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, 2018

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	**Name of Each Exchange on Which Registered**
Common Stock, without par value	The Nasdaq Stock Market, LLC

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 ☒ (Do not check if a smaller reporting 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, 2018, computed by reference to the closing sales price on the Nasdaq Capital Market on that date, was approximately $59.0 million.

As of March 12, 2019, the number of shares of the Registrant's common stock outstanding was 124,197,961.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2018 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, 2018.

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 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"). No published in-human data is available yet for the Orion system. We anticipate enrolling additional feasibility subjects in 2019 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 commercial and clinical operations in Europe, the Middle East and Asia.

Our current 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 subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

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 there is no evidence that it can slow or reverse 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 the remaining international markets. We anticipate that the annual savings from the restructuring will amount to approximately $3.0 million per year and we plan to reallocate savings to the Orion program and other related projects. 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.

We will continue to monitor the efficiency and effectiveness of commercial activities for Argus II and make further changes as needed to ensure sufficient payback on commercial spending while maximizing capital available to support Orion programs.

We are actively developing multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the the Argus II or Orion user experience. In most cases, we collaborate with 3rd party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that are currently researching include: eye tracking, object recognition and localization, thermal imaging and depth-based decluttering. We expect to advance several of these technologies to the point having prototype eyewear suitable for clinical testing in 2019.

Currently, after more than 20 years of research and development, more than $200 million of investment and over $34 million of grants awarded in support of our technology development, we employ over 120 people in the development (research, engineering and clinical), manufacture, and commercialization of the Argus II System and future products such as Orion.

Our Technology

Both the Orion and Argus II systems work by converting video images captured by a miniature camera housed in a patient's glasses into a series of small electrical pulses that are transmitted wirelessly to an array of electrodes. The array is implanted on the visual cortex of brain with the Orion system bypassing the eye and optic nerve and directly stimulating the region of the brain responsible for vision. The array is implanted on the surface of the retina with the Argus II system 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, patients 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 system and Argus II system (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 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. Most of the technology developed for Argus II is also used in Orion. As of December 31, 2018, we have over 380 issued patents and approximately 58 pending patent applications worldwide. Additionally, from a competitive standpoint, the Argus II System possesses attractive technical and other features that include:

- a unique patented design that allows for a demonstrated lifetime and benefit of over 10.7 years,
- surgical implantation that can be performed in three to four hours using standard vitreoretinal techniques,
- a relatively large field of view (20 degrees),
- implanted patients can undergo MRI procedures, and
- individually programmable electrodes on the prosthesis which can permit further optimization of the device after implantation.

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 few select medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review. 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 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.

It is our belief that inclusion in the Breakthrough Devices Program may shorten the timeline required to bring the Orion to market as a commercial product. We are currently evaluating our pivotal trial design for Orion and expect to reach consensus with the FDA on design specifics during early 2019. 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. While negotiations with the FDA are ongoing, we believe the study design will require a minimum sample population of 30 subjects with at least 6 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 AMD and RP. In the US, 1.3 million people are legally blind[2], of whom we estimate 44%, or 575,900, are legally blind due to causes other than preventable/treatable conditions, RP or AMD[3]. We estimate 1.13 million individuals are legally blind in Europe due to causes other than currently treatable conditions (including RP) or AMD.

Retinitis Pigmentosa (RP)

RP is a group of inherited disorders that affect the retina. The retina is a layer of nerve cells at the back of the eye. RP is a disease that gradually robs relatively young people of their vision over time. Onset of RP is often noted in the teen years or early twenties, typically as night blindness. This is followed by a period of peripheral vision loss, until the patient is left with a tunnel of vision and then no remaining sight. Although there are various genetic causes (over 100) and thus variability in the disease progression, many people with advanced RP have lost all functional vision by their 40s or 50s. The Argus II System, bypasses rods and cones which are largely defunct in these patients, by sending electrical signals directly to the retina’s remaining healthy cells.

Although there are reported trials for other treatments underway, to our knowledge the Argus II System remains the only approved therapeutic option for end-stage RP in the US, and to our knowledge it is the only treatment option generally available to commercial patients anywhere in the world.

Worldwide, an estimated 1.5 million people suffer from RP[4], which includes about 100,000 in the US[5]. Pan-European data is not readily available, but we believe it is reasonable to estimate that the average prevalence throughout Europe is similar to the average prevalence within the US, and so the ratio of populations could be used to estimate the number of Europeans affected as 167,000 in the 28 EU countries[6,7]. Approximately 25% of people with RP in the US have vision that is 20/200 or worse (legally blind)[8]. Since the bare light perception or worse vision criterion (in both eyes) for the US indication is worse than 20/200, we estimate the subset of patients that can be treated by the Argus II System is less than 25,000 in the US. Reliable market data estimating the actual number of patients with bare light perception or worse vision is unavailable. We believe the majority of patients with vision 20/200 or worse have vision that is better than bare light perception and thus, are not currently candidates for Argus II. In Europe, the indicated vision loss for Argus II patients is severe to profound which, while better than bare light perception, remains somewhat worse than 20/200. An estimated 42,000 patients in Europe with RP have vision worse than 20/200 and we estimate the subset of RP patients that can be treated in Europe to be somewhat smaller than this number. As in the US, reliable market data estimating the actual number of patients with severe to profound vision loss or worse is unavailable. We believe that the majority of patients with vision 20/200 or worse in Europe have vision that is too good to be considered a candidate for Argus II with current clinical indications and physician practice. Worldwide, we estimate that 375,000 people are legally blind due to RP. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

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1 WHO Fact Sheet, updated October 11, 2018.

2 National Eye Institute (http://www.nei.nih.gov/eyedata/blind.asp).

3 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 US Census data.

4 Weleber, R.G. and Gregory-Evans, K. (2001) 'Retinitis Pigmentosa and allied disorders.' In Ryan, S.J. (ed.), Retina. Mosby, St. Louis, pp, 362-470.

5 Foundation Fighting Blindness estimates that about 100,000 Americans are affected by RP or similar diseases. (http://www.ffb.ca/documents/File/rp_guide/Guide_to_RP_and_Other_Related_Diseases.pdf)

6 Eurostat. Retrieved 1 January 2013.

7 Haim M. Epidemiology of Retinitis Pigmentosa in Denmark. Acta Ophthalmol Scand Suppl 2002; 1-34.

8 Grover et al., 'Visual Acuity Impairment in Patients with Retinitis Pigmentosa at Age 45 Years or Older', Ophthalmology. 1999 Sept; 106(9):1780-5.

Other diseases resulting in blindness that may be treated by Orion

We commissioned 3rd party market research for the potential market for Orion that resulted in initial estimates of over 500,000 individuals in the US who are legally blind due to glaucoma, diabetic retinopathy, optic nerve disease and eye injury. Of this population, the potential US addressable market is more than 70,000 individuals with vision defined as bare light or no light perception. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion.

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.

Our Strategy

Our strategy can be summarized as follows:

- Leverage proven Argus technology to develop the Orion visual cortical stimulator 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,

- Maintain an emphasis on capital efficiency with Argus II commercial activities by focusing on key markets and centers of excellence in those markets. The goal is ultimately a positive cash contribution to the company that supports continued investment in Orion programs.

Commercial Overview and Centers of Excellence Strategy in US

As of December 31, 2018, we have 20 qualified centers in the United States and Canada that are actively implanting the Argus II. Outside of North America we are focusing on 14 active centers in 6 countries between Europe and Asia Pacific.

To date, we have employed direct sales and vision rehabilitation specialists to service our markets in the US and Canada. The majority of our markets in Europe are also serviced by a direct sales and vision specialist team. As of January 31, 2019, the sales/vision specialist team for North America numbered seven persons and the sales team for Europe and Asia Pacific numbered seven persons.

Our COE strategy in the US market is designed to help our exclusive regional partners to more effectively manage Argus II patients and achieve inspiring patient outcomes. The COE strategy consists of four major initiatives: (1) financial, (2) patient recruitment, education and screening, (3) post-surgery programming, and (4) patient support and artificial vision rehabilitation.

- First, there are the financial considerations. As reported, effective January 1, 2019 the CMS hospital outpatient final rule assigned an average payment rate of $152,500 for the Argus II and the associated surgical procedure beginning January 1, 2019. The rate for calendar years 2018, 2017, 2016 was $122,500, $150,000 and $95,000, respectively. Physician fees continue to be reimbursed separately. We expect that our current pricing strategy should generally ensure full reimbursement coverage of hospital surgical procedure costs including the Argus II system. Effective July 1, 2017, CPT codes for post-surgery programming became available. We believe that these developments ought to ensure a favorable economic analysis for any center evaluating an Argus II program.

- Second, regarding patient recruitment, education and screening, we focus extensive outreach efforts to identify those blind individuals who may qualify for Argus II. When identified those individuals are entered into a CRM database, supported by interactive marketing automation programs, with the intent of providing a funnel of patients for each of our strategic sites as patient candidates decide to move forward. We separately clear patient candidates with a team of experienced healthcare professionals, providing our COEs with a streamlined path of higher probability patient candidates.

- Third, in terms of the post-surgery programming, our recent and future product improvements are aimed at simplifying the programming procedure for the site and for the patient. We've reduced the expected time to program our system from two days down to a half day. As with the surgery, repetition will make the programming more routine for the institution. Further, as mentioned above, we have secured CPT codes to allow sites to submit for reimbursement when they program an Argus system.

- Fourth, patient support and artificial vision rehabilitation are an important tool to managing consistent, positive outcomes across all treated patients. Beginning on day-one of initial activation, the brain works to make sense of the entirely new sensory input from Argus. Each individual patient needs guidance on the activities and tasks he or she can engage in, especially early on, that can best guide the brain to create these important new connections. As we have come to understand the important training curriculum of artificial vision rehabilitation, we are deploying today full-time vision rehabilitation specialists who are experts in all the ways Argus has enabled patients to: regain independence with the world around them; enhance social interactions with the people they associate with; and to enjoy the many aesthetic experiences that derive from visual interactivity. Our objective is to deliver outstanding patient outcomes, while building the know-how and infrastructure of vision rehabilitation for a substantially larger patient population in the near future.

In summary, the aim of the COE program is to establish implanting centers and physician clinics that are more intimately knowledgeable, self-sufficient, and confident, enabling them to be able to treat a higher volume of artificial vision patients. We believe the COE program is the ideal platform for the important development work to serve the expanded patient populations in the near future.

Global Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the cost of the Argus II System, our sales would be limited without the availability of third party reimbursement. In the US, coding, coverage, and payment are necessary for the surgical procedure and Argus II system to be reimbursed by payers. Coding has been established for the device and the surgical procedure. Coverage and payment vary by payer. 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 US. 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.

During the year ended December 31, 2018, 38 individuals in the US and Canada were implanted with the Argus II technology. Of these patients, 34 were in the US primarily covered by Medicare FFS or Medicare Advantage plans and the remainder had private commercial, Veteran’s Administration or other insurance plan coverage. Four patients in Canada were covered by regional public reimbursement or private funding.

Second Sight employs dedicated employees and consultants with insurance reimbursement expertise engaged to expand and enhance coverage decisions. Currently, eight of 12 Medicare jurisdictions provide coverage of the Argus II in 31 states, two territories and the District of Columbia when medically necessary, including:

- CGS (J15 -- Ohio and Kentucky),
- Palmetto GBA (JM -- Virginia, (excluding Part B for Arlington and Fairfax counties), West Virginia, North Carolina and South Carolina),
- Palmetto GBA (JJ – Alabama, Georgia and Tennessee),
- NGS (J6 -- Minnesota, Illinois and Wisconsin),
- NGS (JK -- Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont),
- FCSO (JN -- Florida, Puerto Rico and the US Virgin Islands),
- Novitas (JH-- Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas) and
- Novitas (JL -- Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania).

We are actively engaged with the remaining four Medicare jurisdictions covered by two contractors and are committed to supporting their requests for additional information and clinical evidence. We expect that additional positive coverage decisions will be issued over time but cannot predict timing or ultimate success with each MAC.

Within Europe, we have obtained reimbursement approval or funding in Germany and one region of Italy.

In France, we were selected to receive the first "Forfait Innovation" (Innovation Bundle) from the Ministry of Health, which is a special funding program for breakthrough procedures to be introduced into clinical practice. As part of this program, we conducted a post-market study in France which enrolled a total of 18 subjects who were followed for two years. The French program also funded implantation of 18 additional subjects who were not part of the post-market study. We submitted the final clinical report of the Forfait Innovation study late last year and the outcomes of the study are still under review by the French National Health Authority (HAS). Subject to a successful and positive completion of HAS' review of the outcomes of French study, our aim is for Argus II therapy to be covered and funded through the standard payment system in France. However, we can provide no assurance that the French government will make a positive decision to continue to fund the Argus II in future.

In December 2016, NHS England announced it would cover 10 Argus implantations as part of a CtE program. The CtE program is especially designed for treatments that show significant promise for the future, while new clinical and patient experience data are collected within a formal evaluation program. This program is similar to the Forfait Innovation program in France. We are actively and closely working with NHS England to finalize the final details of the program that is expected to be kicked off within next few months.

To date, our marketing activities have focused on raising awareness of the Argus II System with potential patients, implanting physicians, and referring physicians. Our marketing activities include exhibiting, sponsoring symposia, and securing podium presence at professional and trade shows, securing journalist coverage in popular and trade media, attending patient meetings focused on educating patients about existing and future treatments, and sponsoring information sessions for the Argus II System. In the United States advertisements are placed in geographic areas where we have Centers of Excellence committed to Argus II.

Leverage proven Argus technology to restore some vision with cortical stimulation to a broader market of blind individuals

We are in the process of developing a visual cortical prosthesis for a significantly larger market to include profoundly blind individuals, other than those who are blind due to currently treatable diseases or due to direct brain damage of the visual cortex. We refer to this product as Orion. We estimate that there are approximately 5.8 million people worldwide who are legally blind due to causes other than currently treatable conditions (including RP) or AMD. If approved for marketing, the FDA and other regulatory agencies will determine which of these patients are eligible for Orion.

Orion is designed to bypass the eye and optic nerve and directly stimulate the part of the brain responsible for vision. The system is based on technology that we utilize in our Argus II system, thereby reducing engineering investment costs and risks, and leveraging the reliability of the Argus II platform.

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. We anticipate enrolling additional feasibility subjects in 2019 while simultaneously negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

Our Competition

The US 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 (including the Argus II): aimed at giving more visual ability to a blind patient via implanting a device in the eye to stimulate remaining retina cells. Electrical neurostimulation technology has seen growing use in recent years for numerous applications– such as chronic pain, Parkinson's disease, essential tremor, epilepsy, and others.
- Visual Cortical Prosthesis (Orion) – We are developing a visual cortical prosthesis and, to our knowledge, the only company pursuing the development of such technology as a potential therapeutic modality. 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.

- Transplants: transplanting retinal tissue to stimulate remaining retina 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 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 US). 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 also requires infecting the patient's cells with a virus. However, instead of fixing a gene defect, this approach would 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 US and EU.

Commercial efforts to develop retinal implants by others include:

- Retina Implant AG: A privately held German company that is developing the Alpha IMS/Alpha AMS, a wireless sub-retinal implant. Although this company obtained a CE Mark in 2013 and was expected to begin commercialization during 2015 in the EU, to our knowledge this product is still not generally available to commercial patients. Retina Implant has also announced plans for a FDA trial in the US but has not announced any U.S. implants in this trial.

- Pixium Vision S.A.: 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 sugjects, and a second study is planned in Pittsburgh, Pennsylvania with five subjects. To date Pixium has announced the successful implantation and activation of devices in Paris, but to our knowledge no performance data has yet been 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 US.

To our knowledge, no other retinal prosthesis has been successful in long-term human trials, with the Argus II System currently the sole implant generally available to commercial patients for treating RP in the US, Canada, EU, and elsewhere. We anticipate that our competitors are unlikely to obtain significant commercial traction in 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 external components other than batteries and chargers, and

- 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, 2018, 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, and include 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 external (non-implantable) components of our system and for the 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 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 suppler sources before experiencing any such disruptions.

Our manufacturing department currently employs 28 persons and the quality assurance department has an additional nine members. We operate a day shift and smaller swing shift, and at this staffing level we can manufacture approximately 10 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 combined total of approximately 100 Argus II or Orion devices per month.

Employees

As of December 31, 2018, we had 123 employees, including approximately 49 in operations; 27 in selling, marketing and distribution; 31 in clinical, regulatory and research and development; and 16 in administration. Of these persons, we employed 108 in the United States and 15 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, and consists of approximately 45,351 rentable square feet at a current base rent of about $36,600 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 the terms of this lease are at least as favorable as those that may have been obtained from a non-affiliated third party. 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. These premises consist of 180 square meters at a base rent of about 8,200 CHF per month, or currently about $8,161 per month based upon current exchange rates. As part of our restructuring and staffing reductions we have renegotiated this lease to 94 square meters at a base rent of 3,147 CHF or about $3,131 starting on January 1, 2019 based upon current exchange rates.

Legal Proceedings

We are not a party to any pending legal proceedings other than those involving Pixium Vision described in “Risk Factors—Risks 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 such 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 US 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 depend on the success of our first commercial product, the Argus II System, which received European market clearance (CE Mark) in February 2011 and FDA approval in February 2013, in the United States for RP; and on the regulatory approval of our current product and a new device under development, the Orion visual prosthesis (a modified version of the Argus II System), to treat other causes of blindness, in the US and other countries, which may never occur.

Our future success depends upon building a commercial operation in the US and expanding growth in Europe as well as entering additional markets to commercialize our Argus II System for RP. We believe our expanded growth will depend on the further development, regulatory approval and commercialization of the Orion product, which we anticipate can be used by nearly all profoundly blind individuals. If we fail to expand the use of the Argus II System in a timely manner for other forms of retinal degeneration in addition to RP, or to develop the Orion product and penetrate the available markets which those applications are intended to serve, we may not be able to expand our markets or to grow our revenue, our stock values could decline and investors may lose money.

Our revenue from sales of Argus II System and potential future products such as Orion is 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 depends on our ability to price our products in a manner acceptable to government and private payers while still maintaining our profit margins. Numerous factors that may be beyond our control may ultimately impact our pricing of Argus II System 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 the Argus II System 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 US 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 Argus II System.

Similarly in Europe these governmental and other agencies could deny, restrict or limit the reimbursement of Argus II System at the hospital, regional or national level. Our business also could be adversely affected if retinal specialists 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 Argus II System on a basis satisfactory to the administering retinal specialists and their facilities. If the local contractors that administer the Medicare program and other funding agencies are slow to reimburse retinal specialists or provider facilities for the Argus II System, the retinal specialists may delay their payments to us, which would adversely affect our working capital requirements. 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 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 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 the Argus II System's revenue.

Our commercial opportunities for the Argus II System may be reduced if our competitors develop or market products that are more effective, are better tolerated, receive better reimbursement terms, are more accepted by physicians, have better distribution channels, or are less costly.

Currently, to our knowledge, no other medical devices comparable to the Argus II System have been approved by regulatory agencies, in the US or Europe, to restore some functional vision in persons who have become blind due to RP. Other visual prosthesis companies such as Retina Implant AG and Pixium Vision S.A., both based in Europe, are developing retinal implant technologies to partially restore some vision in blind patients. Retina Implant has obtained a CE mark for its Alpha AMS product but has not yet sold it to our knowledge. Pixium Vision has obtained CE Mark for its IRIS II product but has withdrawn it from the market. Neither Retina Implant nor Pixium has filed for market approval with the FDA. Retina Implant has not to our knowledge obtained an Investigational Device Exemption (IDE) to begin the required clinical trials in the US, and Pixium Vision has not obtained an IDE for its IRIS II product to begin the required clinical trials in the US. Pixium Vision has obtained an IDE for its PRIMA product. This IDE trial is directed toward AMD, not RP. These competitive therapies if or when developed or brought to market may result in pricing and market access pressure even if Argus II 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 RP and other indications as 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 staffs 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. We believe these risk factors are partially mitigated by the Argus II System being the sole product that is currently available for commercial implantation in the US and Europe. 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, 2018, we had net revenue of $6.9 million and incurred a net loss of $35.1 million. Our total accumulated deficit through December 31, 2018, was $269.5 million.

As a result of our limited commercial operating history, revenue is difficult to predict with certainty. Current and projected expense levels are based largely on estimates of future revenue. 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 our value 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 no going concern qualification by our auditors.

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. A "going concern" opinion from our auditors may negatively affect the price of our common stock. 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.

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 13,652,341 warrants in connection with a completed rights offering in 2017 and an additional 47,812,371 warrants in connection with a completed rights offering of shares and warrants 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 $1.47 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 these 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.

Materials necessary to manufacture 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 impede the commercial production of the Argus II System, reduce gross profit margins and impact our abilities 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 externals 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. The loss of any management executive or any other principal member of our management team could impair our ability to identify, develop and market new products or effectively deal with regulatory and reimbursement matters.

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

The US Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-US 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 our 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 oppositions in the European Patent Office (EPO) challenging the validity of 22 European patents owned or exclusively licensed by Second Sight. Retina Implant AG has joined Pixium Vision in one opposition, and filed one separate opposition. Two of these patents are owned by Johns Hopkins University (JHU) and exclusively licensed to Second Sight, while 20 of these patents are owned by Second Sight. Second Sight has opposed one Pixium patent. These EPO proceedings involving Pixium, Retina Implant, and Second Sight include:

- EP1061874 *Visual Prosthesis* – upheld by the opposition and appellate divisions. No further appeal is available in the EPO. This patent has recently expired.
- EP1061996 *Apparatus for Preferential Outer Retinal Stimulation* – upheld by the opposition division, cancelled in the appellate division. No further appeal is available in the EPO.
- EP1171188 *Retinal Color Prosthesis for Color Sight Restoration* – cancelled in the Opposition Division, we have withdrawn our appeal due to the patent's impending expiration.
- EP2219728 *Electrode Array for Even Neural Pressure Having Multiple Attachment Points* –upheld in the Opposition Division, pending before the Board of Appeal.
- EP1937352 *Sub-threshold Stimulation to Precondition Neurons for Supra-threshold Stimulation* – cancelled in the Opposition Division, pending before the Board of Appeal.

- EP2192949 – *Return Electrode for a Flexible Circuit Electrode Array* – cancelled in the Opposition Division, Pending before the Board of Appeal.
- EP1949437 - *Implantable Microelectronic Device and Method of Manufacture* –Upheld in the Opposition Division, appeal withdrawn.
- EP1945835 – *Platinum Electrode Surface Coating and Method for Manufacturing the Same* – (Pixium joined by Retina Implant) cancelled in the Opposition Division, We have not appealed in favor of pursuing claims in a divisional application.
- 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, pending before the Board of Appeal.
- EP1562672 – *Field Focusing and Mapping in an Electrode Array* – cancelled in the Opposition Division, we did not appeal.
- EP1497483 – *Platinum Electrode* – Upheld in the Opposition Division, no appeal has been filed.
- EP2077892 – *Automatic Fitting for a Visual Prosthesis* – Upheld in the Opposition Division, pending before the Board of Appeal.
- EP2061549 – *Package for an Implantable Neural Stimulation Device* - Cancelled in the Opposition Division, pending before the Board of Appeal.
- EP2155327 – *System for Providing Stimulation Inputs to a Visual Prosthesis* – Upheld in the Opposition Division. No appeal has been filed.
- EP2114514 – *Flexible Electrode Array with Film Support* - Opposition filed.
- EP2089100 – *Flexible Circuit Electrode Array* – Upheld in the Opposition Division, no appeal has been filed.
- EP2185236 – *Implantable Device for the Brain* – Upheld in the Opposition Division. Pending before the board of appeal.
- EP1843816 – *Micro-Miniature Implantable Coated Device* – Opposition filed, a hearing is scheduled for February 5, 2020. Opposed by Retina Implant.
- EP2364179 – *Techniques and Functional Electrical Stimulation to Eliminate Discomfort during Electrical Stimulation of the Retina* – Cancelled in the Opposition Division. Appeal is withdrawn.
- EP1874397 – *Flexible Circuit Electrode Array* – Upheld in modified form in the Opposition Division, we have appeal to restore the original patent.
- EP2136876 – *Saliency-Based Apparatus for Visual Prosthesis* – Cancelled in the Opposition Division, we did not appeal.
- EP2421602 – *Visual Prosthesis Fitting System* – Cancelled in the Opposition Division, we did not appeal.
- EP2167186 – *Video Processing System for a Visual Prosthetic Apparatus* – Opposition filed, a hearing is scheduled for March 19, 2019.

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 0.25% 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 384 issued patents and 58 pending patent applications worldwide as of December 31, 2018. 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 System, 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 US 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 US.

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 $10,000,000, 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 US 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 US 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 an "emerging growth company," and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies," 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. We may take advantage of these exemptions for as long as we are an "emerging growth company," which could be as long as five years from November 14, 2014, the date of our initial public offering. 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 an "emerging growth 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 for non-emerging growth companies. 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:

- the general commercial success of the Argus II System,
- our ability to improve performance and significantly expand the use of Argus II in the larger RP population by treating better-sighted RP patients,
- our ability to obtain regulatory approval of the Argus II System in additional jurisdictions,
- the emergence of products that compete with our product candidates,
- our ability to leverage Argus II technology to restore useful vision with cortical stimulation,
- 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,
- our ability to obtain reimbursement from government or private payers at levels we deem adequate to sustain our operations.

If our quarterly operating results fall below the expectations of investors or securities analysts, 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, along with the proceeds of approximately $34.6 million from our completed shareholder rights offering of securities in February 2019, together with revenue generated from the sale of Argus II units, may be sufficient to fund our operations for at least twelve months from the date of issuance of this report. 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,
- third party expenses relating to the ongoing commercialization of Argus II System,
- the need and cost of conducting additional clinical trials of the Argus II System for other applications,
- the amount of our research and development, including research and development for 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 the 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. Through December 31, 2017 we sold 598,276 shares of common stock and received net proceeds of $1.1 million under the Sales Agreement and thereafter during January and February 2018 we sold 2.2 million shares of common stock for additional net proceeds of $4.0 million. During 2018 we also sold privately in at the market transactions an aggregate of 15,725,291 shares of common stock for gross proceeds of approximately $22.0 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.

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 ability to generate positive cash flow will also hinge on our ability to correctly price our product to our markets, expand the use of the Argus II System, develop the Orion visual prosthesis and obtain government and private insurance reimbursement. As of December 31, 2018 we had total stockholders' equity of $3.1 million and an accumulated deficit of $269.5 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 derive a significant portion of our revenues from Europe, and we anticipate that revenue from Europe and other countries outside the US will increase. 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-US 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 US, 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 US. 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 payers 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 US 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 have 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, parestthesia, 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 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, for example, 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. We are currently investigating the possible cause(s) for the higher impedance levels, including 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. While our first subject has been implanted with the device for 12.5 months, one subject for 11.5 months and 4 subjects have been implanted for 10 months or less, 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. 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 Argus II System and other product candidates in additional jurisdictions. 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 13485:2003 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 are subject to a significant effort to strengthen the regulatory regime for medical devices which, if adopted, will make clearance 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 adopted a new regulatory scheme that imposes significant additional obligations on medical device companies. As such, devices with a current CE marking 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. We will be audited to this new standard in 2020.

Our CE Mark registration must be renewed on a periodic basis. Our current CE Mark registration will expire on September 1, 2019, if not renewed. If we fail to successfully renew our CE Mark registration, we will not be able to sell Argus II in most international markets after September 1, 2019. Further, the Medical Device Single Audit Program (MDSAP) is a new multi-national standard adopted by Australia, Brazil, Canada, Japan and the European Union. MDSAP may impose a higher compliance burden than CE Mark through more rigorous audit requirements. If we do not comply with the new MDSAP standard, we will not be able to sell Argus II in Canada after December 31, 2019.

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 timely and effectively to 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, 2018, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $69.4 million and $42.5 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 2038 for federal net operating losses and from 2033 through 2038 for state net operating losses. 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 its ability to use them to offset taxable income in periods following the ownership change. In general, the annual use limitation equals the aggregate value of 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.

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

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, or
- 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.

We may be unable to comply with the applicable continued listing requirements of The Nasdaq Capital Market.

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 January 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 become subject to delisting if we did not regain compliance within the compliance period (or the compliance period as may be extended). There can be no assurance that we will continue to be able to comply with the applicable listing standards. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our common stock would need to meet or exceed $1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our shares of common stock would be subject to delisting. 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.

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 22, 2019, entities controlled and beneficially owned by Gregg Williams, our Chairman of the Board, own of record an aggregate of approximately 62.6% of the outstanding shares of our common stock (or 73.0% after giving effect to Mr. Williams' right to acquire beneficial ownership of 48,239,184 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 the election of directors and the approval of significant corporate transactions. 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 2016, 2017, 2018 and 2019, we funded our business primarily through the issuance and sale of our securities. We obtained approximate proceeds of $9,000,000 in 2016, $10,000,000 in 2017, $10,000,000 in May 2018, $5,000,000 in August 2018, $4,000,000 in October 2018, $3,000,000 in December 2018 and $30,000,000 in February 2019 from the sale of our securities to entities affiliated with Mr. Williams, our Chairman of the Board, constituting 45.5%, 49.8%, 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.

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, closing prices of our shares have ranged from $0.69 per share to $23.60 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 payers, 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 10,000,000 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.

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, and consists of approximately 45,351 rentable square feet at a base rent of approximately $36,600 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. The lease consists of 180 square meters at a base rent of 8,200 CHF per month, or about $8,161 per month based upon current exchange rates. Our lease is currently monthly with a six month notice required for termination, with the Foundation for the Innovation Park at EPFL. As part of our restructuring and staffing reductions we have renegotiated this lease to 94 square meters at a base rent of 3,147 CHF or $3,131 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.

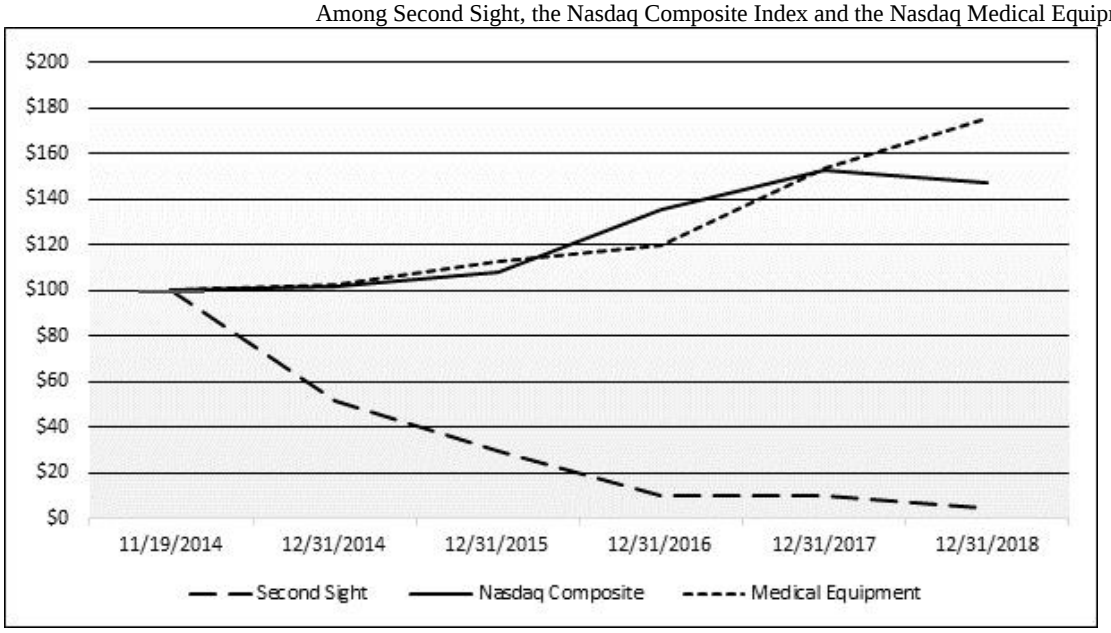
	High	Low
Fiscal Year Ended December 31, 2018		
First quarter	$ 2.31	$ 1.49
Second quarter	$ 2.23	$ 1.48
Third quarter	$ 1.97	$ 1.51
Fourth quarter	$ 1.82	$ 0.73
Fiscal Year Ended December 31, 2017		
First quarter	$ 2.76	$ 1.11
Second quarter	$ 1.31	$ 1.10
Third quarter	$ 1.35	$ 0.96
Fourth quarter	$ 2.35	$ 1.06

On March 12, 2019, the closing sales price reported for our common stock was $0.8189 per share, and as of that date there were approximately 106 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.

The performance graph below compares the cumulative total stockholder return on our common stock with that of the Nasdaq Composite index and the Nasdaq Medical Equipment index. The initial public offering price of our common stock was $9.00 per share and the closing price was $19.97 per share on November 19, 2014 (the date our common stock first commenced trading on Nasdaq). The chart assumes $100 was invested at the close of the market on November 19, 2014 in our common stock, the Nasdaq Composite index and the Nasdaq Medical Equipment index.

Second Sight Medical Products, Inc. Comparison of Total Return
Among Second Sight, the Nasdaq Composite Index and the Nasdaq Medical Equipment Index



	11/19/14	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18
Second Sight	$ 100.00	$ 51.38	$ 29.49	$ 9.86	$ 9.56	$ 4.44
Nasdaq Composite	$ 100.00	$ 101.39	$ 108.45	$ 118.07	$ 153.06	$ 147.12
Medical Equipment	$ 100.00	$ 102.89	$ 112.51	$ 119.97	$ 153.57	$ 175.95

Use of Proceeds from Financings

In March 2017 we completed a Rights Offering to existing stockholders (File No. 333-215463), raising proceeds of approximately $19.7 million net of cash offering costs, and selling 13,652,341 units, each consisting of one share of common stock and one warrant, at $1.47 per unit. We have used the proceeds to further develop and enhance our products, support operations and for general corporate purposes.

In November 2017, we entered into an At 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. Through December 31, 2017 we sold 598,276 shares of common stock and received net proceeds of $1.1 million under the Sales Agreement and thereafter during January and February 2018 we sold 2.2 million shares of common stock for additional net proceeds of $4.0 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 3,275,100, 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at $0.916, $1.62, $1.55 and $1.48 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.

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, 2018, 2017, and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 are derived from, and are qualified in their entirety by reference to, our audited consolidated financial statements included elsewhere in this Form 10-K. The consolidated balance sheet data as of December 31, 2016 and 2015 and the consolidated statements of operations data for the year ended December 31, 2015 is derived from the audited consolidated financial statements not included herein, but which were previously filed with the Securities and Exchange Commission.

	Fiscal Years Ended December 31,			
(in thousands, except per share data)	2018	2017	2016	2015
Net sales	$ 6,896	$ 7,964	$ 3,985	$ 8,950
Cost of sales	4,888	5,117	10,076	5,293
Gross profit (loss)	2,008	2,847	(6,091)	3,657
Operating expenses:				
Research and development, net of grants	10,005	7,893	5,347	3,036
Clinical and regulatory	4,600	3,062	2,703	3,510
Selling and marketing	11,336	9,569	8,989	8,935
General and administrative	10,692	10,932	10,080	8,223
Restructuring charges	555	—	—	—
Total operating expenses	37,188	31,456	27,119	23,704
Loss from operations	(35,680)	(28,609)	(33,210)	(20,047)
Interest income	86	93	31	2
Other income, net	—	—	—	27
Net loss	$ (35,094)	$ (28,516)	$ (33,179)	$ (20,018)
Net loss per common share – Basic and diluted	$ (0.53)	$ (0.53)	$ (0.84)	$ (0.56)
Weighted average shares outstanding – Basic and diluted	66,378	54,152	39,554	35,637

	As of December 31,			
(in thousands)	2018	2017	2016	2015
Cash and cash equivalents	$ 4,471	$ 7,839	$ 10,875	$ 15,960
Working capital	$ 2,022	$ 6,550	$ 9,620	$ 18,782
Total assets	$ 10,682	$ 14,497	$ 16,810	$ 28,245
Stockholders' equity	$ 3,084	$ 7,882	$ 11,148	$ 20,263

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, 2018, 2017 and 2016 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) was founded in 1998 and 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 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"). No published in-human data is available yet for the Orion system. We anticipate enrolling additional feasibility subjects in 2019 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 commercial and clinical operations in Europe, the Middle East and Asia.

Our major corporate, clinical and regulatory milestones include:

- In 1998, Second Sight was founded.
- In 2002, we commenced clinical trials in the US for our prototype product, the Argus I retinal prosthesis.
- In 2007, we commenced clinical trials in the US for the Argus II, which later became our first commercial product.
- In 2011, we received marketing approval in Europe (CE Mark) for the Argus II.
- In 2013, we received marketing approval from the FDA in the U.S. for the Argus II.
- In 2014, we launched the Argus II in the US, completed our initial public offering ("IPO"), and began trading on NASDAQ under the symbol "EYES."
- In January 2016, we successfully implanted and activated a wireless visual cortical prosthesis in a human.
- In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion
- In 2018, we reached a milestone by implanting our 300th patient with the Argus II.
- In the first quarter of 2018, first-in-human Orion was successfully implanted, activated and is being tested at the Ronald Reagan UCLA Medical Center.
- In September 2018, we were awarded a $1.6 million grant from National Institutes of Health to support Orion clinical development (with the intent to fund $6.3 million over five years subject to annual review and approval).

Our current 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 subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market

research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

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 there is no clear evidence that it can slow or reverse 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 the remaining international markets. We anticipate that the annual savings from the restructuring will amount to approximately $3.0 million per year and we plan to reallocate savings to the Orion program and other related projects. 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 are were settled in cash during the fourth quarter of 2018.

We will continue to monitor the efficiency and effectiveness of commercial activities for Argus II and make further changes as needed to ensure sufficient payback on commercial spending while maximizing capital available to support Orion programs.

We are actively developing multiple technologies that we believe to be complimentary to artificial vision and could potentially significantly enhance the Argus II or Orion user experience. In most cases, we collaborate with 3rd party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that are currently researching include: eye tracking, object recognition and localization, thermal imaging and depth-based decluttering. We expect to advance several of these technologies to prototype eyewear suitable for clinical testing in 2019.

Currently, after more than 20 years of research and development, more than $200 million of investment and over $34 million of grants awarded in support of our technology development, we employ over 120 people in the development (research, engineering and clinical), manufacture, and commercialization of the Argus II System and future products such as 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 2016 and 2017 and 2018, we funded our business primarily through:

- Issuance of common stock in our rights offering in June 2016, which provided net cash proceeds of $19.5 million.
- Issuance of common stock and warrants in our rights offering in March 2017, which provided net cash proceeds of $19.7 million.
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2017 and first quarter of 2018, which provided $5.1 million of net cash proceeds.
- Issuance of common stock in a stock purchase agreement in May 2018, which provided net cash proceeds of $10.0 million.
- Issuance of common stock in a stock purchase agreement in August 2018, which provided net cash proceeds of $5.0 million.
- Issuance of common stock in a stock purchase agreement in October 2018, which provided net cash proceeds of $4.0 million.
- Issuance of common stock in a stock purchase agreement in December 2018, which provided net cash proceeds of $3.0 million.
- Revenue of $6.9 million, $8.0 million and $4.0 million, for the years ended December 31, 2018, 2017 and 2016, 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 3,275,100, 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at $0.916, $1.62, $1.55 and $1.48 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 47.8 million units, each priced at $0.724 for gross proceeds of approximately $34.6 million. Each unit consisted of one share and one immediately exercisable warrant having a strike price of $1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately $30 million.

In November 2017, we entered into an At 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 SEC. 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 December 2017, we issued 598,276 shares of common stock for gross proceeds of approximately $1.2 million as part of our Sales Agreement. During January and February 2018, we sold 2.2 million shares of common stock which provided net proceeds of $4.0 million under the Sales Agreement. No shares have been sold since February 2018 under the Sales Agreement.

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 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 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 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 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 US, coding, coverage, and payment are necessary for the surgical procedure and Argus II system to be reimbursed by payers. Coding has been established for the device and the surgical procedure. Coverage and payment vary by payer. 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 US The Argus II is authorized for coverage, when medically necessary in eight of 12 MAC jurisdictions (comprising 31 states). Effective January 1, 2018, the Centers for Medicare and Medicaid Services ("CMS") established a 2018 national average payment rate of $122,500 for both the procedure and the Argus II retinal prosthesis system when furnished in a hospital outpatient department. On July 25, 2018 the Centers for Medicare and Medicaid Services (CMS) posted the proposed rule and related proposed rates for the calendar year (CY) 2019. Medicare Hospital Outpatient Prospective Payment Systems (OPPS) and the CY 2019 Ambulatory Surgical Center (ASC) payment system. In these postings, CMS proposed a national average Medicare hospital outpatient rate for CY 2019 of $137,501 for Argus II and the associated surgical implantation procedure, and a proposed national average ASC rate of approximately $134,225 for the Argus II and related implantation procedure. On November 2, 2018 CMS established a final rule OPPS payment rate of $152,500 and ASC payment rate of $134,051.
- **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 all Medicare Advantage plans in that MAC jurisdiction are required to 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 may allow providers to confirm coverage and payment for the Argus II procedure in advance of implantation. Since 2015 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.

During the year ended December 31, 2018, 38 individuals in the US and Canada were implanted with the Argus II technology. Of these patients, 34 were in the US primarily covered by Medicare FFS or Medicare Advantage plans and the remainder had private commercial, Veteran's Administration or other insurance plan coverage. Four patients in Canada were covered by regional public reimbursement or private funding.

We retain employees and utilize consultants with insurance reimbursement expertise dedicated to expanding and enhancing coverage decisions. Currently, eight of 12 Medicare jurisdictions authorize coverage of the Argus II in 31 states, two territories and the District of Columbia when medically necessary, including:

- CGS (J15 -- Ohio and Kentucky),
    - Palmetto GBA (JM -- Virginia, (excluding Part B for Arlington and Fairfax counties), West Virginia, North Carolina and South Carolina),
- Palmetto GBA (JJ – Alabama, Georgia and Tennessee),

- NGS (J6 -- Minnesota, Illinois and Wisconsin),
- NGS (JK -- Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont),
- FCSO (JN -- Florida, Puerto Rico and the US Virgin Islands),
- Novitas (JH-- Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas) and
- Novitas (JL -- Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania)

We are actively engaged with the remaining MACs and are committed to supporting their requests for additional information and clinical evidence. We expect that additional positive coverage decisions will be issued over time but cannot predict timing or ultimate success with each MAC.

Within Europe, we have obtained reimbursement approval or funding in Germany, France, one region of Italy, and a Commissioning through Evaluation ("CtE") program in England.

We are seeking additional reimbursement approvals in other countries in Europe and international markets.

In France, we were selected to receive the first "Forfait Innovation" (Innovation Bundle) from the Ministry of Health, which is a special funding program for breakthrough procedures to be introduced into clinical practice. As part of this program, we conducted a post-market study in France which enrolled a total of 18 subjects who were followed for two years. The French program also funded implantation of 18 additional patients who were not part of the post-market study. We submitted the final clinical report of the Forfait Innovation study late last year and the outcomes of the study are still under review by the National health reimbursement authority (HAS). Subject to a successful and positive completion of HAS' review of the outcomes of French study, we anticipate that Argus II therapy may be covered and funded through the standard payment system in France, however, we can provide no assurance that the French government will make a positive decision to continue to fund the Argus II in future.

In December 2016, NHS England announced it would cover 10 Argus implantations as part of a CtE program. The CtE program is especially designed for treatments that show significant promise for the future, while new clinical and patient experience data are collected within a formal evaluation program. This program is similar to the Forfait Innovation program in France. We are actively and closely working with NHS England to finalize the final details of the program that is expected to be kicked off within next few months.

To date, our marketing activities have focused on raising awareness of the Argus II with potential patients, implanting physicians, and referring physicians. Our marketing activities include exhibiting, sponsoring symposia, and securing podium presence at professional and trade shows, securing journalist coverage in popular and trade media, attending patient meetings focused on educating patients about existing and future treatments, and sponsoring information sessions for the Argus II. In the United States, our efforts will focus on media advertisements dedicated to RP patients and their families. These advertisements will be placed in geographic areas where we have Centers of Excellence committed to Argus II.

Currently, we are in process of evaluating potential reimbursement pathways for Orion. Compared to Argus II, which is largely catering to Medicare patient population, Orion is expected to address patient population with diverse and more balanced payer mix due to our potential indications profile and expected younger average patient population. As Orion is a part of the FDA's Breakthrough Devices program, we are closely evaluating a variety of fast track reimbursement programs catering to promising breakthrough treatments. If feasible, we also plan to approach some of the key payers during the second half of 2019 and get their feedback to ensure our pivotal clinical trial design will be able to cater to their key coverage requirements.

Product and Clinical Development Plans

Argus II. The Argus II is currently approved for RP patients with bare or no light perception in the US, and in Europe for severe to profound vision loss due to outer retinal degeneration, such as from RP, choroideremia, and other similar conditions. The number of people who are legally blind due to RP is estimated to be about 25,000 in the US, 42,000 in Europe, and about 375,000 total worldwide. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research for the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

Given the limited addressable market of Argus II, we 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. As a result, we evaluate the short-term financial payback to enter new Argus markets or expand geographically; have increased focus on our strongest markets and the top centers of excellence in those markets allowing for more efficient deployment of field resources.

In October 2018, we announced a restructuring of our international commercial activities and personnel. We will maintain a team that will continue support of existing Argus II patients and centers of excellence in our international markets. We anticipate that the annual savings from the restructuring will amount to approximately $3.0 million per year and we plan to reallocate savings to the Orion program and other related projects. 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.

Orion. 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 (e.g. RP or cataracts), individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare. However, of the estimated 36 million blind people worldwide, there are approximately 5.8 million people who are legally blind due to causes that are not otherwise treatable (including RP) or age-related macular degeneration ("AMD"). If approved for marketing, the FDA and other regulatory agencies will determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Our objective in designing and developing the Orion visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for human vision. A six-subject early feasibility study of the Orion device is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles ("UCLA") and Baylor College of Medicine in Houston ("Baylor"). No published in-human data is available yet for the Orion system.

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

- Greater interactive review both for the Investigational Device Exemption and Premarket Approval application;
- Greater reliance on post-market vs. pre-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.

It is our expectation that inclusion in the Breakthrough Devices Program may shorten the timeline required to bring the Orion to market as a commercial product. We are currently evaluating our pivotal trial design for Orion and expect to reach consensus with the FDA on design specifics during 2019. 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. While negotiations with the FDA are ongoing, we believe the study design will require a minimum sample population of 30 subjects with at least 6 months of follow-up data for each patient prior to submittal of a premarket (PMA) application.

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606).* This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. We adopted this ASU on January 1, 2018 retrospectively, the cumulative effect of the initial application on our accumulated deficit on that date was immaterial.

We generate our revenue from sales of our Argus II retinal prosthesis systems, which include the implant and external 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.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASU 2016-02 (Accounting Standards Codification ("ASC") Topic 842) supersedes the previous leases standard, ASC 840, Leases. The standard is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. Subsequently, in July of 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"), and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), both of which clarify and enhance the certain amendments made in ASU 2016-02 and will be adopted in conjunction with ASU 2016-02. ASU 2016-02 is required to be applied with a modified retrospective approach to each prior reporting period presented with various optional practical expedients. We generally do not finance purchases of equipment or other capital but do lease our facilities. We expect most of our lease commitments will be subject to the updated standard and recognized as lease liabilities and right-of-use assets upon adoption.

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 external 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:

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- 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 US 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 and supplemented with average historical volatilities of comparable companies in 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.

Patent Costs. We have over 380 domestic and foreign patents. Due to the uncertainty associated with the successful development of one or more commercially viable products based on our research efforts and any related patent applications, all patent costs, including patent-related legal, filing fees and other costs, including internally generated costs, are expensed as incurred. Patent costs are included in general and administrative expenses in the consolidated statements of operations.

Results of Operations

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 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 retain a team that continues to support existing Argus II patients and Centers of Excellence in the remaining international markets.

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. While we are currently experiencing low yields on our manufacturing process, we expect that over the next few years we will be able to refine our processes and improve our manufacturing yields. We are also producing at less than our capacity which results in unabsorbed overhead costs. In future years, we expect to produce in greater quantities and improve our manufacturing yields and we expect that we will more consistently generate positive gross margins. 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, 2018 and 2017

Worldwide commercial implant volume for the years ended December 31, 2018, 2017 and 2016 was as follows:

	Years Ended December 31,		
	2018	**2017**	**2016**
Europe and the Middle East	19	30	30
Asia	12	7	—
Canada	4	7	1
United States	34	31	11
Total	69	75	42

Net Sales. Our net sales decreased from $8.0 million in 2017 to $6.9 million in 2018, a decrease of $1.1 million, or 14%. This decrease in net sales was due to a lower international sales as we restructured our international commercial activities and a lower average revenue per implant in 2018, due to a lower reimbursement rate set by CMS. In 2018 there were 64 implants recognized compared to 67 in 2017, and the amount of revenue recognized per implant decreased from $119,000 in 2017 to $108,000 in 2018 given the lower 2018 CMS rate as compared to the 2017 CMS rate in the US. The difference between reimbursement rates set by payers 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 payers, 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. We expect our average revenue recognized per implant unit for 2019 to be in a range of $120,000 to $130,000, depending on the geographic mix of implants.

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 $5.1 million in 2017 to $4.9 million in 2018, a decrease of $0.2 million or 4%, resulting in a gross margin of 29% in 2018 compared to a gross margin of 36% in 2017. In 2018, cost of sales were impacted by decreased production volumes which increased per unit production costs. In 2017, cost of sales included a $3.1 million decrease in the inventory reserve for slow-moving inventory and a $2.8 million charge related to unabsorbed overhead costs. At lower volumes, we experience lower gross margins due to our fixed costs of production.

Research and development expense. Research and development expense increased from $7.9 million in 2017 to $10.0 million in 2018, an increase of $2.1 million, or 27%. The increase from the prior year was primarily due to verification and validation activities related to Argus 2s and consists of increased headcount, outside services, and costs for internally produced prototypes partially offset by $0.5 million of costs deferred that are expected to be funded by an NIH grant.

Clinical and regulatory expense. Clinical and regulatory expense increased from $3.1 million in 2017 to $4.6 million in 2018, an increase of $1.5 million, or 48%. The increase of $1.5 million primarily related to costs associated with the Orion feasibility study. We expect clinical and regulatory costs to increase in the future as it conducts additional clinical trials such as with our intent to enroll additional feasibility subjects and to conduct a future pivotal study with Orion.

Selling and marketing expense. Selling and marketing expense increased from $9.6 million in 2017 to $11.3 million in 2018, an increase of $1.7 million or 18%. This increase in spending represents an increase of $0.8 million in personnel related costs, such as salaries, benefits, and stock-based compensation, a $0.5 million increase in expenditures on consultants and outside services for items such as legal services, public relations and customer outreach programs and a $0.5 million increase in travel costs. We will continue to monitor the efficiency and effectiveness of commercial activities for Argus II and make further changes as needed to ensure sufficient payback on commercial spending while maximizing capital available to support Orion programs.

General and administrative expense. General and administrative expense decreased from $10.9 million in 2017 to $10.7 million in 2018, a decrease of $0.2 million, or 2%. The decrease is primarily related to reduced non-cash stock compensation expense due to executive transitions.

Restructuring charges. 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 $35.1 million in 2018, as compared to $28.5 million in 2017. The $6.6 million increase in net loss from 2017 to 2018 was primarily attributable to a $5.7 million increase operating expenses and a decrease in gross profit from reduced volumes.

Comparison of the Years Ended December 31, 2017 and 2016

Net Sales. Our net sales increased from $4.0 million in 2016 to $8.0 million in 2017, an increase of $4.0 million, or 100%. This increase in net sales was due to a higher number of implants in 2017 versus 2016 as well as a higher level of revenue per implant. In 2017 there were 75 implants compared to 42 in 2016, and the amount of revenue recognized per implant increased from $95,000 in 2016 to $106,000 in 2017.

In both 2017 and 2016, there were 30 implants in Europe and the Middle East (EMEA). With the addition of new centers in South Korea and Taiwan, there were seven implants in Asia, compared to none in the prior year. In the North American market, which includes the United States and Canada, implants increased to 38 in 2017 compared to 12 in 2016.

The amount of revenue recognized per implant in a period depends on several factors, including reimbursement policies set by private and government payers, 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. Given the higher 2017 CMS rate in the US, as discussed above, and the higher relative growth in North America compared to the rest of the world, where average selling prices are generally lower than in North America, the overall revenue per implant grew from $95,000 in 2016 to $106,000 in 2017.

Cost of sales. Cost of sales decreased to $5.1 million in 2017 from $10.1 million in 2016, a decrease of $5.0 million or 50%, resulting in a positive gross margin of 36% in 2017 compared to a negative gross margin of 153% in 2016. In 2017, cost of sales included a $3.1 million credit related to the reduction of a reserve for slow-moving inventory and a $2.8 million charge related to unabsorbed overhead costs, which combined nets to a $0.3 million credit. In 2016, cost of sales included a $4.7 million charge to increase a reserve for slow-moving inventory and a $2.8 million charge related to unabsorbed overhead costs, which combined totals to a $7.5 million charge.

Research and development expense. Research and development expense increased from $5.3 million in 2016 to $7.9 million in 2017, an increase of $2.6 million, or 49%. The increase is mainly attributable to a $2.0 million, or 83%, decrease of grant revenues which are used to offset research and development expenses. Grant revenues decreased from $2.4 million in 2016 to $0.4 million in 2017. This decrease in grant revenue relates to a 2014 grant from Johns Hopkins University that had been almost completely utilized in prior years was fully applied by the end of the first quarter of 2017. Excluding the offsetting effect of grant revenue, research and development expense increased by $0.5 million, or 6%, from $7.7 million in 2016 to $8.2 million in 2017. This increase in research and development expenditures relates to $0.9 million of higher spending for people related costs and $0.2 million more spent on consultants and outside services, which was partially offset by $0.6 million in lower expenditures related to supplies and materials used for prototype development.

Clinical and regulatory expense. Clinical and regulatory expense increased from $2.7 million in 2016 to $3.1 million in 2017, an increase of $0.4 million, or 15%. This increase is primarily attributable to higher spending on staff and consultants as we prepared to start new clinical trials for better- vision patients and for the Orion cortical implant.

Selling and marketing expense. Selling and marketing expense increased from $9.0 million in 2016 to $9.6 million in 2017, an increase of $0.6 million or 7%. This increase in spending represents an increase of $1.1 million in personnel costs, such as salaries, benefits, travel and stock-based compensation, partially offset by a $0.4 million decrease in expenditures on consultants and outside services for items such as legal services, public relations and customer outreach programs.

General and administrative expense. General and administrative expense increased from $10.1 million in 2016 to $10.9 million in 2017, an increase of $0.8 million, or 8%. This increase is primarily attributable to $0.7 million of higher people related costs, primarily higher salaries, bonuses and stock-based compensation, and $0.5 million of higher expenditures on outside services for items such as legal and recruiting services. Partially offsetting this was a $0.4 million swing in bad debt expense, which dropped from an expense of $0.3 million in 2016 to a net recovery of previously written off receivables of $0.1 million in 2017.

Net loss. The net loss was $28.5 million in 2017, as compared to $33.2 million in 2016. The $4.7 million decrease in net loss from 2016 to 2017 was primarily attributable to an $8.9 million increase in gross profit, (from a loss in 2016 to a gross margin in 2017), caused mainly by higher revenues and the reversal of charges for excess inventory, offset by $4.3 million in increased operating expenses.

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.

In March 2017, we successfully completed an additional Rights Offering to existing shareholders, raising proceeds of approximately $19.7 million net of cash offering costs, and selling 13,652,341 units at $1.47 per unit. Each unit consists of a share of common stock and a five-year warrant with an exercise price of $1.47.

During December 2017, we issued 598,276 shares of common stock for gross proceeds of approximately $1.2 million as part of our At Market Issuance Sales Agreement with two different investment banks. We paid expenses of approximately $0.1 million resulting in net proceeds of $1.1 million. In the period from January 1, 2018 to February 28, 2018, we sold approximately 2.2 million additional shares through our Sales Agreement, raising gross proceeds of approximately $4.1 million and net proceeds of approximately $4.0 million after expenses. No shares have been sold under the Sales Agreement since February 2018.

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 3,275,100, 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at $0.916, $1.62, $1.55 and $1.48 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 47.8 million units, each priced at $0.724 for gross proceeds of approximately $34.6 million. Each unit consisted of one share and one immediately exercisable warrant having a strike price of $1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately $30 million.

Working capital was $2.0 million at December 31, 2018, as compared to $6.5 million at December 31, 2017, a decrease of $4.5 million. Working capital was $6.5 million at December 31, 2017, as compared to $9.6 million at December 31, 2016, a decrease of $3.1 million. We use our cash, cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

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 used $0.4 million from a net change in operating assets and liabilities.

During 2017, we used $23.9 million of cash in operating activities, consisting primarily of a net loss of $28.5 million, offset by non-cash charges of $1.3 million for depreciation and amortization of property and equipment, stock-based compensation, common stock issuable, bad debt recovery and excess inventory reserve, and used $3.3 million from a net change in operating assets and liabilities.

During 2016, we used $25.1 million of cash in operating activities, consisting primarily of a net loss of $33.2 million, offset by non-cash charges of $9.1 million for depreciation and amortization of property and equipment, stock-based compensation, common stock issuable, bad debt expense, excess inventory reserve, and loss on disposal of property and equipment and generated $1.0 million from a net change in operating assets and liabilities.

Cash Flows from Investing Activities

Investing activities in 2018, 2017 and 2016 used $0.2 million, $0.3 million and $0.5 million, respectively, of cash for the purchase of equipment.

Cash Flows from Financing Activities

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.

Financing activities provided $21.2 million of cash in 2017, including $20.8 million from the net proceeds from the issuance of common stock and warrants and $0.4 million from the issuance of common stock for ESPP purchases.

Financing activities provided $20.5 million of cash in 2016, including $19.5 million from the net proceeds from the issuance of common stock, $0.5 million from stock option and warrant exercises and issuance of common stock for ESPP purchases of $0.5 million.

Financial Commitments

Effective August 2012, we entered into a lease agreement with a company owned by the former major stockholder of us for office space for a term of five years that was to expire on February 28, 2017. The lease included rental of additional space commencing January 1, 2013 and a five year option to renew. The lease requires us to pay real estate taxes, insurance and common area maintenance each year, and is subject to periodic cost of living adjustments. In April 2014, the lease was renegotiated with the term ending on February 28, 2022, and a five year option to renew. The new lease also requires us to pay real estate taxes, insurance and common area maintenance each year and includes

automatic increases in base rent each year. In November 2014, the industrial center in which our premises are located was sold to an independent third party.

Our Swiss subsidiary rents office space in Switzerland on a month-to-month basis for CHF 8,200 (approximately $8,161 based on current exchange rates) per month.

Future minimum rental payments required under the operating leases are as follows for the years ended December 31 (in thousands).

Years	Amount
2019	$ 884
2020	910
2021	937
2022	158
Total	$ 2,889

Off-Balance Sheet Arrangements

At December 31, 2018, 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, 2018, our cash equivalents consisted solely of money market funds.

Exchange Rate Sensitivity

During 2018, approximately 65% of our revenue was denominated in US dollars, 32% in Euros, and 3% in Canadian dollars. This compares with 2017 when approximately 58% of our revenue was denominated in US dollars, 35% in Euros, and 7% in Canadian dollars. For 2018, 2017 and 2016, the majority of our operating expenses were denominated in US 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, 2018, 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 the Jumpstart Our Business Startups Act (the "JOBS Act"). Under the JOBS Act, we are not required to comply with Section 404(b) because we are an "emerging growth company."

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, 2018, 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, 2018 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 2018 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 2019 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 2019 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 2019 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 2019 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 2019 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 2019 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	Restated Articles of Incorporation of the Registrant(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.(1)+
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	Joint Research and Development Agreement between Johns Hopkins University Applied Physics Laboratory and Registrant.(1)
10.9	Second Sight Medical Product, Inc. 2015 Employee Stock Purchase Plan (3)+
10.10	Executive Employment Agreement between Registrant and Will McGuire (4)+
10.11	Executive Employment Agreement between Registrant and John Blake (5)(+)
10.12	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated May 3, 2018(6)
10.13	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated August 14, 2018(7)
10.14	Executive Employment Agreement between Registrant and William Patrick Ryan(8)(+)
10.15	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated October 18, 2018(9)
10.16	Securities Purchase Agreement among Registrant, Gregg G. Williams 2006 Trust and Sam B. William 1995 Generation-Skipping Trust dated December 12, 2018(10)
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

(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 16, 2015.

(5)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 25, 2015.(6)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2018.(7)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2018.(8)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2018.(9)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on September 4, 2018.(10)Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 22, 2018.(11)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 18, 2019

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 Jonathan Will McGuire and John T. Blake, or either of them, jointly and severally, as his true and lawful attorney-in-fact and agent, with full power of substitution, each with power to act alone, 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 each 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 18, 2019
/s/ John T. Blake John T. Blake	Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2019
/s/ Gregg Williams Gregg Williams	Chairman of the Board	March 18, 2019
/s/ William J. Link William J. Link	Director	March 18, 2019
/s/ Aaron Mendelsohn Aaron Mendelsohn	Director	March 18, 2019
/s/ Matthew Pfeffer Matthew Pfeffer	Director	March 18, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Second Sight Medical Products, Inc. and Subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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.

Liquidity

The Company is subject to the risks and uncertainties associated with a business with one product line and limited revenues. The Company has incurred recurring operating losses and negative operating cash flows 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.

/s/ Gumbiner Savett Inc.
We have served as the Company's auditor since 2014
Santa Monica, California
March 18, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Consolidated Balance Sheets
(In thousands)

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,471	$ 7,839
Accounts receivable, net	504	1,831
Inventories, net	3,250	2,700
Prepaid expenses and other current assets	1,395	795
Total current assets	9,620	13,165
Property and equipment, net	1,025	1,299
Deposits and other assets	37	33
Total assets	$ 10,682	$ 14,497
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,305	$ 752
Accrued expenses	2,503	2,425
Accrued compensation expense	2,690	2,611
Accrued clinical trial expenses	933	779
Contract liabilities	167	48
Total current liabilities	7,598	6,615
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 200,000 shares authorized; shares issued and outstanding: 76,336 and 57,630 at December 31, 2018 and December 31, 2017, respectively	229,019	202,156
Common stock issuable	—	153
Additional paid-in capital	44,111	40,522
Accumulated other comprehensive loss	(575)	(572)
Accumulated deficit	(269,471)	(234,377)
Total stockholders' equity	3,084	7,882
Total liabilities and stockholders' equity	$ 10,682	$ 14,497

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,		
	2018	**2017**	**2016**
Net sales	$ 6,896	$ 7,964	$ 3,985
Cost of sales	4,888	5,117	10,076
Gross profit (loss)	2,008	2,847	(6,091)
Operating expenses:			
Research and development, net of grants	10,005	7,893	5,347
Clinical and regulatory	4,600	3,062	2,703
Selling and marketing	11,336	9,569	8,989
General and administrative	10,692	10,932	10,080
Restructuring charges	555	—	—
Total operating expenses	37,188	31,456	27,119
Loss from operations	(35,180)	(28,609)	(33,210)
Interest income	86	93	31
Net loss	$ (35,094)	$ (28,516)	$ (33,179)
Net loss per common share – basic and diluted	$ (0.53)	$ (0.53)	$ (0.84)
Weighted average shares outstanding – basic and diluted	66,378	54,152	39,554

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,		
	2018	**2017**	**2016**
Net loss	$ (35,094)	$ (28,516)	$ (33,179)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(3)	36	(27)
Comprehensive loss	$ (35,097)	$ (28,480)	$ (33,206)

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 Capital	Notes Receivable for Stock Option Exercises	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance, December 31, 2015	35,942	$ 166,049	33	$ 205	$ 27,277	$ (5)	$ (581)	$ (172,682)	$ 20,263
Issuance of common stock and options in connection with rights offering, net of issuance costs	5,978	19,430	—	—	53	—	—	—	19,483
Issuance of shares under long-term investor right	355	—	—	—	—	—	—	—	—
Issuance of common stock in connection with employee stock purchase plan	189	488	—	—	—	—	—	—	488
Exercise of stock options	96	478	—	—	—	3	—	—	481
Stock-based compensation expense	—	—	—	—	3,367	—	—	—	3,367
Stock issued in connection with professional services	82	324	44	(52)	—	—	—	—	272
Release of restricted stock units	59	—	—	—	—	—	—	—	—
Comprehensive loss:									
Net loss	—	—	—	—	—	—	—	(33,179)	(33,179)
Foreign currency translation adjustment	—	—	—	—	—	—	(27)	—	(27)
Comprehensive loss	—	—	—	—	—	—	(27)	(33,179)	(33,206)
Balance, December 31, 2016	42,701	$ 186,769	77	$ 153	$ 30,697	$ (2)	$ (608)	$ (205,861)	$ 11,148

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Common Stock		Common Stock Issuable		Additional Paid-in Capital	Notes Receivable for Stock Option Exercises	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Issuance of common stock and warrants in connection with rights offering, net of issuance costs	13,653	13,647	—	—	6,021	—	—	—	19,668
Issuance of common stock in connection with employee stock purchase plan	407	394	—	—	—	—	—	—	394
Repayment of notes receivable for stock option exercises	—	—	—	—	—	2	—	—	2
Stock-based compensation expense	—	—	—	—	3,784	—	—	—	3,784
Issuance of shares of common stock, net of issuance costs	598	1,084	—	—	—	—	—	—	1,084
Fair value of stock options issued for services	—	—	—	—	20	—	—	—	20
Common stock issuance for services	223	262	5	—	—	—	—	—	262
Release of restricted stock units	48	—	—	—	—	—	—	—	—
Comprehensive loss:									
Net loss	—	—	—	—	—	—	—	(28,516)	(28,516)
Foreign currency translation adjustment	—	—	—	—	—	—	36	—	36
Comprehensive loss	—	—	—	—	—	—	36	(28,516)	(28,480)
Balance, December 31, 2017	57,630	$ 202,156	82	$ 153	$ 40,522	$ —	$ (572)	$ (234,377)	$ 7,882

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Common Stock		Common Stock Issuable		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Issuance of shares common stock, net of issuance costs	17,949	25,936	—	—	—	—	—	25,936
Issuance of common stock in connection with employee stock purchase plan	494	508	—	—	—	—	—	508
Exercise of stock options	76	149	—	—	—	—	—	149
Stock-based compensation expense	—	—	—	—	3,589	—	—	3,589
Issuance of common stock in connection with warrant exercise	6	8	—	—	—	—	—	8
Common stock issuance for services	133	262	(82)	(153)	—	—	—	109
Release of restricted stock units	48	—	—	—	—	—	—	—
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	76,336	$ 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 Cash Flows
(In thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net loss	$ (35,094)	$ (28,516)	$ (33,179)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	435	457	432
Loss on disposal of property and equipment	—	—	2
Stock-based compensation	3,589	3,784	3,367
Bad debt (recovery) expense	107	(142)	258
Excess inventory (recovery) reserve	619	(3,106)	4,728
Common stock issued for services	109	262	272
Changes in operating assets and liabilities:			
Accounts receivable	1,220	(1,413)	955
Inventories	(1,178)	3,868	10
Prepaid expenses and other assets	(605)	(71)	378
Accounts payable	554	(419)	446
Accrued expenses	80	331	44
Accrued compensation expenses	80	1,013	(469)
Accrued clinical trial expenses	153	150	13
Contract liabilities	121	(41)	(234)
Deferred grant revenue	—	(104)	(2,093)
Net cash used in operating activities	(29,810)	(23,947)	(25,070)
Cash flows from investing activities:			
Purchases of property and equipment	(163)	(265)	(490)
Net cash used in investing activities	(163)	(265)	(490)
Cash flows from financing activities:			
Net proceeds from sale of common stock	25,936	20,772	19,483
Proceeds from exercise of options, warrants and employee stock purchase plan options	665	396	969
Net cash provided by financing activities	26,601	21,168	20,452
Effect of exchange rate changes on cash and cash equivalents	4	8	23
Cash and cash equivalents:			
Net decrease	(3,368)	(3,036)	(5,085)
Balance at beginning of year	7,839	10,875	15,960
Balance at end of year	$ 4,471	$ 7,839	$ 10,875

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,		
	2018	**2017**	**2016**
Supplemental cash flow information:			
Non-cash financing and investing activities:			
Fair value of stock options issued for services rendered in connection with rights offering	$ —	$ 20	$ 53

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

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.

Our current product, the Argus II system, entered clinical trials in 2006, received CE Mark approval for marketing and sales in the European Union ("EU") in 2011, and 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 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.

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 2016 and 2017 and 2018, we funded our business primarily through:

- Issuance of common stock in our rights offering in June 2016, which provided net cash proceeds of $19.5 million.
- Issuance of common stock and warrants in our rights offering in March 2017, which provided net cash proceeds of $19.7 million.
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2017 and first quarter of 2018, which provided $5.1 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 $6.9 million, $8.0 million and $4.0 million, for the years ended December 31, 2018, 2017 and 2016, 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 3,275,100, 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at $0.916, $1.62, $1.55 and $1.48 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 47.8 million units, each priced at $0.724 for gross proceeds of approximately $34.6 million. Each unit consisted of one share and one immediately exercisable warrant having a strike price of $1.47 per share. Entities controlled by Gregg Williams, our Chairman of

the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately $30 million.

In November 2017, we entered into an At 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 SEC. 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 December 2017, we issued 598,276 shares of common stock for gross proceeds of approximately $1.2 million as part of our At Market Issuance Sales Agreement. During January and February 2018, we sold 2.2 million shares of common stock which provided net proceeds of $4.0 million under the Sales Agreement. No shares have been sold since February 2018 under the Sales Agreement.

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 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 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 become subject to delisting if we did not regain compliance within the compliance period (or the compliance period as may be extended).

Based on our current plans, we have sufficient funds to continue operating our business at current levels for at least twelve 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 the commercialization 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.

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 issued for services, 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 invests 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 $0.2 million and $0.1 million at December 31, 2018 and 2017, 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 in 2018, 2017, and 2016.

Depreciation and amortization of property and equipment amounted to $0.4 million, $0.5 million and $0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development

Research and development costs are charged to operations in the period incurred and amounted to $10.0 million, $7.9 million and $5.3 million net of grant revenue, for the years ended December 31, 2018, 2017 and 2016, 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 $0.6 million, $0.7 million and $0.7 million for the years ended December 31, 2018, 2017 and 2016, 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 systems, which include the implant and external 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, 2018, 2017 and 2016 grants offset against operating expenses were $0.2 million, $0.4 million and $2.4 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 reputable, 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 a cash balance at a bank in Switzerland. Accounts at such 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, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Direct customers	$ 5,694	$ 6,727	$ 3,822
Indirect channel	1,202	1,237	163
Total	$ 6,896	$ 7,964	$ 3,985

During the year ended December 31, 2018 two customers represented 10% of revenue. During the years ended December 31, 2017 and 2016 one customer represented 10% and 13% of revenue respectively. No other customer represented 10% or more of revenue in any year.

As of December 31, 2018 and 2017, the following customers comprised more than 10% accounts receivable:

	2018	2017
Customer 1	55%	—%
Customer 2	22%	8%
Customer 3	21%	8%
Customer 4	—%	17%
Customer 5	—%	16%
Customer 6	—%	11%

Geographic Concentration

During the years ended December 31, 2018, 2017 and 2016, regional revenue, based on customer locations which comprised more than 10% of revenues, consisted of the following:

	2018	2017	2016
United States	56%	53%	47%
Italy	10%	13%	17%
France	10%	8%	9%
Germany	4%	3%	12%

Sources of Supply

Several of the components, materials and services used in our current Argus II product are available from only one supplier, 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 commercial production of the 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, 2018 and 2017 include assets amounting to approximately $1.5 million and $2.7 million, respectively, relating to our operations in Switzerland. It is always possible unanticipated events in foreign countries could disrupt our operations.

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 includes 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 US 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 supplemented with average historical volatilities of comparable companies in 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, 2018, 2017 and 2016 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, 2018, 2017 and 2016.

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 US dollars in accordance with US 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, 2018, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately $69.4 million and $42.5 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 2038 for federal net operating losses and from 2033 through 2038 for state net operating losses. 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.

On December 22, 2017, the United States government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly revises the existing tax law by, among

other things, lowering the United States corporate income tax rate from 35% to 21% beginning in 2018. We reviewed and incorporated the impact of the Tax Act in our tax calculations and disclosures. The primary impact stems from the re-measurement of our deferred taxes at the new corporate tax rate of 21%, which reduced the our net deferred tax assets, before valuation allowance, by $7.5 million at December 31, 2017. Due to the full valuation allowance, the change in deferred taxes was fully offset by the change in valuation allowance. The Tax Act did not have a significant impact on our consolidated financial statements for the year ended December 31, 2018.

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, 2018, 2017 and 2016, 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, preferred stock warrants and common stock options) as if they had been converted at the beginning of the periods presented, or 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, 2018, 2017 and 2016, 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).

	2018	2017	2016
Underwriter's warrants	802	802	802
Warrants issued with convertible debt	—	676	1,039
Warrants issued with 2017 Rights Offering	13,647	13,652	—
Common stock options	7,120	5,675	3,667
Common stock issuable	—	82	77
Restricted stock units	35	83	131
Employee stock purchase plan	405	271	206
Total	22,009	21,241	5,922

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.

Reclassifications

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

Recently Adopted Accounting Standards

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. We adopted this ASU on January 1, 2018 retrospectively, the cumulative effect of the initial application on our accumulated deficit on that date was immaterial.

We generate our revenue from the sale of our Argus II retinal prosthesis systems, which include the implant and external 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.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), Presentation of Financial Statements — Going Concern (Subtopic 205-10). ASU 2014-15 provided guidance as to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing these financial statements management evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. As fully described in Note 1, we believe that we have sufficient funds to support our operations for at least twelve months.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASU 2016-02 (Accounting Standards Codification ("ASC") Topic 842) supersedes the previous leases standard, ASC 840, Leases. The standard is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. Subsequently, in July of 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"), and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), both of which clarify and enhance certain amendments made in ASU 2016-02 and will be adopted in conjunction with ASU 2016-02. ASU 2016-02 is required to be applied with a modified retrospective approach to each prior reporting period presented with various optional practical expedients. We generally do not finance purchases of equipment or other capital but do lease our facilities. Our lease commitments are subject to the updated standard and will be recognized as lease liabilities and right-of-use assets.

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, 2018 totaled $4.2 million, and include $0.2 million held in a deposit account in Switzerland as security for the performance of contracts. Money market funds included in cash equivalents at December 31, 2017 totaled $7.2 million and consisted of $0.7 million in the City National Rochdale Government Fund Class S, $6.3 million in the FFI Institutional Fund, and $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, 2018 and 2017 (in thousands).

	Total	Level 1	Level 2	Level 3
December 31, 2018:				
Money market funds	$ 4,156	$ 4,156	$ —	$ —
December 31, 2017:				
Money market funds	$ 7,235	$ 7,235	$ —	$ —

4. Selected Balance Sheet Detail

Inventories, net

Inventories consisted of the following at December 31, 2018 and 2017 (in thousands):

	2018	2017
Raw materials	$ 791	$ 485
Work in process	3,055	2,620
Finished goods	2,089	1,660
	5,935	4,765
Allowance for excess and obsolescence	(2,685)	(2,065)
Inventories, net	$ 3,250	$ 2,700

During the year-ended December 31, 2017, we reversed $ 3.1 million of the 2016 charge for excess inventory based upon increased sales volumes in 2017.

Property and equipment, net of accumulated depreciation and amortization

Property and equipment consisted of the following at December 31, 2018 and 2017 (in thousands):

	2018	2017
Laboratory equipment	$ 2,482	$ 2,450
Computer hardware and software	1,456	1,329
Leasehold improvements	298	298
Furniture, fixtures and equipment	46	46
	4,282	4,123
Accumulated depreciation and amortization	(3,257)	(2,824)
Property and equipment, net	$ 1,025	$ 1,299

Contract Liabilities

Contract liabilities consisted of the following at December 31, 2018 and 2017 (in thousands):

	2018	2017
Beginning Balance	$ 48	$ 85
Consideration received in advance of revenue recognition	551	769
Revenue recognized	(432)	(806)
Ending Balance	$ 167	$ 48

Allowance for Doubtful Accounts

Allowance for doubtful accounts consisted of the following at December 31, 2018 and 2017 (in thousands):

	2018	2017
Beginning Balance	$ 74	$ 212
Additions	107	—
(Write-offs)Recoveries	—	(138)
Ending Balance	$ 181	$ 74

5. Grants

In September 2014, we entered into a Joint Research and Development Agreement or JRDA with The Johns Hopkins University Applied Physics Laboratory (‘APL”). The JRDA includes a subcontract to do research under a grant received by APL. Under the JRDA, we have agreed to perform research regarding integration of APL research in to a visual prosthesis system. In October 2014, APL paid us $4.1 million in one lump sum to conduct its portion of the research. The JRDA also includes a license from APL to us, for the life of any patents resulting from APL’s portion of the research. The APL portion of the research includes image processing enhancements for a visual prosthesis. In exchange for the license, we issued 1,000 shares of our common stock to APL**,** have agreed to pay APL patent prosecution costs, and to pay APL a royalty of 0.25% of net sales of licensed products. We recorded funding under the grant as an offset to research and development expenses of zero in 2018, $0.1 million in 2017, and $2.1 million in 2016.

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 FDA. As of December 31, 2018 we recorded $0.5 million of deferred grant costs associated with this grant which will be offset with the related grant funds when received in 2019.

6. Warrants

Warrants Issued with Convertible Debt

During 2012 and 2013, we borrowed money primarily from then existing investors through the issuance of convertible promissory notes (collectively, the “Convertible Notes”) totaling $29.5 million. The Convertible Notes accrued interest at the rate of 7.5% per annum, which was added to the principal amounts. At the time of our November 2014 IPO, and in accordance with their original terms, the Convertible Notes were converted into 6.6 million shares of our common stock.

In connection with the Convertible Notes, we issued warrants to purchase 1.2 million shares of our common stock at a price of $5.00 per share. Until their expiration date, the warrants could be exercised at any time, and from time to time, in whole or in part. In accordance with their amended terms, the warrants expired on the earlier of their expiration dates or upon a change in control event. The 361,909 warrants associated with the Convertible Notes issued in 2012 expired on July 31, 2017. The 676,494 warrants associated with the Convertible Notes 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 805,000 shares of our common stock at an exercise price of $11.25 per share, which was 25 percent above the offering price to the investors. The warrant is 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. Underwriter’s warrants to purchase 802,000 of our common stock are still outstanding at December 31, 2018.

Warrants Issued in March 2017 Rights Offering

On March 6, 2017, we completed a registered Rights Offering to existing stockholders in which we sold 13.7 million Units at $1.47 per Unit, which was the 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 $1.47. The warrants have a five-year life and have been approved for trading on Nasdaq under the symbol EYESW. 5,055 of the warrants associated with the Rights Offering had been exercised as of December 31, 2018. (See Rights Offerings in Note 8.)

A summary of warrant activity for the years ended December 31, 2018, 2017 and 2016 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, 2015	1,840	$ 7.72	
Granted	—	—	
Exercised	—	—	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2016	1,840	$ 7.72	
Granted	13,652	1.47	
Exercised	—	—	
Forfeited or expired	(362)	5.00	
Warrants outstanding at December 31, 2017	15,130	$ 2.15	
Granted	—	—	
Exercised	(5)	1.47	
Forfeited or expired	(676)	5.00	
Warrants outstanding at December 31, 2018	14,449	$ 2.01	3.10
Warrants exercisable at December 31, 2018	14,449	$ 2.01	3.10

Warrants exercisable at December 31, 2018 had no intrinsic value.

7. Employee Benefit Plans

We have a 401(k) Savings Retirement Plan that covers substantially all full-time employees who meet the plan's eligibility requirements and provides for an employee elective contribution. The Plan provides for employer matching contributions. Employer contributions are discretionary and determined annually by the Board of Directors. For the years ended December 31, 2018, 2017 and 2016, employer contributions to the Plan totaled $0.2 million, $0.1 million and $0.1 million, respectively.

We are required to contribute to a government-sponsored pension plan for the employees of our Switzerland-based subsidiary. For the years ended December 31, 2018, 2017 and 2016, the employer's portion of the amounts contributed to the subsidiary's pension plan on behalf of those employees was $0.1 million, $0.1 million and $0.1 million, respectively.

8. Equity Securities

In June 2014, our articles of incorporation were amended to increase authorized common shares to 200,000,000, no par value, and to authorize 10,000,000 shares of preferred stock, no par value. 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 have been paid for their services in common stock on June 1 of each year and the number of shares issued was based on the average closing prices for the immediately preceding twenty trading days. For 2018, we issued a total of 132,996 shares of common stock with a value of $0.3 million for annual service through May 31, 2018. Our Director Compensation Policy was amended in December 2017 and board members receive compensation in cash and stock options, effective with the annual period commencing June 1, 2018. 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 2017, for these services we issued 223,000 shares with a value of $0.3 million and accrued $0.2 million, which equates to 82,000 shares based on the average closing price of $1.86 for our common stock during last 20 trading days as of December 31, 2017. For 2016, for these services we issued 82,000 shares with a value of $0.3 million and accrued $0.2 million, which equates to 77,000 shares based on the average closing price of $1.98 for our common stock during last 20 trading days as of December 31, 2016. The shares, which had not yet been issued, were excluded from the calculation of weighted average common shares outstanding for EPS purposes.

Rights Offerings

In June 2016, we completed a Rights Offering to existing stockholders, raising proceeds of $19.5 million net of cash offering costs, and selling 5,978,465 shares of common stock at $3.315 per share, representing 85% of our stock price at the close of the rights offering. We evaluated the financial impact of FASB ASC 260, “Earnings per Share,” which states, among other things, that if a rights issue is offered to all existing stockholders at an exercise price that is less than the fair value of the stock, then the weighted average shares outstanding and basic and diluted earnings per share shall be adjusted retroactively to reflect the bonus element of the rights offering for all periods presented. We determined that the application of this specific provision of ASC 260 was immaterial to previously issued financial statements and, therefore, did not retroactively adjust previously reported weighted average shares outstanding and basic and diluted earnings per share.

On March 6, 2017, we completed a registered Rights Offering to existing stockholders in which we sold 13.7 million units at $1.47 per unit, which was the 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 $1.47. The warrants have a five-year life and have been approved for trading on Nasdaq under the symbol EYESW. At our discretion, the warrants are redeemable on 30 days’ notice (i) at any time 24 months after the date of issuance, (ii) if the shares of our common stock are trading at $2.94, which is 200% of the Subscription Price, for 15 consecutive trading days and (iii) if all of the independent directors vote in favor of redeeming the warrants. Holders may be able to sell or exercise warrants prior to any announced redemption date and we may redeem outstanding warrants not exercised by the announced redemption date, at our option, for a nominal amount of $0.01 per warrant. (See Note14 about new warrant terms)

At-the-Market Sales Agreement

During December 2017, we issued 598,276 shares of common stock for gross proceeds of approximately $1.2 million as part of our At Market Issuance Sales Agreement with two different investment banks. We paid expenses of approximately $0.1 million resulting in net proceeds of $1.1 million. In the period from January 1, 2018 to February 28, 2018, we sold approximately 2.2 million additional 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 3,275,100, 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at $0.916, $1.62, $1.55 and $1.48 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.

See Note 14- Subsequent Events for information about February 2019 Rights Offering.

9. Stock-Based Compensation

Under the 2003 Plan, as restated in June 2011, we were authorized to issue options covering up to 3,500,000 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 7,500,000 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 Plan was further amended in 2015, 2016, 2017 and 2018 bringing the number of shares issuable under the Plan to 12,000,000.

No option shall be granted under the 2011 Plan after May 31, 2021.

We recognized stock-based compensation cost of $3.6 million, $3.8 million and $3.4 million during 2018, 2017 and 2016, 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:

	2018	2017	2016
Risk-free interest rate	2.32% – 3.05%	1.92% – 2.25%	1.40%–2.03%
Expected dividend yield	0%	0%	0%
Expected volatility	67.0%	48.0%	47.6%–48.2%
Expected term	5.50-6.11 years	6.25 years	6.25 years
Weighted-average grant date calculated fair value	$ 1.20	$ 0.90	$ 1.97

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A summary of stock option activity for the years ended December 31, 2018, 2017 and 2016 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, 2015	3,472	$ 8.01	
Granted	745	4.18	
Exercised	(96)	5.00	
Forfeited or expired	(454)	8.66	
Options outstanding at December 31, 2016	3,667	$ 7.23	
Granted	2,701	1.80	
Exercised	—	—	
Forfeited or expired	(693)	5.38	
Options outstanding at December 31, 2017	5,675	$ 4.87	
Granted	3,178	1.94	
Exercised	(76)	1.95	
Forfeited or expired	(1,657)	3.83	
Options outstanding at December 31, 2018	7,120	$ 3.83	6.81
Options exercisable at December 31, 2018	2,978	$ 5.94	4.42

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2018 (in thousands):

Exercise Price	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.91 to 1.97	3,455	953
$ 2.01 to 2.06	1,305	—
$ 2.07 to 5.00	898	751
$ 5.16 to 9.00	792	724
$ 9.01 to 13.90	670	550
	7,120	2,978

Stock options exercisable at December 31, 2018 had no intrinsic value. As of December 31, 2018, there was $4.0 million of total unrecognized compensation cost related to the outstanding stock options that will be recognized over a weighted average period of 2.60 years.

During the year ended December 31, 2018, we granted stock options to purchase 3,148,252 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 $0.92 to $2.07 per share, which was the fair value of our common stock on the respective grant dates. The options 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 $3.8 million ($0.57 to $1.30 per share). Assumptions used in the model were an expected term of 5.50 to 6.11 years, volatility of 67.0%, a risk-free interest rate of 2.32% to 3.05%, and an expected dividend rate of 0%.

During the year ended December 31, 2018, we recorded $0.4 million of stock-based compensation expense related to stock option modifications for executive transitions.

In March 2017, we granted stock options to purchase 40,000 shares of common stock to an outside attorney in connection with his services relating to our March, 2017 rights offering to stockholders. The options are exercisable for a period of four years from the date of grant at a price of $1.76 per share, which was 120% of the fair value of our common stock on the grant date of March 6, 2017. The options vested as of the date of grant. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be $19,640 ($0.49 per share). Assumptions used in the model were an expected term of 4.0 years, volatility of 48.0%, a risk-free interest rate of 1.81%, and an expected dividend rate of 0%. The cost of these shares was treated as an issuance cost of the offering and was deducted from the gross proceeds from the offering.

In October 2017 and in January 2018 we granted stock options to purchase 150,000 and 30,000 shares of common stock respectively, to an outside contractor in connection with his services. The options are exercisable for a period of ten years from the date of grant at a price of $1.21 and $2.06 respectively, per share, which was the fair value of our common stock on each grant date. The options vest over a four year period. The unvested portion of these stock options is re-measured by us at each reporting period. For the years ended December 31, 2018 and 2017, $43,000 and $11,000 respectively, has been expensed for these grants respectively.

We adopted an employee stock purchase plan in June 2015 for all eligible employees. As of December 31, 2018, the maximum number of shares that may be issued under the plan is 1,550,000. Under the plan, shares of our common stock may be purchased at six-month intervals at 85% of the lower of the closing fair market value 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 100,000 shares of common stock in any one offering period. At December 31, 2018, 1,143,112 shares were issued under the stock purchase plan.

The following table presented below summarizes Restricted Stock Unit (RSU) activity for the years ended December 31, 2018, 2017 and 2016 (in thousands, except per share data):

	Number of Awards		Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2015	190	$	12.43
Awarded	—		—
Vested	59		12.43
Forfeited/canceled	—		—
Outstanding as of December 31, 2016	131	$	12.43
Awarded	—		—
Vested	48		12.43
Forfeited/canceled	—		—
Outstanding as of December 31, 2017	83	$	12.43
Awarded	—		—
Vested	48		12.43
Forfeited/canceled	—		—
Outstanding as of December 31, 2018	35	$	12.43

As of December 31, 2018, there was $0.4 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 0.63 years.

The total stock-based compensation recognized for stock-based awards granted in the consolidated statements of operations for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Cost of sales	$ 279	$ 235	$ 312
Research and development	382	288	303
Clinical and regulatory	152	329	173
Selling and marketing	505	339	104
General and administrative	2,271	2,593	2,475
Total	$ 3,589	$ 3,784	$ 3,367

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, 2018 and 2017 are summarized below (in thousands):

	2018	2017
Stock-based compensation	$ 4,297	$ 3,346
Research credits	7,003	5,858
Depreciation	(48)	(41)
Net operating loss carryforwards	20,315	14,088
Inventory reserve	651	467
Other	643	466
Total deferred tax assets	32,861	24,184
Valuation allowance	(32,861)	(24,184)
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, 2018 and 2017, 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, 2018, 2017 and 2016 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 the 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 determinetax 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, 2018, 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 $69.4 million and $42.5 million, respectively. The federal net operating loss carryforwards will expire at various dates from 2035 through 2038. The state net operating loss carryforwards began to expire at various dates from 2033 through 2038. We also have a federal and state research and development tax credit carryforwards totaling approximately $3,801,000 and $3,202,000, respectively. The federal research and development tax credit carryforwards will expire at various dates from 2023 through 2038. 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 2015 and later and by state authorities for tax years ended 2014 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, 2018,and 2017, 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.

On December 22, 2017, the United States government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly revises the existing tax law by, among other things, lowering the United States corporate income tax rate from 35% to 21% beginning in 2018. We reviewed and incorporated the impact of the Tax Act in our tax calculations and disclosures. The primary impact stems from the re-measurement of our deferred taxes at the new corporate tax rate of 21%, which reduced our net deferred tax assets, before valuation allowance, by $7.5 million at December 31, 2017. Due to the full valuation allowance, the change in deferred taxes was fully offset by the change in valuation allowance. The Tax Act did not have a significant impact on our consolidated financial statements for the year ended December 31, 2018.

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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, 2018, 2017 and 2016 is presented below (in thousands):

	2018	2017	2016
Balance, beginning of year	$ 1,456	$ 1,525	$ 1,066
Additions	193	470	727
Settlements	(264)	(236)	(268)
Adjustments and other	187	(303)	—
Total	$ 1,572	$ 1,456	$ 1,525

12. Commitments and Contingencies

Lease Commitment

Effective August 2012, we entered into a lease agreement with a company owned by the former major stockholder for office space for a term of five years that was initially set to expire on February 28, 2017. The lease included rental of additional space commencing January 1, 2013 and a five year option to renew. The lease requires us to pay real estate taxes, insurance and common area maintenance each year, and is subject to periodic cost of living adjustments. In April 2014, the lease was renegotiated with the term ending on February 28, 2022, and a five year option to renew. The new lease also requires us to pay real estate taxes, insurance and common area maintenance each year and includes automatic increases in base rent each year. In November 2014, the property underlying the lease was sold to an unrelated party. The current base rent at this facility is $36,600 per month.

Second Sight Switzerland rents office space in Switzerland on a month-to-month basis for CHF 8,200 (approximately $8,161, at current exchange rates) per month.

Total rent expense was approximately $1.0 million, $1.0 million and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively, and is allocated based on square footage to general and administrative and manufacturing costs in the accompanying consolidated statement of operations.

Future minimum rental payments required under the operating leases are as follows for the years ended December 31 (in thousands)

Years	Amount
2019	$ 884
2020	910
2021	937
2022	158
Total	$ 2,889

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. 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 $0.1 million , $0.1 million and $0.1 million for the years ended December 31, 2018, 2017 and 2016, 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 twelve 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, which was obtained in February 2013, we are 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 extends this trial through the year 2019. In addition, we are conducting three post-market studies to comply with US FDA, French, and European post-market surveillance regulations and requirements. 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, 2018, 2017 and 2016 were $1.8 million, $0.8 million and $0.8 million, respectively.

Litigation, Claims and Assessments

Twenty-two oppositions have been filed by third-parties in the European Patent Office, each challenging the validity of a European patent owned or exclusively licensed by us. The outcome of the challenges is 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 the company because of defense and settlement costs, diversion of management resources and other factors.

13. Quarterly Financial Summary (unaudited)

	Quarters Ended			
(in thousands, except per share data)	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	$ (0.12)	$ (0.12)	$ (0.12)	$ (0.17)

	Quarters Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Product sales	$ 3,109	$ 1,610	$ 2,236	$ 1,009
Gross profit (loss)	$ 1,247	$ 609	$ (1,109)	$ (118)
Operating loss	$ (7,433)	$ (6,749)	$ (6,872)	$ (7,555)
Net loss	$ (7,409)	$ (6,716)	$ (6,843)	$ (7,548)
Net loss per share – basic and diluted	$ (0.13)	$ (0.12)	$ (0.12)	$ (0.16)

14. Subsequent Events

Stock Option Grants

In January and February 2019, we granted long term incentive stock options to our current employees to purchase 1,893,862 shares of common stock, including 975,000 options that were granted to senior management. The options are exercisable for a period of ten years from the date of grant with exercise prices ranging from $0.74 to $0.82 per share. The options vest over a four year term, on an equal monthly basis. In addition, senior management was awarded 489,000 RSU's which were valued on the grant date at a fair value of $0.4 million. These RSUs vest annually over a four year period from the date of the grant.

2019 Rights Offering

In a Rights Offering completed on February 22, 2019 we sold approximately 47.8 million units, each priced at $0.724 for gross proceeds of approximately $34.6 million. Each unit consisted of one share and one immediately exercisable warrant having a strike price of $1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately $30 million. The expiration date of the warrants being issued pursuant to this Rights Offering is March 14, 2024, and the expiration date of all outstanding warrants listed for trading under the symbol “EYESW” were extended to March 14, 2024.

Nasdaq Deficiency Letter

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 become subject to delisting if we did not regain compliance within the compliance period (or the compliance period as may be extended).

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 18, 2019

/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 18, 2019

/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, 2018, 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 18, 2019

/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.