind down, all of which were substantially paid by December 31, 2020.

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, 2021 were $69.5 million. Money market funds included in cash equivalents at December 31, 2020 totaled $3.1 million.

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2020 and 2019 (in thousands).

	Total	Level 1	Level 2	Level 3
December 31, 2021:				
Money market funds	$ 69,487	$ 69,487	$ —	$ —
December 31, 2020:				
Money market funds	$ 3,122	$ 3,122	$ —	$ —

4. **Selected Balance Sheet Detail**

Property and equipment, net of accumulated depreciation and amortization

Property and equipment consisted of the following at December 31, 2021 and 2020 (in thousands):

	2021	2020
Laboratory equipment	$ 584	$ 584
Computer hardware and software	82	69
	666	653
Accumulated depreciation and amortization	(549)	(479)
Property and equipment, net	$ 117	$ 174

As a result of our decision to cease marketing of Argus II we recorded an impairment of $0.7 million in 2020 related to our fixed assets used primarily for Argus activities which is recorded in restructuring charges in the consolidated statements of operations. We sold a substantial number of our fixed assets for net proceeds of $0.4 million in July 2020.

Debt

On December 8, 2020, we borrowed $1 million from Gregg Williams, Chairman of the Board of Directors of the Company and $1.2 million from two unaffiliated shareholders. Each promissory note was unsecured and accrued interest at a rate of twelve percent (12%) per annum beginning on receipt of the loan amounts. We repaid the principal and accrued interest of $135,000 during the quarter ended June 30, 2021.

Contract Liabilities

Contract liabilities amounted to $335,000 at December 31, 2021 and 2020 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). Accrued expenses related to grants amounted to $0.5 million and $0.6 million for the years ended December 31, 2021 and 2020, respectively, and are included in accrued clinical trial and grant expenses on the consolidated balance sheets. During the years ended December 31, 2021 and 2020, grants offset against operating expenses were $1.4 million and $1.3 million, respectively.

6. Warrants

Underwriter's Warrant Issued in Public Offering

As a component of the funding underwriting fee of our May 5, 2020 public underwriting offer, we issued 375,000 warrants at an exercise price of $1.25 which expire on May 5, 2025. At December 31, 2021, 10,125 of the warrants are still outstanding. Warrants of 67,125 and 297,750 were exercised on a cash-less basis in 2021 and 2020 respectively, resulting in the issuance of 44,482 and 95,434 shares, respectively, of common stock.

Warrants Issued in Rights Offerings

On February 22, 2019, we completed a registered rights offering to existing stockholders in which we sold approximately 5,976,000 units at $5.792 per unit, which was the adjusted closing price of our common stock on that date. Each Unit consisted of a share of our common stock and a warrant to purchase an additional share of our stock for $11.76. The warrants have a five-year life and trade on Nasdaq under the symbol EYESW.

On March 6, 2017, we completed a registered rights offering to existing stockholders in which we sold approximately 1,706,000 units at $11.76 per unit, which was the adjusted closing price of our common stock on that date. Each unit consisted of a share of our comm11.76 on stock and a warrant to purchase an additional share of our stock for $11.76. The warrants had a five-year life but were extended to expire in February, 2024 to coincide with the February 22, 2019 warrants.

A summary of warrant activity for the years ended December 31, 2021 and 2020 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)
Warrants outstanding at December 31, 2019	7,682	11.76	
Granted	375	1.25	
Exercised	(298)	1.25	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2020	7,759	11.66	
Granted	—	—	
Exercised	(68)	1.25	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2021	7,691	11.75	2.21
Warrants exercisable at December 31, 2021	7,691	11.75	2.21

Warrants exercisable at December 31, 2021 had $4,000 in intrinsic value.

7. 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, 2021 and 2020, employer contributions to the Plan totaled $0.1 million and $0.1 million, respectively.

8. Equity Securities

On June 4, 2019, our shareholders approved an amendment to our articles of incorporation increasing our authorized no par value common shares from 200,000,000 to 300,000,000. The Board of Directors has the authority to establish the rights, preferences, privileges and restrictions granted to and imposed upon the holders of preferred stock and common stock.

Common Stock Issuable

For the twelve months ended December 31, 2020 our non-employee members of our Board were compensated $0.1 million and $0.1 million was accrued for future stock option grants at December 31, 2020. Stock option grants were suspended in 2021.

9. Stock-Based Compensation

Stock Options

Under the 2003 Plan, as restated in June 2011, we were authorized to issue options covering up to 437,500 shares of common stock. Effective June 1, 2011, we adopted the 2011 Equity Incentive Plan (the "2011 Plan"). The maximum number of shares with respect to which options could be granted under the 2011 Plan was 937,500 shares, which is offset and reduced by options previously granted under the 2003 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 either four or five years and expire ten years from the grant date. Both plans provide for accelerated vesting if there is a change of control, as defined in the plans.

The 2011 Plan was further amended in 2015, 2016, 2017 and 2018 bringing the number of shares issuable under the Plan to 1,500,000.

No option were granted under the 2011 Plan in 2021 and the plan expired at May 31, 2021.

We recognized stock-based compensation cost of $0.1 million and $0.4 million during 2021 and 2020, 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:

	2020
Risk-free interest rate	0.31% – 1.50%
Expected dividend yield	0%
Expected volatility	78.0% to 96.0%
Expected term	6.02 years
Weighted-average grant date calculated fair value	$ 3.72

A summary of stock option activity for the years ended December 31, 2021 and 2020 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, 2019	984	$ 21.75	
Granted	228	5.49	
Exercised	—	—	
Forfeited or expired	(1,016)	19.34	
Options outstanding at December 31, 2020	196	15.48	
Granted	—	—	
Exercised	—	—	
Forfeited or expired	(14)	12.95	
Options outstanding, vested and expected to vest at December 31, 2021	182	$ 15.68	6.59
Options exercisable at December 31, 2021	148	$ 18.38	6.25

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2021 (in thousands):

Exercise Price	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.90 to 0.91	22	8
$ 5.67 to 6.64	85	64
$ 13.84 to 16.40	52	52
$ 32.80 to 40.00	10	10
$ 72.08 to 104.72	13	14
	182	148

Stock options exercisable at December 31, 2021 had minimal intrinsic value. As of December 31, 2021, there was $0.1 million of total unrecognized compensation cost related to the outstanding stock options that will be recognized over a weighted average period of 2.03 years.

Employee Stock Purchase Plan

We adopted an employee stock purchase plan in June 2015 for all eligible employees. Under the plan, shares of our common stock may be purchased at six-month intervals at 85% of the lower of the closing price of the common stock (i) on the first trading day of the offering period or (ii) on the last trading day of the purchase period. An employee may purchase in any one calendar year shares of common stock having an aggregate fair market value of up to $25,000 determined as of the first trading day of the offering period. Additionally, a participating employee may not purchase more than 12,500 shares of common stock in any one offering period. At December 31, 2020, 241,719 shares were issued under the stock purchase plan. Although we originally registered shares for sale to employees under our 2015 Employee Stock Purchase Plan, as amended, we discovered that we had inadvertently exceeded the number of shares registered. We offered to rescind the sale of up to 45,468 shares of our common stock to persons who purchased those shares under the ESPP and to reimburse any losses upon the sale of up to an additional 2,470 shares of our common stock from persons who purchased shares from our ESPP but have resold such shares, in each case, because these shares may not have been exempt from registration under the Securities Act of 1933. It may also be possible that by not disclosing that the shares were unregistered, we may face contingent liability for noncompliance with applicable federal and state securities laws. The rescission of these share purchases resulted in the repurchase and cancelation of 39,467 shares of our common stock. The total cost for the repurchase of these shares and the reimbursement of any losses from the sale of such shares totaled approximately $270,000. The ESPP plan was suspended in 2020 and no shares were issued in 2021.

We may continue to have potential liability even after this rescission offer is made due to our issuances of securities in possible violation of the federal and state securities laws. The Securities Act does not expressly provide that a rescission offer will terminate a purchaser's right to rescind a sale of stock that was not registered or exempt from the registration requirements of the Securities Act. Should any offerees reject the rescission offer, we may continue to be potentially liable under the Securities Act for the purchase price or for certain losses if the shares have been sold.

Restricted Stock Units

The following table presented below summarizes Restricted Stock Unit (RSU) activity for the year ended December 31, 2020 (in thousands, except per share data):

	Number of Awards	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2019	61	$ 5.92
Awarded	—	
Vested	(15)	5.92
Forfeited/canceled	(46)	5.92
Outstanding as of December 31, 2020	—	

There was no activity in the year ended December 31, 2021. As of December 31, 2021, there was no unrecognized compensation cost related to RSUs as they have all been canceled.

The total stock-based compensation recognized for stock-based awards granted in the consolidated statements of operations for the years ended December 31, 2021 and 2020 is as follows (in thousands):

	2021	2020
Research and development	$ 22	$ 127
Clinical and regulatory	35	51
Selling and marketing	—	41
General and administrative	18	202
Total	$ 75	$ 421

10. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets as of December 31, 2021 and 2020 are summarized below (in thousands):

	2021	2020
Stock-based compensation	$ 401	$ 380
Research credits	8,629	8,848
Depreciation	(52)	(52)
Net operating loss carryforwards	33,033	30,492
Inventory write down	81	82
Other	454	375
Total deferred tax assets	42,399	40,125
Valuation allowance	(42,399)	(40,125)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of these deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon us attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2021 and 2020, management determined it was not more likely than not that our deferred tax assets will be realized, and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

No federal tax provision has been provided for the years ended December 31, 2021 and 2020 due to the losses incurred during such periods. Our effective tax rate is different from the federal statutory rate of 21% due primarily to operating losses that receive no tax benefit as a result of a valuation allowance recorded for such losses.

We experienced an “ownership change” within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended, during the second quarter of 2017. The ownership change will subject our net operating loss carryforwards to an annual limitation, which will significantly restrict our 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 our stock at the time of the ownership change multiplied by a tax-exempt interest rate specified by the Internal Revenue Service. We analyzed the available information to determine the amount of the annual limitation. Based on information available to us, the 2017 limitation is estimated to range between $1.4 million and $3.7 million annually. In total, we estimate that the 2017 ownership change will result in approximately $120 million and $56 million of federal and state net operating loss carryforwards, respectively, expiring unused.

As of December 31, 2021, after the ownership change under Section 382(g), we had federal and state income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $124.3 million and $76.8 million, respectively. The federal net operating loss carryforwards for years before 2018 will expire at various dates from 2035 through 2037. The federal net operating loss carryforwards for 2018 and forward do not expire. The state net operating loss carryforwards will expire at various dates from 2033 through 2041. We also have a federal and state research and development tax credit carryforwards totaling approximately $4,755,000 and $4,903,000, respectively. The federal research and development tax credit carryforwards will expire at various dates from 2023 through 2041. The state research and development tax credit carryforwards do not expire.

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. Product Warranties

A summary of activity of our warranty liabilities, which are included in accrued expenses in the accompanying consolidated balance sheets, for the years ended December 31, 2021 and 2020 is presented below (in thousands):

	2021	2020
Balance, beginning of year	$ 200	$ 1,575
Additions	—	—
Settlements	—	(875)
Adjustments and other	(150)	(500)
Total	$ 50	$ 200

During 2021and 2020 we reduced our warranty expense by $0.1 million and $0.5 million, respectively due to the discontinued sales of Argus II and the resultant end of the product warranty periods.

12. 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 of 10% based on the information available at commencement date in determining the present value of lease payments. On May 18, 2020 we entered into a Letter Agreement with Sylmar Biomedical Park, LLC (the “Landlord”), pursuant to which the parties agreed to accelerate the expiration dates of our existing leases (the “Leases”), to a date not later than June 18, 2020 (“Accelerated Termination Date”). We agreed to pay the Landlord (i) $210,730 to bring the Leases current (the “Owed Rent”) and to remit (ii) a one-time early termination fee in the amount of $150,000 (the “Early Termination Amount”). Prior to the early termination agreed in this letter we were obligated to pay aggregate base rent of approximately $0.9 million and common area maintenance expenses for the term remaining under the Leases through the respective expiration dates in February 2022 and April 2023. The Landlord acknowledged that as of the date of the Letter Agreement the Owed Rent and the Early Termination Amount constituted all amounts owing to the Landlord under the Leases. As a result of the letter agreement, we wrote down the right-of-use assets and extinguished related lease liabilities in the amounts of $2.3 million and $2.4 million, respectively. We paid an early termination fee of $150,000 which was expensed in our restructuring charges for the nine months ended September 30, 2020. Due to the termination of this lease there are no right-of-use assets or current or long term lease liabilities at December 31, 2020.

On January 22, 2021, we entered into a lease agreement, effective February 1, 2021, to sub-lease office space to replace our existing headquarters. We pay $17,000 per month, increasing to $17,500 per month on February 1, 2022, plus operating expenses, to lease 17,290 square feet of office space at 13170 Telfair Avenue, Sylmar, CA 91342. Additionally, we received full rent abatement for March 2021, and will receive half rent abatement during March 2022. The sub-lease is for two years and two months. We are not affiliates of, are not related to, or otherwise have any other relationship with, the other parties, other than the lease.

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:

2022	$ 201
2023	52
Total lease payments	253
Less imputed interest	(16)
Total lease liabilities	$ 237

Other supplemental information:	
Current operating lease liabilities	$ 185
Long term operating lease liabilities	52
Total lease liabilities	$ 237
Discount rate	10%

	For the year ended December 31, 2021	For the year ended December 31, 2020
Cash paid for operating lease liabilities	170	303

Rent expense, including common area maintenance charges, was $179,000 and $303,000 during 2021 and 2020, respectively.

13. Commitments and Contingencies

License Agreements

We have exclusive licensing agreements to utilize certain patents, related to the technology for visual prostheses. We have determined that only the agreement with Doheny Eye Institute (“DEI”) applies to Argus II and Orion requiring future royalty payments through 2033. We have agreed to pay to DEI royalties for licensed products sold or leased by us. The royalty rate is 0.5%, based on related net sales of the patented portion of licensed products.

In the past we have paid royalties under a license agreement with the Johns Hopkins University (“JHU”). The JHU agreement expired, along with the underlying patents, in 2018. Pursuant to these agreements, DEI and JHU, we have incurred costs of approximately $1,000 for the year ended December 31, 2020 and zero in 2021.

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. 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 years ended December 31, 2021 and 2020 were $0.4 million and $1.1 million, respectively.

California Board Representation

As of January 1, 2021, all publicly held domestic or foreign corporations whose principal executive offices are located in California must meet the minimum requirements for female directors and for directors from underrepresented communities on their boards as required respectively by Women on Boards (SB 826) and Underrepresented Communities on Boards (AB 979). California law authorizes the California Secretary of State to impose fines to enforce compliance of SB 826 including a $100,000 fine for "failure to timely file board member information with the Secretary of State"; a $100,000 fine for a first violation, defined as "each director seat required by this section to be held by a female, which is not held by a female during at least a portion of a calendar year"; and a $300,000 fine for subsequent violations. The Company currently has one female director and under California’s staggered compliance schedule as of December 31, 2021 the Company is required to have to have a minimum of three female directors. To date the Company has not filed board information with the Secretary of State. To the knowledge of the Company the Secretary of State has not to date imposed any fines. California has also instituted a parallel Board diversity compliance and reporting framework focused on directors "from an underrepresented community," which is defined to mean "an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender." Under the law’s staggered compliance schedule a publicly held corporation whose principal executive offices are located in California must have at least one director from an underrepresented community on its board as of December 31, 2021. Companies that fail to timely comply with AB 979 may be fined $100,000 for the first violation and $300,000 for subsequent violations. The Company is not in compliance with these provisions and has accrued $100,000 as of December 31, 2021.

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 and thus the Company does not believe any further loss accrual is necessary.

In November 2020, we and Pixium retained Oppenheimer & Co. Inc. as placement agent for a proposed private placement of securities in connection with the Business Combination. On April 1, 2021, we received an invoice from Oppenheimer for more than $1.86 million. This amount includes a requested commission of 6.5% on $27.9 million raised in the private placement. We believe that claims for payment presented by this invoice are without merit.

On or about July 19, 2021, Martin Sumichrast filed a complaint with the Superior Court of the State of California, County of Los Angeles—Central District, claiming that he is entitled to compensation for services, as well as exemplary and other damages in an amount to be determined at trial but not less than $2 million, which arise from his allegedly arranging and securing financing that the Company obtained in May 2020 via a registered underwritten public offering of common stock. The complaint was dismissed by the court on January 18, 2022. Sumichrast appealed the dismissal, however the appeal was subsequently abandoned on March 1, 2022.

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. Quarterly Financial Summary (unaudited)

(in thousands, except per share data)	Three Months Ended December 31, 2021	September 30, 2021	June 30, 2021	March 31, 2021
Product sales	$ —	$ —	$ —	$ —
Gross profit	$ 130	$ —	$ —	$ —
Operating loss	$ (1,291)	$ (2,503)	$ (2,296)	$ (2,843)
Net loss	$ (1,283)	$ (2,501)	$ (2,294)	$ (2,843)
Net loss per share – basic and diluted	$ (0.03)	$ (0.06)	$ (0.08)	$ (0.12)

	Three Months Ended December 31, 2020	September 30, 2020	June 30, 2020	March 31, 2020
Product sales	$ —	$ —	$ —	$ —
Gross profit	$ 500	$ —	$ —	$ —
Operating loss	$ (1,274)	$ (1,602)	$ (3,116)	$ (8,904)
Net loss	$ (1,291)	$ (1,603)	$ (3,100)	$ (8,886)
Net loss per share – basic and diluted	$ (0.06)	$ (0.07)	$ (0.15)	$ (0.57)

14. Subsequent Event

On February 4, 2022, we entered into an agreement and plan of merger with Nano Precision Medical, Inc., a California corporation (“NPM”), and, upon and subject to the execution of a joinder, NPM Acquisition Corp., a California corporation and a wholly-owned subsidiary of the Company (“Merger Sub”). Pursuant to the agreement and subject to the terms and conditions set forth therein, NPM will merge with and into Merger Sub (the “Merger”), and upon consummation of the merger, Merger Sub will cease to exist and NPM will become a wholly-owned subsidiary of the Company. Upon completion of the merger and subject to shareholder approval, the Company will change its name as agreed in the future and intends to change its trading symbol as NPM requests in writing following consultation with Nasdaq.

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, and 333-237266) of our report dated March 28, 2022, relating to the consolidated financial statements of Second Sight Medical Products, Inc. as of and for the year ended December 31, 2021, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP

March 28, 2022
Santa Monica, California

Exhibit 23.2

GUMBINER SAVETT INC.
CERTIFIED PUBLIC ACCOUNTANTS
& BUSINESS ADVISORS
Santa Monica, California

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, and 333-237266) of our report dated March 16, 2021, relating to the consolidated financial statements of Second Sight Medical Products, Inc. as of and for the year ended December 31, 2020, which appears in this Annual Report on Form 10-K.

/s/ Gumbiner Savett Inc.

March 28, 2022
Santa Monica, 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, Scott Dunbar, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Second Sight Medical Products, 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 28, 2022

/s/ Scott Dunbar
Scott Dunbar
Acting 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, Edward Sedo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Second Sight Medical Products, 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 28, 2022

/s/ Edward Sedo
Edward Sedo
Acting Chief Accounting 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), Scott Dunbar, Acting Chief Executive Officer (Principal Executive Officer) and Edward Sedo, Acting Chief Accounting Officer (Principal Financial and Accounting Officer) of Second Sight Medical Products, 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, 2021, 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 28, 2022

/s/ Scott Dunbar
Scott Dunbar
Acting Chief Executive Officer
(Principal Executive Officer)

Date: March 28, 2022

/s/ Edward Sedo
Edward Sedo
Acting Chief Accounting 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 Second Sight Medical Products, 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.