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, 2019

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.)*

12744 San Fernando Road, Suite 400, 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 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, 2019, computed by reference to the closing sales price on the Nasdaq Capital Market on June 28, 2019, was approximately $32.6 million.

As of March 13, 2020, the number of shares of the Registrant's common stock outstanding was 15,657,700.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2019 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. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

SECOND SIGHT MEDICAL PRODUCTS INC.

FORM 10-K

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PART I

Item 1. Business

Our Company

Overview

Second Sight Medical Products, Inc. (NASDAQ: EYES) develops, manufactures and markets 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 retinitis pigmentosa ("RP"), 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. A six-subject Early 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 12 month results for the six subjects indicate to us that:

- We have a good safety profile. Subjects experienced a total of eight adverse events ("AEs") over this time period related to the device or to the surgery. One was considered a serious adverse event ("SAE"), and all of the adverse events were in the expected category. The SAE was resolved quickly and did not require a hospital stay. We believe the safety profile experienced thus far with the first six subjects supports advancement into a larger clinical study.
- The efficacy data is encouraging. We measure efficacy by looking at three measures of visual function and one measure of functional vision. The first visual function measure is called 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. On Square Localization, five of the six subjects performed significantly better with the system on than off at 12 months. On Direction of Motion, all six performed significantly better on than off at 12 months. On our third visual function measure, Grating Visual Acuity, three had measurable visual acuity on the scale of this test (versus none who can do it with the device off) at 12 months. Our functional vision measure is called FLORA, which stands 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 and surrounding area. 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. Our FLORA results at 12 months show that for five of the six subjects, the Orion system is providing benefit. The system's impact was rated as neutral for the sixth subject. 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 in early 2020. While our experience is limited to the six subjects in our Early Feasibility Study, we believe these efficacy data indicate that Orion performance is comparable to Argus II performance and support advancement into a larger clinical study.

No peer-reviewed data is available yet for the Orion system. We are currently evaluating whether to enroll additional feasibility subjects while simultaneously 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. We also have an office in Lausanne, Switzerland, that manages our clinical and research and development operations in Europe, the Middle East and Asia.

Our current commercially approved product, the Argus® II Retinal Prosthesis System ("Argus II"), treats outer retinal degenerations, such as retinitis pigmentosa, also referred to as RP. 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. The Argus II is 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. A relatively small subset of RP patients would be eligible for the Argus II since the approved baseline vision for the Argus II is bare light perception or worse in the better seeing eye. We commissioned third-party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the U.S. with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

The Argus II system provides an artificial form of vision that differs from the vision of people with normal sight. It does not restore normal vision nor slow the progression of the disease. A majority of patients receive a significant benefit from the Argus II, however results can vary and some patients report receiving little or no benefit. By creating an artificial form of useful vision in patients who otherwise have total sight loss, the Argus II can provide benefits that include:

- restoring independence through a renewed ability to navigate independently in unfamiliar environments;
- improving patients' orientation and mobility, such as locating doors and windows, avoiding obstacles, and following the lines of a crosswalk;
- allowing patients to feel more connected with people in their surroundings, such as seeing when someone is approaching or moving away;
- providing patients with enjoyment from being "visual" again, such as locating the moon, tracking groups of players as they move around a field, and watching moving streams of lights from fireworks;
- enabling some patients to re-enter the workforce with more confidence that becomes possible because of Argus II; and
- improving patients' well-being and ability to perform activities of daily living.

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 encouraging results for Orion in our Early Feasibility Study and the limited addressable market of Argus II, we made the decision in 2018 to reduce our investment in Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. In October 2018, we announced a restructuring of our international commercial activities and personnel. This restructuring resulted in a decision to no longer support new implants of Argus II in Turkey, Iran, Singapore and Russia. We retained a team that continues to support existing Argus II patients and our implanting clinics that we refer to as Centers of Excellence in all markets. We recognized approximately $0.6 million of pre-tax restructuring charges in the fourth quarter of fiscal year 2018 in connection with this restructuring, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Based on assessments of the development of our Orion technology and Orion's positive results in our Early Feasibility Study of the six subjects implanted with the Orion at UCLA and Baylor, on May 10, 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 with the Orion technology. As a result, we have or will:

- 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 systems;
- manufacture additional Orion devices that we will require to support FDA approval of the Orion as an approved commercial product;
- seek to expand our Early Feasibility Study and/or conduct a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;
- reduced our commercial activities and other costs associated with expanding or maintaining Argus II sales;
- limit future sales and implants of the Argus II to finished units and inventory on hand;
- incurred non-cash impairment charges of our inventory of approximately $2.6 million in the year ended December 31, 2019;
- incurred cash severance and related expenses of approximately $800,000 in the year ended December 31, 2019 affecting employees primarily associated with Argus II operations; and
- continue to support our existing and future Argus II users, which includes our commitment to bring the Argus 2s enhanced software and peripherals to market in a limited manner which may improve the current user experience.

We received CE Mark and conditional FDA approval for our Argus 2s (pending final Agency review of some labeling changes) which includes our next generation of wearables and a more powerful video processing unit (VPU), an improved camera and more ergonomically and esthetically pleasing glasses. This technology will serve as the base for our next generation Orion system to be used in our U.S. pivotal study.

We are actively developing multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Argus II or 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.

Currently, after more than 20 years of research and development, more than $260 million of investment and over $34 million of grants awarded in support of our technology development, we employ over 110 people in the development (research, engineering and clinical), manufacture, and support of the Argus II and Orion.

We are subject to the risks and uncertainties associated with a business with one product line and diminishing commercial product revenues, including limitations on our operating capital resources and uncertain 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.

Our Technology

Both the Orion and Argus II systems work 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 Argus II array is implanted on the surface of the retina and directly stimulates the retina to bypass degenerated photoreceptor cells and to stimulate remaining viable retinal cells. The pulses generated by both systems 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 both the Orion and Argus II systems (including their implantable components) possess 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, 2019, we have more than 300 issued patents and over 40 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 six years, with one patient having used the device for over 10 years. The Argus II system has been implanted in over 300 patients. The average implant duration for these patients is nearly four 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 expect to reach consensus with the FDA on design specifics during 2020 with an expected IDE filing date in the first half of 2021. 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 anticipate completing the validation study in the first half of 2020. 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, including those blind due to AMD and RP, or 5.8 million excluding age-related macular degeneration[2] ("AMD") and RP. 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 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.

In the U.S., 1.3 million people are legally blind[3]. 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 due to retinitis pigmentosa, glaucoma, diabetic retinopathy, optic nerve disease and eye injury. 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 Argus or 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 minimizing our overall investment in Argus II activities.

Global Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the price of the Argus II system, our 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 Argus II system to be reimbursed by payors. Coding has been established for the device and the surgical procedure. The same will be required for Orion. Coverage and payment vary by payor. The majority of Argus II 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. Positive coverage decisions for the Argus II are effective in eight of 12 MAC jurisdictions (comprising 31 states, two territories and the District of Columbia). Effective January 1, 2019, the Centers for Medicare and Medicaid Services (CMS) established a 2019 average payment rate of $152,500 for both the procedure and the Argus II Retinal Prosthesis System.

- **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 the Argus II, then typically Medicare Advantage plans in that MAC jurisdiction offer the same coverage for the Argus II. Individual hospitals and ASCs may negotiate contracts specific to that individual facility, which may include additional separate payment for the Argus II implant system. 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 Argus II procedure in advance of implantation. Over the last several years a large majority of all Medicare Advantage pre-authorization requests for Argus II procedures were granted.

- **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.

Within Europe, Argus II obtained reimbursement approval or funding in Germany (NUB Innovation Funding Program), France (Forfait Innovation Funding Program), and one region of Italy (Regional Funding). We were in the process of obtaining reimbursement through the Commissioning through Evaluation ("CtE") program in England and discontinued these efforts in connection with our restructuring of the Argus II program. If Argus II was still available, the Forfait Innovation Funding Program and CtE program could have resulted in permanent national funding for Argus II assuming positive outcomes in the program, especially in France where we were in the final stages of the reimbursement review process.

Currently, we are in the process of evaluating potential reimbursement pathways for Orion in the U.S. market. Compared to Argus II, which is largely catering to the Medicare patient population, Orion is expected to address a patient population with a diverse and more 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. During the second half of 2019, we 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.

During the year ended December 31, 2019, 16 individuals in the U.S. were implanted with the Argus II technology. These patients were primarily covered by Medicare FFS or Medicare Advantage plans and the remainder had private commercial, Veteran's Administration or other insurance plan coverage.

Product and Clinical Development Plans

In November 2017, we received full FDA approval to begin the first human clinical Early Feasibility Study of the Orion visual prosthesis system. During 2018, we implanted and activated the first five subjects in the study, four subjects at UCLA and one subject at Baylor. To date, clinical results have been positive. In addition, during the second quarter of 2018, we submitted and received approval from the FDA to enroll a sixth subject. We implanted the sixth subject at Baylor in January 2019. We are currently evaluating whether to enroll additional feasibility subjects while simultaneously negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

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:

- 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. There are two primary approaches to this: 1) Epiretinal Prosthesis, which is placed on the surface of the retina, and 2) Subretinal Prosthesis, which is placed beneath the retina and between the retina and choroid.

- 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. 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 groups worldwide are developing an intracortical visual prosthesis with electrodes that penetrate the brain, but none have advanced to human clinical trials of potentially commercializable devices.

  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 are also being recruited in Los Angeles for a similar study. No data is yet available as to safety or efficacy of these implantations. A patient in Japan with AMD was implanted with induced pluripotent stem (ips) cells. These are mature cells reprogramed to be stem cells.

- 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 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 in 2018. We believe that there is virtually no overlap with our current market since our patients generally are older (Argus II is indicated for an age minimum of 25 in the U.S.). The other company also injects better sighted patients since its treatment is aimed at improving residual vision. In contrast, Argus II seeks to create artificial vision where vision is completely lost. Pricing for these injections is reported to be approximately $850,000 for both eyes.

- 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. The regulatory body in the UK, the Medicines and Healthcare products Regulatory Agency, has recently cleared optogenetic clinical trials to begin.

- 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 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").

Commercial efforts to develop retinal implants by others include:

- Pixium Vision SA: 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 one device 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, but to our knowledge none of these efforts has resulted in a completed system that has been tested clinically in patients.

- 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 (preclinical 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 none has received FDA approval to begin clinical trials in the U.S.

To our knowledge, no other retinal prosthesis has been successful in long-term human trials, with the Argus II system currently the sole implant available to commercial patients for treating RP in the U.S., Canada, the EU, and elsewhere. We anticipate that our competitors are unlikely to obtain significant commercial traction in the EU until they have developed in-depth clinical data showing the reliability and functionality of their products.

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 $1.6 million as of December 31, 2019, which is based upon our historical experience rate.

Our Manufacturing and Quality Assurance

We have a single manufacturing facility, located at our principal office in Los Angeles, California. The manufacturing areas at this location are housed in a single building, which includes approximately 10,000 square feet of controlled environment rooms (CERs) suitable for implant manufacturing. We currently utilize less than half of this space for Argus II implant production. At the same site we maintain spaces for assembling the wearable (non-implantable) components of our system and for labeling, receiving and shipping, and stockroom functions. Finished goods are held at this location and at our contracted logistics partner in Europe.

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.

Our manufacturing department currently employs 22 persons and the quality assurance department has an additional nine members. We operate a single day shift, and at this staffing level we can manufacture approximately 5 devices per month. We believe that the space available at the current facility when fully utilized and operating at two full shifts will prove sufficient to build and assemble a total of approximately 100 Orion devices per month.

Employees

As of December 31, 2019, we had 112 employees, including approximately 31 in operations; 12 in selling, marketing and distribution; 52 in clinical, regulatory and research and development; and 17 in administration. Of these persons, we employed 107 in the United States and 5 in Europe. 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 12744 San Fernando Road, Suite 400, Sylmar, California 91342, which consists of approximately 45,351 rentable square feet at a current base rent of about $39,800 per month. Our lease expires in February 2022 and grants us an option to extend the lease term for an additional 60 months. We believe that these premises are adequate for our foreseeable needs.

Our European office is located on the Innovation Park at École Polytechnique Fédérale de Lausanne (EPFL), Rue Jean-Daniel Colladon, CH 1015 Lausanne, Switzerland. As part of our restructuring and staffing reductions we have renegotiated this lease to a base rent of 1,573 CHF or about $1,623 starting on January 1, 2019 based upon current exchange rates.

Legal Proceedings

We are not a party to any threatened or pending legal proceedings, other than those involving Pixium described in Risk Factors related to intellectual property and other legal matters.

Available Information

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

Item 1A. Risk Factors

The statements that are not historical facts contained in this Form 10-K are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements reflect the current belief, expectations or intent of our management and are subject to and involve certain risks and uncertainties. Many of these risks and uncertainties are outside of our control and are difficult for us to forecast or mitigate. An investment in our common stock is speculative and involves a high degree of risk. In addition to the risks described elsewhere in this Form 10-K and in certain of our other filings with the U.S. Securities and Exchange Commission, the following important factors, among others, could cause our actual results to differ materially from those expressed or implied by us in any forward-looking statements contained herein or made elsewhere by or on behalf of us. The risks described below are not the only risks we face. If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties later materialize, that are not presently known to us or that we currently deem immaterial, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common stock or our warrants could decline, and you may lose all or part of your investment in our shares or in our warrants.

Risks Related to Dependence on Our Commercial Products

We are dependent on the development and acceptance of our new device under development, the Orion Visual Cortical Prosthesis System (a modified version of the Argus II system), to treat various causes of blindness and our transition from the Argus II to the Orion may not result in the development of a commercial product.

Based on assessments of the development of our Orion technology and Orion's positive results in our Early Feasibility Study of six subjects implanted with Orion at UCLA and Baylor, on May 10, 2019 our Board approved an acceleration of our transition from Argus II to the Orion platform so we may more rapidly implement our strategy of treating blindness with the Orion technology. As a result, we have ceased producing and deemphasized marketing the Argus II system and have made other changes in our operations including:

- we are implementing the changeover to our manufacturing and quality assurance processes as well as our facilities and resources to the Orion program;
- producing the additional Orion devices that we will require to support FDA approval of the Orion program as we suspend the production of the Argus II devices;
- evaluating the expansion of our Early Feasibility Study and/or conducting a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the United States;
- reducing our commercial activities and other costs associated with expanding or maintaining Argus II sales domestically and outside the United States;
- limiting future sales and implants of the Argus II to finished units and inventory on hand; and
- continuing to support our existing and future Argus II users, which includes our commitment to bring the Argus 2s enhanced software and peripherals, following regulatory approval, to market in a limited manner which may improve the current user experience.

If we are unable to implement the foregoing business strategy we may not be able to commercialize our product, we will continue to incur losses and we may not be able to continue viable operations.

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, 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 Argus II 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 preventable causes. Other visual prosthesis companies such as Pixium Vision SA, based in Europe, are developing retinal implant technologies to partially restore some vision in blind patients mainly from age related macular degeneration. Pixium Vision'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 have filed for market approval with the FDA. To our knowledge Pixium has obtained an IDE to begin the required clinical trials in the U.S. for its PRIMA product, which is directed toward AMD. 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. Our customers consider many factors including product reliability, clinical outcomes, product availability, inventory consignment, price, and product services provided by the manufacturer. Market share 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 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 technologies 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.

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, 2019, we had net revenue of $3.4 million and incurred a net loss of $33.6 million. Our total accumulated deficit through December 31, 2019, was $304.8 million.

As a result of our limited commercial operating history, revenue is difficult to predict with certainty. We expect expenses to increase in the future as we expand our activities in connection with the further development of Orion and complete planned enhancements of Argus II. 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.

Our financial statements have been prepared assuming we are a going concern.

Our ability to continue as a going concern is dependent upon our ability to obtain additional financing, obtain further operating efficiencies, reduce expenditures, attain favorable gross margins and ultimately, generate greater sales and create profitable operations. Such financings may not be available or may not be available on reasonable terms. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our independent registered public accounting firm, in its report on our 2019 consolidated financial statements has raised substantial doubt about our ability to continue as a going concern which may negatively affect the price of our common stock.

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.

The warrants we issued in our recent rights offering to shareholders may create an overhang on the market and have a negative effect on the market price for our common stock.

We issued approximately 1,706,000 warrants in connection with a completed rights offering in 2017 and approximately an additional 5,976,000 warrants in connection with a completed rights offering in February 2019. These warrants expire on March 14, 2024. These warrants may be used in arbitrage transactions and can cause the price of our common stock to remain below the warrant exercise price of $11.76 regardless of our performance.

We have identified and reported on weaknesses in our internal control over financial reporting in past periods and if our internal control over financial reporting were again to become ineffective, investor confidence in our Company may be adversely affected.

In response to identified and reported material weaknesses in our internal control over financial reporting in prior years, we updated and improved our system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. In connection with the audit of our consolidated financial statements in past years, our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We have remediated the reported weaknesses and have completed written documentation of our internal control policies, procedures and controls and fully completed testing of our key controls. We evaluated and tested these key controls and procedures and 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.

If we were in the future unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm were unable to express an opinion on the effectiveness of our internal controls when it is required to do so by the applicable rules, we could cause investors to lose confidence in the accuracy

and completeness of our financial reports, which could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the regulatory authorities.

Our remediation efforts while effective at present may not enable us to avoid a material weakness in the future.

Risks Related Our Rescission Offer to certain Employee Stock Purchase Plan Participants

Although we originally registered shares for sale to employees under our 2015 Employee Stock Purchase Plan, as amended, which we refer to as our "ESPP," the company discovered that it had inadvertently exceeded the number of shares registered. We are voluntarily offering 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, and may face resale or other limitations, we may face contingent liability for noncompliance with applicable federal and state securities laws. Therefore, we are conducting a rescission offer to those employee purchasers to attempt to extinguish any federal or state registration requirements or related contingent liability. This offer is being made to those persons who purchased common stock from our ESPP on November 30, 2018, May 31, 2019 and November 30, 2019, which we refer to as the "Offering Dates." We refer to the shares sold on the Offering Dates as the "Eligible Rescission Shares." The 45,468 shares eligible for rescission represents the total number of Eligible Rescission Shares that had not been resold by ESPP participants as of March 12, 2020. We expect that if our offers to rescind for those who are still holding shares and to reimburse losses for those who sold their shares will not exceed $281,000 if exercised in full.

Our inadvertent failure to register with the Securities and Exchange Commission the sale of certain shares of our common stock under the ESPP may have constituted a violation of Section 5 of the Securities Act (which generally requires registration of offers and sales of securities) and may give rise to liability under Section 12 of the Securities Act (which generally provides a rescission remedy for offers and sales of securities in violation of Section 5) as well as potential liability under the antifraud provisions of federal and state securities laws. Because the sale of our common stock through the ESPP may not have complied with the federal securities laws, the purchasers of those shares may be able to assert claims against us. In an effort to reduce the risk of claims being made against us in the future or, if made, the amount of potential liability, we are making a rescission offer to purchasers.

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.

Materials necessary to manufacture Orion and Argus II 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 Argus II 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 for the next generation of the Argus II system, 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.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, 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.

Our executives have significant medical device, regulatory, sales and marketing, operational, and/or corporate finance experience. Our 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 has appointed Gregg Williams, our Chairman, as acting chief executive officer. Mr. Williams, an experienced executive, has been involved with our company almost since inception and while we believe that we have qualified, experienced senior management who are capable of implementing our Orion business plan to commercialization, no assurance can be given that we will be able to retain a qualified successor. 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 of improvements in the Argus II system or new product candidates. Further, the validity of some of our patents has been challenged.

Pixium Vision (Pixium) has filed eleven currently pending oppositions in the European Patent Office (EPO) challenging the validity of European patents owned by Second Sight. Second Sight has one currently pending opposition in the EPO challenging the validity of a Pixium patent. The EPO proceedings involving Pixium and Second Sight are:

- EP1497483 – *Platinum Electrode* – Upheld in the Opposition Division, appeal possible.
- EP1874397 – *Flexible Circuit Electrode Array* – Upheld in modified form in the Opposition Division, appeal pending.
- EP1937352 *Sub-Threshold Stimulation to Precondition Neurons for Supra-Threshold Stimulation* – cancelled in the Opposition Division, appeal pending.
- EP1945835 – *Platinum Electrode Surface Coating and Method for Manufacturing the Same* – (Pixium joined by Retina Implant) Cancelled in the Opposition Division, appeal pending.
- EP1949437 - *Implantable Microelectronic Device and Method of Manufacture* –Upheld in the Opposition Division, appeal possible.
- EP2061549 – *Package for an Implantable Neural Stimulation Device* - Cancelled in the Opposition Division, appeal pending.
- EP2077892 – *Automatic Fitting for a Visual Prosthesis* – Upheld in the Opposition Division, appeal pending.
- EP2089100 – *Flexible Circuit Electrode Array* – Upheld in the Opposition Division, appeal possible.
- EP2185236 – *Implantable Device for the Brain* – Upheld in the Opposition Division, appeal pending.
- EP2192949 – *Return Electrode for a Flexible Circuit Electrode Array* – Cancelled in the Opposition Division, appeal pending.
- EP2219728 *Electrode Array for Even Neural Pressure Having Multiple Attachment Points* –Upheld in the Opposition Division, appeal pending.
- EP1986733 (Pixium's Patent opposed by Second Sight) – *Device with Flexible Multilayer System for Contacting or Electro-stimulation of Living Tissue Cells or Nerves* –significantly narrowed 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 40 pending patent applications worldwide as of December 31, 2019. 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 expanded commercialization efforts for Argus II and our development and commercialization activities for other product candidates including 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 inserted into the eye, 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 the Argus II system and other 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.

We are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, and any adverse results from such evaluation could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish a report by our management on our internal control over financial reporting. The report contains, among other matters, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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.

The revenues we generate and 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 suspend the production of the Argus II systems, deemphasize our marketing and limit implants of the Argus II to finished units and inventory on hand;
- 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);
- 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 with 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 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.

Our business requires additional capital for implementation of our long term business plan. We believe our cash, cash equivalents and other investments, together with revenue generated from the current sales and cash resources, will not be sufficient to fund our operations for at least twelve months from the date of issuance of this report. We currently estimate that our existing cash and cash equivalents can sustain our operations into April 2020. 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;
- 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.

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 further commercialization of the Argus II system, 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 independent registered public accounting firm, in its report on our 2019 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern.

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 have not been sufficient to cover our operating expenses. Our sales of the Argus II is currently limited to finished units and inventory on hand, as a result of which we expect diminishing revenue from the Argus II. 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, 2019 we had total stockholders' equity of $7.3 million and an accumulated deficit of $304.8 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.

Our 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 Argus II 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 at UCLA and Baylor a six subject initial feasibility clinical study of Orion, 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 explantation 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 generate a phosphene, or observable spot of light, for the subject. The subject continues to use the device and is continuing to participate in the clinical study. 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 are not used. Root cause(s) for the higher impedance levels cannot be conclusively determined while the device remains implanted but could include any combination of the following: potential manufacturing defects, damage due to improper or excessive handling of the device, materials chosen for the design, and related processes. The first subject has been implanted with the device for 24 months, four subjects have been implanted for 20-22 months, and one subject for 12 months. We currently have no indication that the issue exists with any of the Orion devices implanted in each of the other five EFS subjects. 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 (i.e., may be subject related) and may or may not continue to improve or worsen again.

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 maintain our ISO 13485:2016 certification and CE mark certification, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to maintain the ISO 13485:2003

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.

The CE marking regulations in the European Union are subject to a significant effort to strengthen the regulatory regime for medical devices which, if adopted, will make the approval process more time consuming and costly for us to obtain access to and continue to market within the European markets.

We are subject to an annual audit of compliance with the rules necessary to support our CE Mark. In April 2017 the European Commission published a new regulatory scheme that imposes significant additional obligations on medical device companies. As such, devices with a current CE marking, such as the Argus 2s, will have to comply with additional, more challenging regulatory obligations. The changes being made to the regulations include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third-party testing by government accredited groups for some types of medical devices, and tightened and streamlined quality management system assessment procedures. With the additional provisions adopted by the European Parliament, the European Medicines Agency (EMA) may be involved in regulation of some types of medical devices in the qualification and monitoring of notified bodies (NBs), and enhancing the roles of other bodies, including a new Medical Devices Coordination Group (MDCG). The European Parliament's revisions also impose enhanced competence requirements for NBs and "special notified bodies" (SNBs) for specific categories of devices, such as implantable devices. These changes are anticipated to result in stricter conformity assessment procedures. The medical device industry anticipates that there will be significant changes under these initiatives to the regulation of medical devices which will increase the time and costs for obtaining CE marking after May 2020. A grace period of four years provides medical device companies the opportunity to be compliant with the new standard before May 2024. We anticipate being audited to this new standard by 2024.

Our CE Mark registration must be renewed on a periodic basis. We commenced our recertification audit in June 2019 and received CE certification of the Argus 2s system through May 2024. The Medical Device Single Audit Program (MDSAP) is a new multi-national standard adopted by Australia, Brazil, Canada, Japan and the United States. MDSAP may impose a higher compliance burden than CE Mark through more rigorous audit requirements. In connection with our strategic decision to accelerate Orion development, we decided not to pursue MDSAP compliance during 2019 and suspended our commercial activities for Argus II in Canada until further notice. We believe we are able to support current Argus II users through Health Canada's special access program, but no assurance of approval can be made.

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

Our limited manufacturing experience may not enable us to make 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 and we currently experience low yields on our manufacturing process. As we move from making small quantities of our product for clinical trials to larger quantities for greater commercial distribution, we must develop new 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 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 Argus II system. We may face substantial difficulties in establishing and maintaining manufacturing 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 Argus II 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 existing 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.

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

As of December 31, 2019, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $97.6 million and $43.3 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 2039. 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 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, including the Retinitis Pigmentosa population, we will incur material near term losses, market uncertainty and our stock may experience significant fluctuations as we complete the transition from the Argus II to 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 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 expand our Early Feasibility Study and/or conduct a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;
- reduced our commercial activities and other costs associated with expanding or maintaining Argus II sales;
- limit future sales and implants of the Argus II to finished units and inventory on hand;
- incurred non-cash impairment charges of approximately $2.6 million relating to Argus II inventory in the year ended December 31, 2019;
- incurred cash severance and related expenses of approximately $800,000 in the year ended December 31, 2019 affecting employees primarily associated with Argus II operations; and
- continue to support our existing and future Argus II patient population, which includes our commitment to bring the Argus 2s enhanced software and peripherals, following regulatory approval, to market in a limited manner which may improve the current patient experience.

Our decision to accelerate Orion development has likely cause physicians or individuals who are eligible for Argus II to delay implantation of Argus II in favor of Orion which will adversely affect our Argus II sales and results of operations.

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 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.

Our revenues for Argus II have decreased and we expect that they will continue to decrease as we sell through our remaining inventory and that our expenses will increase in connection with our ongoing activities, particularly as we expand and continue clinical trials of Orion, initiate new research and development projects and seek marketing approval for the Orion and any product candidates that we successfully develop. In addition, if we obtain marketing approval for Orion, we expect to continue incurring significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize that product. Nevertheless no assurance can be given that Orion will achieve commercial success or result in profitable operations, in which case investors may lose all or substantially all 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.

While we have regained compliance with the continued listing rules of the Nasdaq Capital Market, we may be unable to comply with Nasdaq's applicable continued listing requirements going forward, which could adversely affect our liquidity and the trading volume and market price of our ordinary shares.

Our common stock is currently listed on The Nasdaq Capital Market, or Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our common stock of $1.00 per share. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, our ability to fund our business plan may be adversely affected and it could become more difficult to dispose of or obtain accurate price quotations for our common stock and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. On January 6, 2020, we effected a 1-for-8 (1:8) reverse stock split in order to regain compliance with Nasdaq's Listing Rule 5550(a) which requires a minimum bid price of $1 per share. By letter to us in January 2020 Nasdaq confirmed that we had regained compliance. In case of future non-compliance we can provide no assurance that we will be able to regain compliance with applicable rules.

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 will 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 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 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.

As of February 1, 2020, entities controlled and beneficially owned by Gregg Williams, our Chairman of the Board, own of record an aggregate of approximately 63.2% of the outstanding shares of our common stock (or 73.5% after giving effect to Mr. Williams' right to acquire beneficial ownership of 6,029,896 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
- controlling 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 majority 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.

We have obtained significant invested amounts from entities affiliated with Mr. Williams, our Chairman of the Board, and if as we seek additional funding to support our business Mr. Williams does not participate in our future offerings, we may not be able to raise needed amounts and our operations may be adversely affected.

During 2018 and 2019, we funded our business primarily through the issuance and sale of our securities. We obtained approximate proceeds of $10 million in May 2018, $5 million in August 2018, $4 million in October 2018, $3 million in December 2018 and $30 million in February 2019 from the sale of our securities to entities affiliated with Mr. Williams, our Chairman of the Board, constituting 100%, 100%, 100%, 100% and 86.7% respectively, of amounts received in the offerings we completed. To the extent that we may need additional capital we expect that we will seek to fund our operations through public or private equity or debt financings, grants, collaborations, strategic partnerships or other sources. No assurance can be given that Mr. Williams or entities affiliated with him will continue

to participate in any offerings of our securities or that we will be able to obtain additional capital from him. If we are unable to obtain funding on a timely basis, our business and operations may be materially and adversely affected.

Gregg Williams could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

Mr. Williams is not subject to any contractual restrictions with us on his ability to sell or transfer our common stock or warrants on the open market, in privately negotiated transactions or otherwise, and these sales or transfers, should they occur, could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by Mr. Williams of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

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, through March 13, 2020 the closing prices of our shares have ranged from $3.06 per share to $188.80 per share and day-to-day trading often has 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) 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 statute which requires publicly held companies to have a minimum of one female on boards of directors as of the end of 2019.

California's gender diversity law, which went into effect on January 1, 2019, requires publicly held corporations with principal executive offices in California to have at least one female director by December 31, 2019 and a minimum that increases to two or three female directors by December 31, 2021 if the corporation has five directors or six or more directors, respectively. We have no female board members currently nor as of December 31, 2019. The law authorized the imposition of fines or penalties for violations of the new law in amounts of $100,000 for the first violation and $300,000 for each subsequent violation. Moreover the California Secretary of State was authorized to adopt regulations that could impose a $100,000 penalty for failure to timely comply and file board member information with the Secretary of State however no such regulations have been promulgated to date. We are aware of two cases challenging implementation of the new, *Crest v. Alex Padilla* and *Creighton Meland v. Alex Padilla, Secretary of State of California*, challenging the validity of the law and seeking a permanent injunction against enforcement of the statute.

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 shut downs 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal office and facilities are located at 12744 San Fernando Road, Suite 400, Sylmar, California 91342, which consists of approximately 45,351 rentable square feet at a base rent of approximately $39,800 per month. Our lease expires in February 2022 and grants us an option to extend the lease term for an additional 60 months period. We believe that these premises are adequate for our foreseeable needs.

Our European office is located on the Innovation Park at EPFL, Rue Jean-Daniel Colladon, CH 1015 Lausanne. As part of our restructuring and staffing reductions we have renegotiated this lease at a base rent of 1,573 CHF or $1,623 starting on January 1, 2019 based upon current exchange rates.

Item 3. Legal Proceedings

We are not a party to threatened or pending material legal proceedings other than those involving Pixium Vision described in “Risk Factors—Risks Related to Intellectual Property and Other Legal Matters”.

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." The following table sets forth the high and low closing sales prices of our common stock as reported on the Nasdaq Capital Market for the following time periods.

	High	Low
Fiscal Year Ended December 31, 2019		
First quarter	$ 8.00	$ 5.48
Second quarter	$ 9.12	$ 5.22
Third quarter	$ 7.68	$ 5.84
Fourth quarter	$ 7.34	$ 5.80
Fiscal Year Ended December 31, 2018		
First quarter	$ 18.48	$ 11.92
Second quarter	$ 17.84	$ 11.84
Third quarter	$ 15.76	$ 12.08
Fourth quarter	$ 14.56	$ 5.84

On March 13, 2020, the closing sales price reported for our common stock was $3.06 per share, and as of that date there were approximately 100 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

In November 2017, we entered into an At the Market Issuance 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 (File No. 333-221228). 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 additional net proceeds of $4.0 million. During December 2019 we sold approximately 17,000 shares of common stock for additional net proceeds of $0.1 million. We used these proceeds to further develop and enhance our products, support operations and for general corporate purposes.

We entered into stock purchase agreements on December 12, 2018, October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 409,387, 308,465, 403,225 and 844,594 shares, respectively of common stock priced at $7.33, $12.96, $12.40 and $11.84 per share, respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of the Board of Directors of Second Sight. These placements of common stock provided net proceeds of $3.0 million, $4.0 million, $5.0 million and $10.0 million, respectively. We used these proceeds to further develop and enhance our products, support operations and for general corporate purposes.

In a Rights Offering completed on February 22, 2019, we sold approximately 5,976,000 units, each priced at $5.792 for gross proceeds of approximately $34.6 million. Each unit consisted of one share and one immediately exercisable warrant having a strike 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.

Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the notes to those consolidated financial statements. The consolidated statements of operations data set forth below for the years ended December 31, 2019 and 2018 and the consolidated balance sheet data as of December 31, 2019 and 2018 are derived from, and are qualified in their entirety by reference to, our audited consolidated financial statements included elsewhere in this Form 10-K.

	Years Ended December 31,	
(in thousands, except per share data)	2019	2018
Net sales	$ 3,379	$ 6,896
Cost of sales	2,152	4,888
Gross profit (loss)	1,227	2,008
Operating expenses:		
Research and development, net of grants	13,143	10,005
Clinical and regulatory, net of grants	3,354	4,600
Selling and marketing	6,101	11,336
General and administrative	9,226	10,692
Restructuring charges	3,357	555
Total operating expenses	35,181	37,188
Loss from operations	(33,954)	(35,180)
Interest income	362	86
Other income, net	—	—
Net loss	$ (33,592)	$ (35,094)
Net loss per common share – Basic and diluted	$ (2.28)	$ (4.23)
Weighted average shares outstanding – Basic and diluted	14,708	8,297

	As of December 31,	
(in thousands)	2019	2018
Cash and cash equivalents	$ 11,327	$ 4,471
Working capital	$ 6,151	$ 2,022
Total assets	$ 16,599	$ 10,682
Stockholders' equity	$ 7,275	$ 3,084

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, 2019 and 2018 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) develops, manufactures and markets 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 retinitis pigmentosa ("RP"), 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. A six-subject Early 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 12 month results for the six subjects indicate to us that:

- We have a good safety profile. Subjects experienced a total of eight adverse events ("AEs") over this time period related to the device or to the surgery. One was considered a serious adverse event ("SAE"), and all of the adverse events were in the expected category. The SAE was resolved quickly and did not require a hospital stay.
- The efficacy data is encouraging. We measure efficacy by looking at three measures of visual function and one measure of functional vision. The first visual function measure is called 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. On Square Localization, five of the six subjects performed significantly better with the system on than off at 12 months. On Direction of Motion, all six performed significantly better on than off at 12 months. On our third visual function measure, Grating Visual Acuity, three had measurable visual acuity on the scale of this test (versus none who can do it with the device off) at 12 months. Our functional vision measure is called FLORA, which stands 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 and surrounding area. 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. Our FLORA results at 12 months show that for five of the six subjects, the Orion system is providing benefit. The system's impact was rated as neutral for the sixth subject. 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 in early 2020.

No peer-reviewed data is available yet for the Orion system. We are currently evaluating whether to enroll additional feasibility subjects while simultaneously 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. We also have an office in Lausanne, Switzerland, that manages our clinical and research and development operations in Europe, the Middle East and Asia.

Our current commercially approved product, the Argus® II Retinal Prosthesis System ("Argus II"), treats outer retinal degenerations, such as retinitis pigmentosa, also referred to as RP. 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. The Argus II is 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. A relatively small subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is bare light perception or worse in the better seeing eye. We commissioned third-party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the U.S. with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

The Argus II system provides an artificial form of vision that differs from the vision of people with normal sight. It does not restore normal vision and has not yet been proven it can slow the progression of the disease. The majority of patients receive a significant benefit from the Argus II, however results can vary and some patients report receiving little or no benefit. By creating an artificial form of useful vision in patients who otherwise have total sight loss, the Argus II can provide benefits that include:

- restoring independence through a renewed ability to navigate independently in unfamiliar environments;
- improving patients' orientation and mobility, such as locating doors and windows, avoiding obstacles, and following the lines of a crosswalk;
- allowing patients to feel more connected with people in their surroundings, such as seeing when someone is approaching or moving away;
- providing patients with enjoyment from being "visual" again, such as locating the moon, tracking groups of players as they move around a field, and watching moving streams of lights from fireworks;
- enabling some patients to re-enter the workforce through multiple vocations that become possible because of Argus II; and
- improving patients' well-being and ability to perform activities of daily living.

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 made the decision in 2018 to maximize capital efficiency with our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. In October 2018, we announced a restructuring of our international commercial activities and personnel. This restructuring resulted in a decision to no longer support new implants of Argus II in Turkey, Iran, Singapore and Russia. We retained a team that continues to support existing Argus II patients and Centers of Excellence in all markets. We recognized approximately $0.6 million of pre-tax restructuring charges in the fourth quarter of fiscal year 2018 in connection with this restructuring, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Based on assessments of the development of our Orion technology and Orion's positive results in our Early Feasibility Study of the six subjects implanted with the Orion at UCLA and Baylor, on May 10, 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 with the Orion technology. As a result, we have or will:

- accelerate 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 suspend production of Argus II systems;
- plan for the manufacture of the relatively large number of additional Orion devices that we will require to support FDA approval of the Orion as an approved commercial product;
- seek to expand our Early Feasibility Study and/or conduct a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;
- reduce our commercial activities and other costs associated with expanding or maintaining Argus II sales domestically and outside the United States;
- limit future sales and implants of the Argus II to finished units and inventory on hand;
- incurred non-cash impairment charges of our inventory of approximately $2.6 million in the year ended December 31, 2019;
- incurred cash severance and related expenses of approximately $800,000 in the year ended December 31, 2019 covering employees associated with Argus II operations; and
- continue to support our existing and future Argus II users, which includes our commitment to bring the Argus 2s enhanced software and peripherals to market in a limited manner which may improve the current user experience.

We received CE Mark and conditional FDA approval for our Argus 2s (pending final Agency review of some labeling changes) which includes our next generation of wearables and a more powerful VPU, an improved camera and more ergonomically and esthetically pleasing glasses. This technology will serve as the base for our next generation Orion system to be used in our U.S. pivotal study.

We are actively developing multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Argus II or 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 decluttering and virtual reality.

Currently, after more than 20 years of research and development, more than $260 million of investment and over $34 million of grants awarded in support of our technology development, we employ over 110 people in the development (research, engineering and clinical), manufacture, and support of the Argus II and Orion.

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. During 2019 and 2018, we funded our business primarily through:

- Issuance of common stock and warrants in a Rights Offering in February 2019 which provided $34.4 million of net cash proceeds
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2019 which provided $0.1 million of net cash proceeds
- Issuance of common stock through our At Market Issuance Sales Agreement during the first quarter of 2018, which provided $4.0 million of net cash proceeds
- Issuance of common stock in a stock purchase agreement in May, August, October and December 2018, which provided net cash proceeds of $22.0 million
- Revenue of $3.4 million and $6.9 million, for the years ended December 31, 2019 and 2018, respectively, generated by sales of our Argus II product

We entered into stock purchase agreements on December 12, 2018, October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 409,387, 308,465, 403,225 and 844,594 shares, respectively of common stock priced at $7.33, $12.96, $12.40 and $11.84 per share, respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of the Board of Directors of Second Sight. These placements of common stock provided net proceeds of $3.0 million, $4.0 million, $5.0 million and $10.0 million, respectively. No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were issued pursuant to an exemption from registration under Rule 506 of Regulation D, which is promulgated under the Securities Act of 1933. We relied on this exemption from registration based in part on representations made by the purchasers.

In a Rights Offering completed on February 22, 2019, we sold approximately 5,976,000 units, each priced at $5.792 for net proceeds of approximately $34.4 million. Each unit consisted of one share and one immediately exercisable warrant having a strike 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.

During January and February 2018, we sold approximately 278,000 shares of common stock which provided net proceeds of $4.0 million under the Sales Agreement.

During December 2019, we sold approximately 17,000 shares of common stock which provided net proceeds of $0.1 million under the Sales Agreement.

We are subject to the risks and uncertainties associated with a business with one product line and diminishing commercial product revenues, including limitations on our operating capital resources and uncertain demand for our products. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future. 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. 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 or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of Argus II or any other approved product candidates, 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.

Insurance Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the price of the Argus II system, our 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 Argus II system to be reimbursed by payors. Coding has been established for the device and the surgical procedure. The same will be required for Orion. Coverage and payment vary by payor. The majority of Argus II 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. Positive coverage decisions for the Argus II are effective in eight of 12 MAC jurisdictions (comprising 31 states, two territories and the District of Columbia). Effective January 1, 2019, the Centers for Medicare and Medicaid Services (CMS) established a 2019 average payment rate of $152,500 for both the procedure and the Argus II Retinal Prosthesis System.

- **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 the Argus II, then typically Medicare Advantage plans in that MAC jurisdiction offer the same coverage for the Argus II. Individual hospitals and ASCs may negotiate contracts specific to that individual facility, which may include additional separate payment for the Argus II implant system. 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 Argus II procedure in advance of implantation. Over the last several years a large majority of all Medicare Advantage pre-authorization requests for Argus II procedures were granted.

- **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.

Within Europe, Argus II obtained reimbursement approval or funding in Germany (NUB Innovation Funding Program), France (Forfait Innovation Funding Program), and one region of Italy (Regional Funding). We were in the process of obtaining reimbursement through the Commissioning through Evaluation ("CtE") program in England and discontinued these efforts in connection with our restructuring of the Argus II program. If Argus II was still available, the Forfait Innovation Funding Program and CtE program could have resulted in permanent national funding for Argus II assuming positive outcomes in the program, especially in France where we were in the final stages of reimbursement review process.

Currently, we are in process of evaluating potential reimbursement pathways for Orion in the U.S. market. Compared to Argus II, which is largely catering to the Medicare patient population, Orion is expected to address a patient population with diverse and more 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. During the second half of 2019, we 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

In November 2017, we received full FDA approval to begin the first human clinical feasibility study of the Orion visual prosthesis system. During 2018, we implanted and activated the first five subjects in the study, four subjects at UCLA and one subject at Baylor. To date, clinical results have been positive. In addition, during the second quarter of 2018, we submitted and received approval from the FDA to enroll a sixth subject. We implanted the sixth subject at Baylor in January 2019.

Recently Adopted Accounting Standards

ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. was issued with an effective date for public companies fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. For all other entities, the effective date is fiscal years beginning after December 15, 2019. Previously, share-based payments to nonemployees were accounted for under Subtopic 505-50, which significantly differs from the guidance for share-based payments to employees under Topic 718. This ASU supersedes Subtopic 505-50 by expanding the scope of Topic 718 to include nonemployee awards and generally aligning the accounting for nonemployee awards with the accounting for employee awards. We adopted this ASU on January 1, 2019 with no material impact on our results of operations, financial position and cash flows.

We adopted ASU No. 2016-02—*Leases (Topic 842)*, as amended, as of January 1, 2019, using the modified retrospective approach. The modified retrospective approach provides a method for recording existing leases at the period of adoption without restating prior comparative periods which is the method we have chosen. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. Adoption of the new standard resulted in the recording of right-of-use assets and operating lease liabilities of approximately $2.6 million and $2.8 million, respectively, as of January 1, 2019. The difference of $0.2 million between the right-of-use assets and operating lease liabilities, net of the deferred tax impact, was recorded as an adjustment to accumulated deficit at January 1, 2019. The standard did not materially impact our consolidated net earnings and had no impact on cash flows.

We believe that any other 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.

Revenue Recognition. We generate our revenue from sales of our Argus II Retinal Prosthesis Systems, which include the implant and wearable components. Our product sales generally consist of the implant and related surgical supplies and may include a performance obligation related to post-surgical support.

We sell our products through two main sales channels: 1) directly to customers who use our products (the “Direct Channel”) and 2) to distribution partners who resell our products (the “Indirect Channel”).

Under the Direct Channel, we sell our systems to and we receive payment directly from customers who implant our products. Under our Indirect Channel, we have entered into distribution agreements that allow the distributors to sell our systems and fulfill performance obligations for surgical support and post-surgical support.

We determine revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

Revenue is generally recognized upon surgical implant, unless we have a significant performance obligation for post-surgical support. We recognize revenue when a material reversal is no longer probable. Conditions that preclude us from recognizing revenue generally involve new customers with no reimbursement or reimbursement history, and depends on third-party behavior beyond our control, uncertain payment cycles over an extended period of time, and our limited historical experience with these arrangements.

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.

Discontinued Operations Policy. It is our policy to report operations as discontinued when all cash flow and sales cease from our abandoned product including run-off operations. When each of these criteria are met we would than report these operations as discontinued.

Results of Operations

Net sales. Our net sales are derived primarily from the sale of our Argus II product. 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 the Argus II, we made the decision in 2018 to maximize capital efficiency with our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. In October 2018, we announced a restructuring of our international commercial activities and personnel. This restructuring resulted in a decision to no longer support new implants of Argus II in Turkey, Iran, Singapore and Russia. Our sales were also impacted by our decision in May 2019 to suspend Argus II production and focus on our Orion platform.

Cost of sales. Cost of sales includes the salaries, benefits, material, overhead, third-party costs, warranty, charges for excess and obsolete inventory, and other costs required to make our Argus II system at our Los Angeles, California facility. Our product involves technologically complex materials and processes. We record cost of sales when products are implanted, which may differ from the period we are able to record revenue. Such timing differences may cause our reported results of operations to be difficult to compare from period to period.

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 expect sales and marketing expenses to increase as we hire additional sales personnel, initiate additional marketing programs, develop relationships with new distributors, and expand the number of doctors and medical centers that buy and implant our Argus II product and any future products.
- 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, 2019 and 2018

Worldwide commercial implant volume for the years ended December 31, 2019 and 2018 was as follows:

	Years Ended December 31,	
	2019	**2018**
Europe and the Middle East	6	19
Asia	6	12
Canada	—	4
United States	16	34
Total	28	69

Net Sales. Our net sales decreased from $6.9 million in 2018 to $3.4 million in 2018, a decrease of $3.5 million, or 51%. This decrease in net sales was due to lower implant volumes as we restructured our commercial activities to emphasize our transition from the Argus II to our Orion platform. In 2019 there were 26 implants recognized compared to 64 in 2018, and the amount of revenue recognized per implant increased from $108,000 in 2018 to $130,000 in 2019 given the higher 2019 CMS rate as compared to the 2018 CMS rate in the U.S. The difference between reimbursement rates set by payors and our average selling prices primarily relate to the procedure costs retained by our hospital customers.

The amount of revenue recognized per implant in a period depends on several factors, including reimbursement policies set by private and government payors, the mix of implants between North America and the rest of the world, exchange rates, payment terms that may affect revenue recognition, and sales of ancillary products, such as clinical start-up kits and surgical supplies.

In the United States, the amount of sales revenue recognized per unit has been limited in some situations due to the uncertainties of the reimbursement environment and payment terms. Favorable claims outcomes and the development of positive coverage policies in the United States may eventually result in greater and earlier revenue recognition.

Cost of sales. Cost of sales decreased from $4.9 million in 2018 to $2.2 million in 2019, a decrease of $2.7 million or 56%, resulting in a gross margin of 36% in 2019 compared to a gross margin of 29% in 2018. In 2018, cost of sales were impacted by decreased production volumes which increased per unit production costs. In 2019 we ceased production of Argus II, thus a significant portion of our manufacturing activity related to Argus 2s and Orion prototypes were reported in our research and development expenses.

Research and development expense. Research and development expense increased from $10.0 million in 2018 to $13.1 million in 2019, an increase of $3.1 million, or 31%. The increase from the prior year was primarily due to increased headcount, outside services, and costs for internally produced prototypes related to our Orion platform offset by decreased outside services and $0.2 million in costs offset by grants.

Clinical and regulatory expense. Clinical and regulatory expense decreased from $4.6 million in 2018 to $3.4 million in 2019, a decrease of $1.2 million, or 27%. The decrease of $1.2 million primarily related to costs associated with the Orion feasibility study which were higher in 2018 at the times of the implants and a $0.5 million increase in costs offset by grants. We expect clinical and regulatory costs to increase in the future as we conduct additional clinical trials, such as with a future pivotal study with Orion and if we enroll additional subjects in our Early Feasibility Study.

Selling and marketing expense. Selling and marketing expense decreased from $11.3 million in 2018 to $6.1 million in 2019, a decrease of $5.2 million or 46%. This decrease in spending is the result of our de-emphasis of our commercial activities in support of Argus II and advancement of our Orion platform.

General and administrative expense. General and administrative expense decreased from $10.7 million in 2018 to $9.2 million in 2019, a decrease of $1.5 million, or 14%. The decrease is primarily related to reduced personnel costs of $1.0 million which includes a reduction in non-cash stock compensation expense of $0.7 million primarily due to executive transitions. We also reduced patent costs by $0.2 million, outside services by $0.2 million.

Restructuring charges. We recorded a non-cash restructuring charge of $2.6 million in 2019 to our reserve for excess and obsolete inventory in connection with our plans to suspend Argus II production. In addition, we recognized $0.8 million of pre-tax restructuring charges in 2019 consisting of severance and other employee termination benefits, substantially all of which was settled in cash during 2019. We incurred $0.6 million in restructuring charges in 2018, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Net loss. The net loss was $33.6 million in 2019, as compared to $35.1 million in 2018. The $1.5 million decrease in net loss from 2018 to 2019 was primarily attributable to a $2.0 million decrease in operating expenses due to cessation of Argus II commercial activities offset by a $0.8 million decrease in gross profit.

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.

Based on our current plans, we do not have sufficient funds to continue operating our business at current levels for at least 12 months from the date of issuance of this Form 10K. 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 or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of Argus II or any other approved product candidates, 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. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern, and the

Company's independent registered public accounting firm, in its report on the Company's 2019 consolidated financial statements, has raised substantial doubt about the Company's ability to continue as a going concern.

In the period from January 1, 2018 to February 28, 2018, we sold approximately 278,000 additional shares through our At Market Issuance Sales agreement, raising gross proceeds of approximately $4.1 million and net proceeds of approximately $4.0 million after expenses. During December 2019, we sold approximately 17,000 shares of common stock through the same agreement which provided net proceeds of $0.1 million.

We entered into stock purchase agreements on December 12, 2018, October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 409,387, 308,465, 403,225 and 844,594 shares respectively of common stock priced at $7.33, $12.96, $12.40 and $11.84 per share respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of the Board of Directors of Second Sight. These placements of common stock provided net proceeds of $3.0 million, $4.0 million, $5.0 million and $10.0 million, respectively. No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were issued pursuant to an exemption from registration under Rule 506 of Regulation D, which is promulgated under the Securities Act of 1933. We relied on this exemption from registration based in part on representations made by the purchasers.

In a Rights Offering completed on February 22, 2019 we sold approximately 5,976,000 units, each priced at $5.792 for net proceeds of approximately $34.4 million. Each unit consisted of one share and one immediately exercisable warrant having a strike 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.

Working capital was $6.2 million at December 31, 2019, as compared to $2.0 million at December 31, 2018, an increase of $4.2 million.

Cash Flows from Operating Activities

During 2019, we used $27.6 million of cash in operating activities, consisting primarily of a net loss of $33.6 million, offset by non-cash charges of $5.9 million for depreciation and amortization of property and equipment, stock-based compensation, restructuring charges for inventory impairment, and $0.1 million from a net change in operating assets and liabilities.

During 2018, we used $29.8 million of cash in operating activities, consisting primarily of a net loss of $35.1 million, offset by non-cash charges of $4.9 million for depreciation and amortization of property and equipment, stock-based compensation, common stock issuable, bad debt recovery and excess inventory reserve, and $0.4 million from a net change in operating assets and liabilities.

Cash Flows from Investing Activities

Investing activities in 2019 and 2018 used $0.5 million and $0.2 million, respectively, of cash for the purchase of equipment.

Cash Flows from Financing Activities

Financing activities provided $35.0 million of cash in 2019, including $34.5 million from the net proceeds from the issuance of common stock and warrants and $0.5 million from the issuance of common stock for ESPP purchases.

Financing activities provided $26.6 million of cash in 2018, including $25.9 million from the net proceeds from the issuance of common stock, $0.5 million from the issuance of common stock for ESPP purchases and $0.2 million from stock option and warrant exercises.

Financial Commitments

Minimum future payments under the Company's leases at December 31, 2019 and their application to the corresponding lease liabilities are as follows (unaudited):

	Discounted lease liability payments	Payments due under lease agreements
2020	$ 237	$ 491
2021	278	505
2022	322	521
2023	352	516
2024	393	521
Thereafter	1,020	1,183
Total	$ 2,602	$ 3,737

Off-Balance Sheet Arrangements

At December 31, 2019, 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, 2019, our cash equivalents consisted solely of money market funds.

Exchange Rate Sensitivity

During 2019, approximately 69% of our revenue was denominated in U.S. dollars and 31% in Euros. This compares with 2018 when approximately 65% of our revenue was denominated in U.S. dollars, 32% in Euros, and 3% in Canadian dollars. For 2019 and 2018, 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, 2019, management has concluded that our disclosure controls and procedures were effective based upon testing of our key internal controls. Our management, including our CEO and CFO, has concluded that the consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in this Annual Report on Form 10-K in conformity with GAAP.

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

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

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

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

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

As of December 31, 2019, 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, 2019 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.

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 2019 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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(1)
3.1(a)	Restated Articles of Incorporation of the Registrant as amended(1)
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect(1)
4.1	Form of the Registrant's common stock certificate(1)
4.2	Form of Underwriter's Warrant(1)
4.3	Form of Warrant Agreement and Form of Warrant Certificate(2)
4.4	Form of Amendment No.1 to Warrant Agreement(3)
10.1	Form of Indemnification Agreement between Registrant and each of its directors and officers(1)+
10.2	2003 Equity Incentive Plan(1)+
10.3	2003 Form of Employee Option Agreement(1)+
10.4	2011 Equity Incentive Plan, as amended(4)+
10.5	2011 Form of Employee Option Agreement(1)+
10.6	Standard Multi-Tenant Office Lease – Net, dated April 15, 2014, between Registrant and Mann Biomedical Park LLC(1)
10.7	Cost Reimbursement Consortium Research Agreement between Registrant and Doheny Eye Institute(1)
10.8	Second Sight Medical Product, Inc. 2015 Employee Stock Purchase Plan (5)+
10.9	Executive Employment Agreement between Registrant and Will McGuire (6)+
10.10	Executive Employment Agreement between Registrant and John Blake (7)(+)
10.11	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated May 3, 2018(8)
10.12	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated August 14, 2018(9)
10.13	Executive Employment Agreement between Registrant and William Patrick Ryan(10)(+)
10.14	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated October 18, 2018(11)
10.15	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated December 12, 2018(12)
21.1	List of subsidiaries of the Registrant.(1)
24.1	Power of Attorney (include on signature page)
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

* Included herein.
\+ 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

(1) 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.
(2) 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.

(3) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on February 22, 2019.
(4) Incorporated by reference to registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 15, 2016.
(5) Incorporated by reference to registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 16, 2015.
(6) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 25, 2015.
(7) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2018.
(8) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2018.
(9) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2018.
(10) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on September 4, 2018.
(11) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 22, 2018.
(12) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2018.

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 19, 2020

Second Sight Medical Products, Inc.

/s/ Jonathan Will McGuire
Jonathan Will McGuire
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 John T. Blake 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/ Jonathan Will McGuire Jonathan Will McGuire	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2020
/s/ John T. Blake John T. Blake	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2020
/s/ Gregg Williams Gregg Williams	Chairman of the Board	March 19, 2020
/s/ William J. Link William J. Link	Director	March 19, 2020
/s/ Aaron Mendelsohn Aaron Mendelsohn	Director	March 19, 2020
/s/ Matthew Pfeffer Matthew Pfeffer	Director	March 19, 2020

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 Financial Statements
We have audited the accompanying consolidated balance sheets of Second Sight Medical Products, Inc. and Subsidiary (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern
The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 1 to the consolidated financial statements, 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 raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits. 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 audits 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 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Gumbiner Savett Inc.
We have served as the Company's auditor since 2014
Santa Monica, California
March 19, 2020

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

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,327	$ 4,471
Accounts receivable, net	455	504
Inventories, net	1,029	3,250
Prepaid expenses and other current assets	299	1,395
Total current assets	13,110	9,620
Property and equipment, net	1,122	1,025
Right-of-use assets	2,342	—
Deposits and other assets	25	37
Total assets	$ 16,599	$ 10,682
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,093	$ 1,305
Accrued expenses	1,889	2,503
Accrued compensation expense	2,698	2,690
Accrued clinical trial expenses	707	933
Current operating lease liabilities	237	—
Contract liabilities	335	167
Total current liabilities	6,959	7,598
Long term operating lease liabilities	2,365	—
Total liabilities	9,324	7,598
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 15,643 and 9,542 at December 31, 2019 and December 31, 2018, respectively	264,008	229,019
Additional paid-in capital	48,613	44,111
Accumulated other comprehensive loss	(562)	(575)
Accumulated deficit	(304,784)	(269,471)
Total stockholders' equity	7,275	3,084
Total liabilities and stockholders' equity	$ 16,599	$ 10,682

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,	
	2019	**2018**
Net sales	$ 3,379	$ 6,896
Cost of sales	2,152	4,888
Gross profit	1,227	2,008
Operating expenses:		
Research and development, net of grants	13,143	10,005
Clinical and regulatory, net of grants	3,354	4,600
Selling and marketing	6,101	11,336
General and administrative	9,226	10,692
Restructuring charges	3,357	555
Total operating expenses	35,181	37,188
Loss from operations	(33,954)	(35,180)
Interest income	362	86
Net loss	$ (33,592)	$ (35,094)
Net loss per common share – basic and diluted	$ (2.28)	$ (4.23)
Weighted average shares outstanding – basic and diluted	14,708	8,297

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,	
	2019	**2018**
Net loss	$ (33,592)	$ (35,094)
Other comprehensive income (loss):		
Foreign currency translation adjustments	13	(3)
Comprehensive loss	$ (33,579)	$ (35,097)

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Consolidated Statements of Stockholders' Equity
(In thousands)

	Common Stock		Common Stock Issuable		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, December 31, 2017	7,204	$ 202,156	10	$ 153	$ 40,522	$ (572)	$ (234,377)	$ 7,882
Issuance of shares of common stock, net of issuance costs	2,243	25,936	—	—	—	—	—	25,936
Issuance of common stock in connection with employee stock purchase plan	62	508	—	—	—	—	—	508
Exercise of stock options	9	149	—	—	—	—	—	149
Stock-based compensation expense	—	—	—	—	3,589	—	—	3,589
Issuance of common stock in connection with warrant exercise	1	8	—	—	—	—	—	8
Common stock issuance for services	17	262	(10)	(153)	—	—	—	109
Release of restricted stock units	6	—	—	—	—	—	—	—
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(35,094)	(35,094)
Foreign currency translation adjustment	—	—	—	—	—	(3)	—	(3)
Comprehensive loss	—	—	—	—	—	(3)	(35,094)	(35,097)
Balance, December 31, 2018	9,542	$ 229,019	—	$ —	$ 44,111	$ (575)	$ (269,471)	$ 3,084

See accompanying notes to consolidated financial statements.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Adoption of ASC Topic 842 Leases (see note 2)	—	—	—	—	(144)	(144)
Warrants modification (see note 6)	—	—	1,577	—	(1,577)	—
Issuance of common stock and warrants in connection with rights offering, net of issuance costs	5,976	34,399	—	—	—	34,399
Issuance of common stock in connection with employee stock purchase plan	99	484	—	—	—	484
Stock-based compensation expense	—	—	2,925	—	—	2,925
Issuance of shares of common stock, net of issuance costs	17	106	—	—	—	106
Release of restricted stock units	9	—	—	—	—	—
Comprehensive loss:						
Net loss	—	—	—	—	(33,592)	(33,592)
Foreign currency translation adjustment	—	—	—	13	—	13
Comprehensive loss	—	—	—	13	(33,592)	(33,579)
Balance, December 31, 2019	15,643	$ 264,008	$ 48,613	$ (562)	$ (304,784)	$ 7,275

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (33,592)	$ (35,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	397	435
Stock-based compensation	2,925	3,589
Non-cash lease expense	17	—
Bad debt expense	—	107
Restructuring charges-inventory impairment	2,587	—
Excess inventory reserve	—	619
Common stock issued for services	—	109
Changes in operating assets and liabilities:		
Accounts receivable	48	1,220
Inventories	(347)	(1,178)
Prepaid expenses and other assets	1,070	(605)
Accounts payable	(213)	554
Accrued expenses	(472)	80
Accrued compensation expenses	8	80
Accrued clinical trial expenses	(226)	153
Contract liabilities	169	121
Net cash used in operating activities	(27,629)	(29,810)
Cash flows from investing activities:		
Purchases of property and equipment	(493)	(163)
Net cash used in investing activities	(493)	(163)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	34,505	25,936
Proceeds from exercise of options, warrants and employee stock purchase plan options	484	665
Net cash provided by financing activities	34,989	26,601
Effect of exchange rate changes on cash and cash equivalents	(11)	4
Cash and cash equivalents:		
Net Increase (decrease)	6,856	(3,368)
Balance at beginning of year	4,471	7,839
Balance at end of year	$ 11,327	$ 4,471

See accompanying notes to consolidated financial statements.

1. Organization and Business Operations

Second Sight Medical Products, Inc. ("Second Sight" or "the Company"), 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 with our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. See Note 2 for discussion of Discontinued Operations.

Going Concern

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. During 2019 and 2018, we funded our business primarily through:

- Issuance of common stock and warrants in a Rights Offering in February 2019 which provided $34.4 million of net cash proceeds
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2019 which provided $0.1 million of net cash proceeds
- Issuance of common stock through our At Market Issuance Sales Agreement during the first quarter of 2018, which provided $4.0 million of net cash proceeds
- Issuance of common stock in a stock purchase agreement in May, August, October and December 2018, which provided net cash proceeds of $22.0 million
- Revenue of $3.4 million and $6.9 million, for the years ended December 31, 2019 and 2018, respectively, generated by sales of our Argus II product

We entered into stock purchase agreements on December 12, 2018, October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 409,387, 308,465, 403,225 and 844,594 shares respectively of common stock priced at $7.33, $12.96, $12.40 and $11.84 per share respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of the Board of Directors of Second Sight. These placements of common stock provided net proceeds of $3.0 million, $4.0 million,

$5.0 million and $10.0 million, respectively. No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were issued pursuant to an exemption from registration under Rule 506 of Regulation D, which is promulgated under the Securities Act of 1933. We relied on this exemption from registration based in part on representations made by the purchasers.

In a Rights Offering completed on February 22, 2019 we sold approximately 5,976,000 units, each priced at $5.792 for net proceeds of approximately $34.4 million. Each unit consisted of one share and one immediately exercisable warrant having a strike 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.

During February 2018, we sold approximately 278,000 shares of common stock which provided net proceeds of $4.0 million under the Sales Agreement.

During December 2019, we sold approximately 17,000 shares of common stock which provided net proceeds of $0.1 million under the Sales Agreement.

The Company's financial statements have been presented on the basis that its business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business with one product line and limited commercial product revenues, including limitations on our operating capital resources and uncertain 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 at least the next few years. On January 25, 2019, we received a letter from The Nasdaq Stock Market advising us that for 30 consecutive trading days preceding the date of the letter, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to listing rules, and therefore we could have been subject to delisting if we did not regain compliance within the compliance period (or the compliance period as may be extended). On January 6, 2020 we initiated a reverse 1-for-8 (1:8) reverse stock split, which reduced our outstanding shares and increased our per share price which regained compliance with Nasdaq rules.(See Note 14)

Based on our current plans, we do not have sufficient funds to continue operating our business at current levels for at least 12 months from the date of issuance of these financial statements. 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 or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or any other approved product candidates, 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. As a result, management has concluded that there is substantial doubt about our ability to continue as a going concern, and our independent registered public accounting firm, in its report on our 2019 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern.

Reverse Stock Split

On December 31, 2019, the Company effected a reverse stock split of the outstanding shares of its no-par value common stock and outstanding warrants to purchase its common stock by a ratio of 1-for-8 (1:8). The common stock and warrants began trading on the Nasdaq Capital Market on a split-adjusted basis on January 6, 2020.

The accompanying consolidated financial statements and notes thereto give retrospective effect to the reverse stock split for all periods presented. All issued and outstanding common stock, options and warrants exercisable for common stock, restricted stock units, and per share amounts contained in our consolidated financial statements have been retrospectively adjusted.

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

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.

Accounts receivable

Trade accounts receivable are stated net of an allowance for doubtful accounts. We perform ongoing credit evaluations of our customers' financial condition and generally require no collateral from our customers or interest on past due amounts. We estimate the allowance for doubtful accounts based on review and analysis of specific customer balances that may not be collectible and how recently payments have been received. Accounts are considered for write-off when they become past due and when it is determined that the probability of collection is remote. Allowance for doubtful accounts amounted to approximately $0.1 million and $0.2 million at December 31, 2019 and 2018, respectively.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method. Inventories consist primarily of raw materials, work in progress and finished goods, which includes all direct material, labor and other overhead costs. We establish a reserve to mark down our inventory for estimated unmarketable inventory equal to the difference between the cost of inventory and the estimated net realizable value based on assumptions about the usability of the inventory, future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory reserve may be required.

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. There were no impairment losses recognized for property and equipment in 2019 and 2018.

Depreciation and amortization of property and equipment amounted to $0.4 million and $0.4 million for the years ended December 31, 2019 and 2018, respectively.

Research and Development

Research and development costs are charged to operations in the period incurred and amounted to $13.1 million, and $10.0 million net of grant revenue, for the years ended December 31, 2019 and 2018, 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 $0.6 million for the years ended December 31, 2019 and 2018, respectively, and are included in general and administrative expenses in the consolidated statements of operations.

Revenue Recognition

We generate our revenue from the sale of our Argus II Retinal Prosthesis System, which includes the implant and wearable components. Our product sales generally consist of the implant and related surgical supplies and may include a performance obligation related to post-surgical support.

We sell our products through two main sales channels: 1) directly to customers who use our products (the “Direct Channel”) and 2) to distribution partners who resell our products (the “Indirect Channel”).

Under the Direct Channel, we sell our systems to and we receive payment directly from customers who implant our products. Under our Indirect Channel, we have entered into distribution agreements that allow the distributors to sell our systems and fulfill performance obligations for surgical support and post-surgical support.

We determine revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

Revenue is generally recognized upon surgical implant, unless we have a significant performance obligation for post-surgical support. We recognize revenue when a material reversal is no longer probable. Conditions that preclude us from recognizing revenue generally involve new customers with no reimbursement or reimbursement history, and depends on third-party behavior beyond our control, uncertain payment cycles over an extended period of time, and our limited historical experience with these arrangements.

Grant Receipts and Liabilities

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, 2019 and 2018 grants offset against operating expenses were $0.9 million and $0.2 million, respectively.

Concentration of Risk

Credit Risk

Financial instruments that subject us to concentrations of credit risk consist primarily of cash, money market funds, and trade accounts receivable. 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 extend differing levels of credit to customers, and typically do not require collateral.

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.

Customer Concentration

The following tables provide information about disaggregated revenue by service type, customer and geographical market.

The following table shows our revenues by customer type during the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Direct Channel	$ 2,861	$ 5,694
Indirect Channel	518	1,202
Total	$ 3,379	$ 6,896

During the year ended December 31, 2019, five customers represented 61% of revenue. During the year ended December 31, 2018 two customers represented 20% of revenue. No other customer represented 10% or more of revenue in any year.

As of December 31, 2019 and 2018, the following customers comprised more than 10% accounts receivable:

	2019	2018
Customer 1	35%	—%
Customer 2	33%	—%
Customer 3	32%	—%
Customer 4	—%	55%
Customer 5	—%	22%
Customer 6	—%	21%

Geographic Concentration

During the years ended December 31, 2019 and 2018, regional revenue, based on customer locations which comprised 10% or more of revenues, consisted of the following:

	2019	2018
United States	65%	56%
Italy	19%	10%
China	10%	8%
France	—%	10%

Sources of Supply

Several of the components, materials and services used in our current Argus II product are available from only single suppliers, and substitutes for these items cannot be obtained easily or would require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers could result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Even where we could qualify alternative suppliers, the substitution of suppliers may be at a higher cost and cause time delays that impede the production of Orion and Argus II, reduce gross profit margins and impact our ability to deliver our products as may be timely required to meet demand.

Foreign Operations

The accompanying consolidated financial statements as of December 31, 2019 and 2018 include assets amounting to approximately $1.3 million and $1.5 million, 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, 2019 and 2018 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, 2019 and 2018.

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, 2019, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $97.6 million and $43.3 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 2039. 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. Although any such adjustments were not material in the years ended December 31, 2019 and 2018, any such adjustments could be material in the future if estimates differ significantly from actual warranty expense. The warranty liabilities are included in accrued expenses in the consolidated balance sheets.

Presentation of sales and value added taxes

We collect value added tax on our sales in Europe and certain states in the United Sates impose a sales tax on our sales to nonexempt customers. We collect that valued added and sales tax from customers and remit the entire amount to the respective authorities. Our accounting policy is to exclude the tax collected and remitted to the authorities from revenues and cost of revenues.

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, 2019, and 2018, 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).

	2019	2018
Underwriter's warrants	—	100
Warrants issued with rights offerings	7,682	1,706
Common stock options	984	890
Restricted stock units	61	4
Employee stock purchase plan	53	51
Total	8,780	2,751

Discontinued operations

Based upon our decision on May 10, 2019 to accelerate our transition to the Orion platform, we evaluated our accounting policies related to the disposition in accordance with ASC 205-20 *Discontinued Operations*, and assessed our long-lived assets for any indications that their carrying values may not be recoverable in accordance with ASC 360, *Property, Plant, and Equipment*, for any impairment. Based upon these reviews we recorded in the year ended December 31, 2019 an impairment charge of $2.6 million related to inventory of Argus II based on our plans to suspend production of Argus II. As part of this transition we commenced a corporate restructuring plan to focus on development of Orion and other key research projects. Specifically, we reduced expenses and personnel related to commercial activities and production for the Argus II. We recognized approximately $0.8 million of pre-tax restructuring charges in the year ended December 31, 2019 in connection with this restructuring, consisting of severance and other employee termination benefits which was substantially settled in cash by the end of 2019. Based upon our review of the applicable accounting standards we determined that there was no impairment of any other assets. It is our policy to report operations as discontinued when all cash flows and sales cease from our abandoned product including run-off operations. When each of these criteria are met, we would then report these operations as discontinued.

Restructuring Charges

In October 2018, we announced a restructuring of our international commercial activities and personnel. This restructuring resulted in a decision to no longer support new implants of Argus II in Turkey, Iran, Singapore and Russia. We retained a team that continues to support existing Argus II patients and Centers of Excellence in the remaining international markets. We recognized approximately $0.6 million of pre-tax restructuring charges in the fourth quarter of fiscal year 2018 in connection with this restructuring, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Recently Adopted Accounting Standards

ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* was issued with the effective date for public companies fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. For all other entities, the effective date is fiscal years beginning after December 15, 2019. Previously, share-based payments to nonemployees were accounted for under Subtopic 505-50, which significantly differs from the guidance for share-based payments to employees under Topic 718. This ASU supersedes Subtopic 505-50 by expanding the scope of Topic 718 to include nonemployee awards and generally aligning the accounting for nonemployee awards with the accounting for employee awards. We adopted this ASU on January 1, 2019 with no material impact on our results of operations, financial position and cash flows.

We adopted ASU No. 2016-02—*Leases (Topic 842)*, as amended, as of January 1, 2019, using the modified retrospective approach. The modified retrospective approach provides a method for recording existing leases at the

period of adoption without restating prior comparative periods. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in the recording of right-of-use assets and operating lease liabilities of approximately $2.6 million and $2.8 million respectively, as of January 1, 2019. The difference of $0.2 million between the right-of-use assets and operating lease liabilities, net of the deferred tax impact, was recorded as an adjustment to accumulated deficit at January 1, 2019. The standard did not materially impact our consolidated net loss and had no impact on cash flows.

We believe that any other 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, 2019 totaled $11.3 million. Money market funds included in cash equivalents at December 31, 2018 totaled $4.2 million and included $0.2 million held in a deposit account in Switzerland as security for the performance of contracts.

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2019 and 2018 (in thousands).

	Total	Level 1	Level 2	Level 3
December 31, 2019:				
Money market funds	$ 11,307	$ 11,307	$ —	$ —
December 31, 2018:				
Money market funds	$ 4,156	$ 4,156	$ —	$ —

4. Selected Balance Sheet Detail

Inventories, net

Inventories consisted of the following at December 31, 2019 and 2018 (in thousands):

	2019	2018
Raw materials	$ 803	$ 791
Work in process	1,716	3,055
Finished goods	2,069	2,089
	4,588	5,935
Allowance for excess and obsolescence	(3,559)	(2,685)
Inventories, net	$ 1,029	$ 3,250

We recorded $2.6 million as an impairment charge during the year ended December 31, 2019, related to our plans to suspend Argus II production. See note 2 for further details.

Property and equipment, net of accumulated depreciation and amortization

Property and equipment consisted of the following at December 31, 2019 and 2018 (in thousands):

	2019	2018
Laboratory equipment	$ 2,724	$ 2,482
Computer hardware and software	1,672	1,456
Leasehold improvements	304	298
Furniture, fixtures and equipment	78	46
	4,778	4,282
Accumulated depreciation and amortization	(3,656)	(3,257)
Property and equipment, net	$ 1,122	$ 1,025

Contract Liabilities

Contract liabilities consisted of the following at December 31, 2019 and 2018 (in thousands):

	2019	2018
Beginning Balance	$ 167	$ 48
Consideration received in advance of revenue recognition	387	551
Revenue recognized	(219)	(432)
Ending Balance	$ 335	$ 167

Allowance for Doubtful Accounts

Allowance for doubtful accounts consisted of the following at December 31, 2019 and 2018 (in thousands):

	2019	2018
Beginning Balance	$ 181	$ 74
Additions	1	107
Write-offs	(65)	—
Ending Balance	$ 117	$ 181

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 will be used to conduct and support clinical testing of five 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), and fund an Institutional Review Board approval for a larger and final clinical study as approved by the FDA. As of December 31, 2018 we recorded $0.5 million of deferred grant costs associated with this grant which were offset with the related grant funds when received in 2019. During the year ended December 31, 2019, we received a total of $0.9 million of grant funds primarily from this grant.

6. Warrants

Warrants Issued with Convertible Debt

Approximately 84,600 warrants associated with the Convertible Notes originally issued in 2013 expired on February 28, 2018.

Underwriter's Warrant

As a component of the IPO underwriting fee, we granted the underwriter a warrant to purchase 100,625 shares of our common stock at an exercise price of $90.00 per share, which was 25 percent above the offering price to the investors. The warrant was exercisable, in whole or in part, for a period commencing 180 days after the effective date of the registration statement (November 18, 2014) and ending on the fifth anniversary date of the effective date of the registration statement. The remaining underwriter's warrants to purchase 100,250 of our common stock expired on November 18, 2019.

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 had 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 common stock and a warrant to purchase an additional share of our stock for $11.76. The warrants have a five-year life and have been approved for trading on Nasdaq under the symbol EYESW. As of December 31, 2019, 632 of the warrants associated with the rights offering had been exercised.

We extended the term of 1.7 million warrants issued in our March 2017 rights offering by approximately two years effective as of February 15, 2019 as part of our February 2019 rights offering. We determined the fair value of the March 2017 Warrants immediately before and after the modification. The fair value of the March 2017 Warrants after the modification was increased by approximately $1.6 million, resulting in an accounting adjustment to additional paid-in capital and accumulated deficit in the consolidated statements of shareholders' equity. The assumptions used in the determination of fair value of the warrants before and after the extension included a risk free interest rate of 2.50% and 2.49%, expected volatility of 81% and 82%, and expected lives of 3.08 years and 5.08 years, respectively and 0% dividend yields for both.

A summary of warrant activity for the years ended December 31, 2019 and 2018 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, 2017	1,891	$ 17.20	
Granted	—	—	
Exercised	(1)	11.76	
Forfeited or expired	(84)	40.00	
Warrants outstanding at December 31, 2018	1,806	$ 16.08	
Granted	5,976	11.76	
Exercised	—	—	
Forfeited or expired	(100)	90.00	
Warrants outstanding at December 31, 2019	7,682	$ 11.76	4.21
Warrants exercisable at December 31, 2019	7,682	$ 11.76	4.21

Warrants exercisable at December 31, 2019 had no 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 each of the years ended December 31, 2019 and 2018, employer contributions to the Plan totaled $0.2 million.

We are required to contribute to a government-sponsored pension plan for the employees of our Switzerland-based subsidiary. For each of the years ended December 31, 2019 and 2018, the employer's portion of the amounts contributed to the subsidiary's pension plan on behalf of those employees was $0.1 million.

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

Non-employee members of our Board of Directors were primarily paid for their services in common stock in 2018. For 2018, we issued a total of approximately 17,000 shares of common stock with a value of $0.3 million for annual service through May 31, 2018. Since June 1, 2018 our board members receive compensation in cash and stock options. For the seven months ended December 31, 2018 our board members were compensated $0.1 million and also received stock options valued at $0.1 million. For the twelve months ended December 31, 2019 our members were compensated $0.2 million and also received stock options valued at $0.2 million.

Rights Offerings

In a rights offering completed on February 22, 2019, we sold approximately 5,976,000 units, each priced at $5.792 for net 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.

At-the-Market Sales Agreement

During December 2019, we issued approximately 17,000 shares of common stock for net proceeds of approximately $0.1 million as part of our At the Market Issuance Sales Agreement ("Sales Agreement"). In the period from January 1, 2018 to February 28, 2018, we sold approximately 278,000 shares through our Sales Agreement, raising gross proceeds of approximately $4.1 million and net proceeds of approximately $4.0 million after expenses.

Stock Purchase Agreements

We entered into stock purchase agreements on December 12, 2018, October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 409,387, 308,465, 403,225 and 844,594 shares, respectively, of common stock priced at $7.33, $12.96, $12.40 and $11.84 per share, respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of the Board of Directors of Second Sight. These placements of common stock provided net proceeds of $3.0 million, $4.0 million, $5.0 million and $10.0 million, respectively.

No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were issued pursuant to an exemption from registration under Rule 506 of Regulation D, which is promulgated under

the Securities Act of 1933. We relied on this exemption from registration based in part on representations made by the purchasers.

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 shall be granted under the 2011 Plan after May 31, 2021.

We recognized stock-based compensation cost of $2.9 million and $3.6 million during 2019 and 2018, 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:

	2019	2018
Risk-free interest rate	1.43% – 2.63%	2.32% – 3.05%
Expected dividend yield	0%	0%
Expected volatility	72.0%	67.0%
Expected term	5.50-6.08 years	5.50-6.11 years
Weighted-average grant date calculated fair value	$ 3.97	$ 9.60

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A summary of stock option activity for the years ended December 31, 2019 and 2018 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, 2017	709	$ 38.96	
Granted	397	15.51	
Exercised	(9)	15.63	
Forfeited or expired	(207)	30.64	
Options outstanding at December 31, 2018	890	$ 30.68	
Granted	336	6.13	
Exercised	—	—	
Forfeited or expired	(242)	32.75	
Options outstanding at December 31, 2019	984	$ 21.78	7.70
Options exercisable at December 31, 2019	498	$ 32.42	6.88

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2019 (in thousands):

Exercise Price	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 5.54 to 6.63	286	48
$ 6.64 to 13.83	111	40
$ 13.84 to 16.55	408	238
$ 16.56 to 72.00	101	94
$ 72.08 to 111.20	78	78
	984	498

Stock options exercisable at December 31, 2019 had minimal intrinsic value. As of December 31, 2019, there was $2.8 million of total unrecognized compensation cost related to the outstanding stock options that will be recognized over a weighted average period of 2.31 years.

During the year ended December 31, 2019, we granted stock options to purchase 336,318 shares of common stock to certain employees and directors. The options are exercisable for a period of ten years from the date of grant at prices ranging from $5.48 to $8.00 per share, which was the fair value of our common stock on the respective grant dates. The options generally vest over a period of four years. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $1.3 million ($3.52 to $5.20 per share).

In October 2017 and in January 2018 we granted stock options to purchase 18,750 and 3,750 shares of common stock, respectively, to an outside contractor in connection with his services. The options were exercisable for a period of ten years from the date of grant at a price of $9.68 and $16.48 respectively, per share, which was the fair value of our common stock on each grant date. The options were scheduled to vest over a four year period. The unvested portion of these stock options was re-measured by us at each reporting period. The contractor's services ended during 2019 and these options expired. For the years ended December 31, 2019 and 2018, $12,000 and $43,000 was expensed for these grants, respectively.

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, 2019, 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 are voluntarily offering 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. Therefore, we are conducting a rescission offer to those employee purchasers to attempt to extinguish any federal or state registration requirements or related contingent liability. This offer is being made to those persons who purchased common stock from our ESPP on November 30, 2018, May 31, 2019 and November 30, 2019. The eligible 45,468 shares for rescission represent the total number of Eligible Rescission Shares that had not been resold by ESPP participants as of March 12, 2020. We expect if our offers to rescind for those who are still holding shares and to reimburse losses for those who sold their shares will not exceed $281,000 if exercised in full.

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

During 2019, we awarded RSUs of 65,813 to certain employees. The fair value of these RSUs totaled $0.4 million. The RSUs generally vest over a four year period, and were awarded at the fair value of our common stock on the respective award dates.

The following table presented below summarizes Restricted Stock Unit (RSU) activity for the years ended December 31, 2019 and 2018 (in thousands, except per share data):

	Number of Awards	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2017	10	$ 99.44
Awarded	—	—
Vested	6	99.44
Forfeited/canceled	—	—
Outstanding as of December 31, 2018	4	$ 99.44
Awarded	66	6.00
Vested	9	52.08
Forfeited/canceled	—	—
Outstanding as of December 31, 2019	61	$ 5.92

As of December 31, 2018, there was $0.3 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 3.14 years.

The total stock-based compensation recognized for stock-based awards granted in the consolidated statements of operations for the years ended December 31, 2019 and 2018 is as follows (in thousands):

	2019	2018
Cost of sales	$ 172	$ 279
Research and development	552	382
Clinical and regulatory	107	152
Selling and marketing	481	505
General and administrative	1,613	2,271
Total	$ 2,925	$ 3,589

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, 2019 and 2018 are summarized below (in thousands):

	2019	2018
Stock-based compensation	$ 4,637	$ 4,297
Research credits	8,208	7,003
Depreciation	(45)	(48)
Net operating loss carryforwards	26,339	20,315
Inventory reserve	827	651
Other	669	643
Total deferred tax assets	40,635	32,861
Valuation allowance	(40,635)	(32,861)
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, 2019 and 2018, management was unable to determine if it is 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, 2019 and 2018 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, 2019, 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 $97.6 million and $43.3 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 began to expire at various dates from 2033 through 2039. We also have a federal and state research and development tax credit carryforwards totaling approximately $4,514,000 and $3,694,000, respectively. The federal research and development tax credit carryforwards will expire at various dates from 2023 through 2039. 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 2016 and later and by state authorities for tax years ended 2015 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, 2019, and 2018, 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, 2019 and 2018 is presented below (in thousands):

	2019	2018
Balance, beginning of year	$ 1,572	$ 1,456
Additions	359	193
Settlements	(356)	(264)
Adjustments and other	—	187
Total	$ 1,575	$ 1,572

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. Our operating lease for office space includes one option to renew, with a five-year renewal term that can extend the lease term to 2027. The exercise of this lease renewal option is at our sole discretion. 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.

Lease assets and liabilities consisted of the following (in thousands):

Assets	**Classification**	**December 31, 2019**
Non-current assets	Right-of-use assets	$ 2,342
Liabilities		
Current	Current operating lease liabilities	$ 237
Long term	Long-term operating lease liabilities	$ 2,365

The components of lease expense for the year ended December 31, 2019 were as follows:

	Year ended December 31, 2019
Lease expense:	
Operating lease expense	$ 493
Short-term lease expense	—
Total lease expense	$ 493

Other information:

Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	476
For operating lease:		
Weighted average remaining lease term (in years)		7.1
Weighted average discount rate		10%

Minimum future payments under the Company's leases at December 31, 2019 and their application to the corresponding lease liabilities are as follows:

	Discounted lease liability payments	Payments due under lease agreements
2020	$ 237	$ 491
2021	278	505
2022	322	521
2023	352	516
2024	393	521
Thereafter	1,020	1,183
Total	$ 2,602	$ 3,737

Second Sight Switzerland rents office space in Switzerland on a month-to-month basis for CHF 1,573 (approximately $1,623, at current exchange rates) per month.

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 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 $7,000 and $0.1 million for the years ended December 31, 2019 and 2018, respectively.

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.

Employment Agreements

We have entered into employment agreements and have an approved Change in Control Plan for three of our executive officers which provides for 12 months of severance benefits including salary, bonus and COBRA benefits in the event of a termination in connection with a change in control, subject to the terms in these agreements. Our

Change in Control Plan also provides, for certain other officers, six months of salary, bonus, and COBRA benefits in the event of a termination in connection with a change in control, subject to the terms of the Change in Control Plan.

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 are conducting three post-market studies to comply with U.S. FDA, French, and European post-market surveillance regulations and requirements and a six subject initial 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, 2019 and 2018 were $2.4 million and $1.8 million, respectively.

California Board Representation

California's gender diversity law, which went into effect on January 1, 2019, requires publicly held corporations with principal executive offices in California to have at least one female director by December 31, 2019 and a minimum that increases to two or three female directors by December 31, 2021 if the corporation has five directors or six or more directors, respectively. We have no female board members currently. We may be assessed penalties and fines under California's board gender diversity statute and have accrued $100,000 as of December 31, 2019.

Litigation, Claims and Assessments

Eleven oppositions filed by Pixium Vision are pending in the European Patent Office, each challenging the validity of a European patent owned by us. We have filed one opposition that is currently pending in the European Patent Office challenging the validity of a patent owned by Pixium Vision. The outcome 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.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will have 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)

	Three Months Ended			
(in thousands, except per share data)	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Product sales	$ 497	$ 472	$ 1,282	$ 1,128
Gross profit	$ 373	$ 108	$ 349	$ 397
Operating loss	$ (8,126)	$ (7,619)	$ (8,441)	$ (9,768)
Net loss	$ (7,868)	$ (7,584)	$ (8,440)	$ (9,700)
Net loss per share – basic and diluted	$ (0.50)	$ (0.48)	$ (0.56)	$ (0.80)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Product sales	$ 1,767	$ 2,246	$ 1,907	$ 976
Gross profit	$ 167	$ 462	$ 1,071	$ 308
Operating loss	$ (8,877)	$ (8,546)	$ (7,988)	$ (9,769)
Net loss	$ (8,858)	$ (8,522)	$ (7,961)	$ (9,753)
Net loss per share – basic and diluted	$ (0.96)	$ (0.96)	$ (0.96)	$ (1.36)

14. Subsequent Events

Stock Option Grants

In February 2020, we granted long term incentive stock options to our current employees to purchase 205,701 shares of common stock, including 118,781 options that were granted to senior management. The options are exercisable for a period of ten years from the date of grant with an exercise price of $5.98 per share. The options vest over a four-year term, on an equal monthly basis.

Nasdaq Compliance Letter

By letter dated January 21, 2020, Nasdaq confirmed to Second Sight Medical Products Inc. (the “Company”) that for the last 10 consecutive business days, from January 6 to January 17, 2020, the closing bid price of the Company’s common stock has been at $1.00 per share or greater. Nasdaq had previously informed the Company in January 2019 that the common stock of the Company failed to maintain a bid price of $1.00 over the previous 30 consecutive business days as required by the Listing Rules of the Nasdaq Stock Market. Accordingly, the Company has regained compliance with Listing Rule 5550(a)(2).

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, Jonathan Will McGuire, 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 19, 2020

/s/ Jonathan Will McGuire
Jonathan Will McGuire
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, John T. Blake, 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 19, 2020

/s/ John T. Blake
John T. Blake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certifications of Principal Executive Officer and Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant To
Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), Jonathan Will McGuire, Chief Executive Officer (Principal Executive Officer) and John T. Blake, Chief Financial 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, 2019, 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 19, 2020

/s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer
(Principal Executive Officer)

/s/ John T. Blake
John T. Blake
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of 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.