

# SECOND SIGHT MEDICAL PRODUCTS INC

## FORM 10-K (Annual Report)

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**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, 2015

**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 333-198073

**Second Sight Medical Products, Inc.**

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

**California**

*(State or other jurisdiction of incorporation or organization)*

**02-0692322**

*(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:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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, 2015, computed by reference to the closing sales price on the Nasdaq Global Select Market on that date, was approximately \$183 million.

As of March 8, 2016, the number of shares of the Registrant's common stock outstanding was 36,019,086.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2016 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, 2015.

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SECOND SIGHT MEDICAL PRODUCTS INC.

FORM 10-K

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## PART I

### Item 1. Business

#### Overview

Second Sight was founded in 1998 with a mission to develop, manufacture, and market prosthetic devices that restore some useful vision to blind individuals. Our principal offices are located in Sylmar, California, approximately 25 miles northwest of downtown Los Angeles. We also have an office in Lausanne, Switzerland, that manages our commercial and clinical operations in Europe and the Middle East.

Our current product, the Argus<sup>®</sup> II System, treats outer retinal degenerations, such as retinitis pigmentosa, which we refer 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 System 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. By restoring some useful vision in patients who otherwise have total sight loss, the Argus II System can provide benefits which include:

- 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 the moving streams of lights from fireworks, and
- improving patients' well-being and ability to perform activities of daily living.

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 it does not slow or reverse the progression of the disease. Results vary among patients and while the majority of patients receive significant benefit from the Argus II, some patients report receiving little or no benefit.

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 System, which later became our first commercial product.
- In 2011, we received marketing approval in Europe (CE Mark) for the Argus II System.
- In 2013, we received marketing approval in the United States (FDA) for the Argus II System.
- 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 2015, we commenced a clinical trial in the UK for an expanded indication for the Argus II System in individuals with dry age related macular degeneration (AMD).

Currently, after more than 16 years of research and development, more than \$160 million of investment and over \$33 million of grants received in support of our technology development, we employ over 100 people in the development (engineering and clinical), manufacture, and commercialization of the Argus II System and future products.

#### Our Technology

The Argus II System employs electrical stimulation to bypass degenerated photoreceptor cells and to stimulate remaining viable retinal cells thereby inducing visual perception in blind individuals. The Argus II System works 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 that are implanted on the surface of the retina. These pulses are intended to stimulate the retina's remaining cells, resulting in a corresponding perception of patterns of light in the brain. Following the implant surgery, patients learn to interpret these visual patterns thereby regaining some useful vision, allowing them to detect shapes of people and objects in their surroundings.

We believe the Argus II System possesses several unique technological advancements compared to other neurostimulation devices including a hermetic package with the smallest size and largest number of individually programmable electrodes, and a patented electrode material that allows 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 product and these solutions have been protected both by patents and by trade secrets. As of March 1, 2016, we have 347 issued patents and 156 pending patent applications, on a worldwide basis. Additionally, from a competitive standpoint, the Argus II System possesses attractive technical and other features that include:

- A unique patented design that allows a demonstrated lifetime over 8.5 years, and a demonstrated stable clinical benefit over six 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 5.8 years, with one patient having used the Argus I device for over 10 years. The Argus II System has been implanted in over 178 patients. The average implant duration for these patients is 2.4 years with several users continuing to use the system more than eight years following implantation.

## **Our Markets**

### **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 works by bypassing rods and cones which are defunct in these patients and 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<sup>1</sup>, which includes about 100,000 in the US<sup>2</sup>. 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<sup>3,4</sup>. Approximately 25% of people with RP in the US have vision that is 20/200 or worse (legally blind)<sup>5</sup>. Since the bare light perception or worse vision criterion for the US indication is worse than 20/200, we believe that the subset of patients that can be treated by the Argus II System is less than 25,000 in the US. 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 that the subset of RP patients that can be treated in Europe to be somewhat smaller than this number. Worldwide, we estimate that 375,000 people are legally blind due to RP, and that a portion of these would be candidates for the Argus II System.

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1 . 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.

2 . 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](http://www.ffb.ca/documents/File/rp_guide/Guide_to_RP_and_Other_Related_Diseases.pdf)).

3 . Eurostat. Retrieved 1 January 2013.

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

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## **Age Related Macular Degeneration (AMD)**

AMD is a relatively common eye condition and the leading cause of vision loss among people age 65 and older<sup>6</sup>. The macula is a small spot near the center of the retina and its damage results in loss of central vision. AMD can start as a blurred area near the center of vision and over time it can grow larger until loss of central vision occurs. Central vision is extremely important for everyday tasks such as reading, writing, and face recognition.

There are three stages of AMD defined in part by the size of drusen (yellow deposits) under the retina. Early and intermediate stage AMD has few symptoms or vision loss. These earlier stages of the disease are usually left untreated or dealt with using diet supplementation. People with advanced AMD have vision loss from damage to the macula. There are two types of late stage AMD:

- Dry AMD: There is a breakdown of light sensitive cells in the macula that send visual information to the brain, and the supporting tissue beneath the macula. This damage causes vision loss.
- Wet AMD: Blood vessels grow underneath the retina. These vessels might leak blood which may lead to swelling and damage of the macula. This damage may be severe and can progress quickly.

Worldwide, between 20 and 25 million people suffer from vision loss due to AMD<sup>7</sup>, and of these about 2 million have vision that is considered legally blind, or worse<sup>8</sup>. In the US, just over two million people experience vision loss due to AMD according to a 2010 study by the National Eye Institute. Of the 1.3 million legally blind Americans<sup>9</sup>, we estimate that 42.5% (or 552,500) are due to AMD<sup>10</sup>. Applying this percent of legally blind due to AMD (42.5%) to the total number of legally blind people in Europe (2.55 million)<sup>11</sup>, we estimate the population of legally blind individuals from AMD to be about 1.08 million individuals in Europe, we believe the Argus II System may be able to help a subset of these legally blind AMD patients who have severe to profound vision loss.

## **Other diseases resulting in blindness that may be treated by Orion I cortical visual prosthesis system**

Many diseases outside of RP and AMD 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. Some other causes of blindness, such as brain trauma, 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, retinopathy of prematurity and many others can result in severe visual impairment that we anticipate to be treatable by an Orion I visual prosthesis system.

According to the World Health Organization (WHO)<sup>12</sup>, 285 million people suffer from vision loss worldwide. Of these, 39 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<sup>13</sup> of which we estimate 44.3%, or 575,900, are legally blind due to causes other than preventable/treatable conditions, RP or AMD<sup>14</sup>. Applying the same logic, we estimate 1.13 million individuals are legally blind in Europe due to causes other than preventable/treatable conditions, RP or AMD.

## **Our Strategy**

Second Sight's strategy can be summarized as follows:

- Grow our commercial footprint, continue to expand reimbursement coverage in our target markets, and reach a larger proportion of eligible patients.
- Expand Argus II use in the RP population with improved product performance.
- Enter the AMD market with Argus II to access a substantially larger market.
- Leverage proven ARGUS technology to restore some vision with cortical stimulation and expand addressable markets to those patients who are blind from eye trauma, optic nerve disease, and other causes.

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6 . The Eye Diseases Prevalence Research Group, 2004a; CDC, 2009.

7 . Choptar, A., Chakravarthy, U., and Verma, D. 'Age Related Macular Degeneration'. *BJM* 2003;326:485.

8 . Global Data on Visual Impairments 2010, World Health Organization.

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

10 . 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.

11 . Global Data on Visual Impairments 2010, World Health Organization.

12 . WHO Fact Sheet number 282, updated October 2013.

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

14 . 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.

## Grow commercial footprint, secure adequate reimbursement and connect with patients

We launched the Argus II System in Italy and Germany at the end of 2011; in Saudi Arabia, France, the Netherlands and the United Kingdom in 2013; in Switzerland, Spain, the US and Canada in 2014; and Austria and Turkey in 2015. We continue to employ a Centers of Excellence sales strategy, deploying the Argus II at prominent and reputable eye centers. We believe this strategy represents an efficient use of our capital after giving consideration to the following factors:

- The size of the RP patient population.
- The complexity of the technology, surgery, and treatment paradigm.
- The cost of selecting, qualifying, training and supporting new centers.

When selecting new sites, we focus on high quality health providers considering the following factors:

- Geographic location.
- Facility and surgeon skill & reputation.
- Access to a pool of RP patients.
- Known regulatory pathway.
- Established reimbursement.
- Desire and capability of institution to perform a meaningful number of surgeries annually.

As we expand our commercial footprint beyond the initial eye centers, the capability and desire of the center to perform a meaningful number of surgeries and the presence of established reimbursement become increasingly critical to our ability to expand access to patients.

As of December 31, 2015, we had 15 centers in the United States and Canada that are actively implanting the Argus II. We believe that we will be able to serve the domestic RP market by having approximately 50 implanting centers across the US. In Europe and the Middle East, we have 18 eye centers that are actively implanting the Argus II (eight in Germany, three in France, one in Saudi Arabia, two in Turkey, two in Spain, and two in Italy). We believe that we will be able to serve the European and Middle East markets for RP by having approximately 50 – 75 centers across Europe and the Middle East.

To date, we have employed direct sales and clinical 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 clinical specialist team. As of December 31, 2015, the sales/clinical specialist team for North America numbered five persons and the sales team for Europe and the Middle East numbered four persons. In some cases, we believe that we can more efficiently expand our reach by securing distributors in key markets. To date, we have appointed distributors in Argentina, Spain, Turkey and Saudi Arabia. We expect that our distributors will commit to providing support services that include marketing, market access, sales, surgical support and service.

The company is evaluating potential new markets including countries in Eastern Europe, the Middle East, Latin America or Asia Pacific regions. We will selectively enter markets based on multiple factors including: the presence of RP patients, skilled surgeons, a facility with the necessary support infrastructure, a reliable source of funding or reimbursement, and our ability to effectively provide needed clinical or surgical support.

Obtaining reimbursement from governmental and private insurance companies is critical to our future 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. 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 patient s** – Coverage is determined by Medicare Administrative Contractors (MACs) that administer various geographic regions of the US. As of March 1, 2016, five of 12 MACs (17 states, Puerto Rico and US Virgin Islands) have made positive coverage decisions for the Argus II. Effective January 1, 2016, the Centers for Medicare & Medicaid Services (CMS) established a New Technology Ambulatory Payment Class (APC) 1599, Level 48, with a payment rate of \$95,000 for both the procedure and the Argus II Retinal Prosthesis System. From October 1, 2013 through December 31, 2015, the Argus II was classified as having pass-through payment status and the device was paid separately from the procedure.



- **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 Medicare Advantage 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. In 2015, 93% or 13 of 14 Medicare Advantage pre-authorization requests were granted.
- **Commercially insured patients** – Commercial insurance plans make coverage and payment rate decisions independent of Medicare decisions and contracts are individually negotiated with facility and physician providers.

In 2015, 32 individuals in the US and Canada received and were implanted with the Argus II technology. Of these, nine were Medicare FFS patients, 13 were Medicare Advantage patients and three were commercially insured patients. The remaining seven patients were covered by private pay, Veteran's Administration, or other insurers.

A significant focus for 2016, and beyond, will be expanding US reimbursement coverage and working with Centers for Medicare and Medicaid Services (CMS) to establish Medicare hospital outpatient and ambulatory surgery center payment rates that are in line with facility costs. We have individuals working at Second Sight dedicated to reimbursement and employ a variety of consultants with expertise in this field. Currently, five MACs that oversee 17 states and two US Territories have agreed to cover the Argus II System when medically necessary for the FDA approved indications. The MACs now covering the Argus II include First Coast Service Options (covers on a case-by-case basis for Florida, Puerto Rico and US Virgin Islands), CGS Administrators, LLC (for the states of Ohio and Kentucky), Palmetto GBA (for the states of North and South Carolina, West Virginia and Virginia, other than the counties of Arlington and Fairfax in Virginia and the City of Arlington in Virginia), National Government Services, Inc. (NGS), Jurisdiction 6 (for the states of Illinois, Minnesota and Wisconsin), and NGS, Jurisdiction K (for the states of Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont). We are actively engaged with the remaining MACs and are committed to providing them with clinical evidence to support our requests for coverage. We expect that additional positive coverage decisions will be issued over time but cannot predict timing or ultimate success with each MAC.

We are actively engaged with CMS concerning the outpatient payment rate for Medicare FFS patients. As discussed above, the 2016 Medicare hospital outpatient payment rate for the Argus procedure is \$95,000. Based on available cost information, the Medicare hospital outpatient payment rate should be at least \$150,000 to fully cover the hospitals' costs for the device and procedure (with physician fees being billed and reimbursed separately). Our efforts have been focused on changing the 2016 payment rate to be more reflective of hospitals' actual costs. As of March 1, 2016, we are operating our business with the belief that the US outpatient payment rate will remain \$95,000 in 2016. In parallel, the company is focused on obtaining a 2017 outpatient payment rate that adequately covers hospital costs. Several paths exist to accomplishing this goal including continued education of hospitals concerning the importance of properly coding, billing and submitting Argus II Medicare claims. This activity is important to establish an accurate claims data base that CMS will use to set future payment rates. Finally, the company is exploring other options for changes to Medicare payment policy that may facilitate appropriate reimbursement. No assurance can be given that the company will be successful in any of these endeavors.

Within Europe, we have obtained reimbursement approval in Germany, France and two regions of Italy. We also are seeking reimbursement approval in other countries including the United Kingdom, Belgium, Netherlands, Switzerland and Turkey. In France, Second Sight was 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, Second Sight is conducting a post-market study in France which will enroll a total of 18 subjects and follow them for two years. The French program will fund implantation of up to 18 additional patients that will not be part of the post-market study. After review of the study's results, we expect 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 continue to fund the Argus II after the first 36 implants.

To date, we have not faced traditional sales challenges in any of our markets, largely due to the currently unmet clinical need and the lack of any other available device or competitive treatment for RP-caused profound blindness. 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 US, our efforts in 2016 will focus on presenting media ads dedicated to RP patients and their families. These ads will be placed in geographic areas where we have proven implanting centers and established reimbursement. Based on pilot efforts we conducted in 2015 we believe this may be a cost-efficient method to connect qualified patients with Argus II implanting centers. As of March 1, 2016 the Company had a patient interest list with over 150 verbally qualified individuals.

### **Expand Argus II use in RP population with improved product performance**

The Argus II System 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 retinitis pigmentosa, 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 System since the approved baseline vision for the Argus II System is worse than legally blind (20/200). Scarce epidemiological data on visual acuity below legal blindness make it difficult to determine a precise estimate of the potential patient population for this device.

The company believes an opportunity exists to expand the use of its technology to better sighted individuals with RP than are currently being treated. In order to achieve this market expansion, the company is undertaking multiple development efforts to improve the technology's performance. These efforts include:

- **External hardware** - We expect to launch new externals in early 2017. These new externals will include the head mounted telemetry system (eyewear), camera and the video processing unit (VPU). We anticipate that the new VPU will possess processing power over 25 times greater than the current Argus II system and will enable enhanced image processing and retina stimulation protocols discussed further below.
- **Image processing software** – We are developing advanced software to improve the quality and usefulness of the Argus II vision delivered to patients. The development of these software packages is in the early phases and no assurance can be made that our efforts will be successful. If successful, we expect that these software packages, which will run on the new external hardware platform, should be available commercially in 2017.
- **Retina stimulation protocols** – Preliminary animal and human data by our team and other researchers suggests that we can achieve improved resolution by adjusting retinal stimulation protocols. Examples include long pulses and sine waves to create a more focused percept, and current steering to cause perception of pixels between electrodes. We expect to test these protocols in patients using the new external hardware platform in 2017 and, if successful, they could be available commercially in 2018.
- **3<sup>rd</sup> generation retina implants and external hardware** – We are developing and evaluating multiple next generation retinal implants and external hardware that could improve visual performance in RP patients and patients with other forms of blindness.

As these development efforts proceed, the company will prioritize the technologies or approaches that offer the most potential benefit and attempt further to define the regulatory and reimbursement pathway to bring each to the market.

### **Enter AMD market with Argus II to access a substantially larger market**

We believe we can expand the market for the Argus II System beyond RP to patients with severe to profound vision loss due to dry age-related macular degeneration or dry AMD. We began a five-subject pilot study in the United Kingdom in June 2015, to determine the utility of the Argus II System for use in persons suffering from dry AMD. As of December 31, 2015, we have enrolled four of five patients. We expect that the fifth patient will be enrolled by end of the first Quarter or during early second Quarter of 2016. If this small study yields positive results, then we will conduct a larger pivotal study in Europe and the United States intended to demonstrate the safety and effectiveness of this therapy. We intend to use these clinical trial data to support regulatory approval in the US and Europe that may expand our indications for use specifically to cover dry AMD, and seek reimbursement in these markets for this expanded indication. We estimate the population of people who are legally blind due to AMD to be about 552,500 in the US, 1.08 million in Europe, and two million worldwide. If approved for marketing, a subset of these patients (such as those with dry AMD) would be eligible for the Argus II.

The size and timing of the pivotal study are dependent on multiple factors including the actual subset of AMD patients we target and whether we decide to modify the Argus II system prior to commencing a pivotal study. The subset of patients will influence the regulatory and reimbursement pathways, the size of the study and the length of time required to enroll the study. The company is also evaluating the potential benefits of system changes optimized for AMD. No assurance can be given that we will be successful in any of these endeavors.

**Leverage proven ARGUS technology to restore vision with cortical stimulation and expand addressable market to those who are blind from eye trauma, optic nerve disease, and other causes.**

We are developing another product for cortical stimulation that we expect will be able to treat nearly all forms of profound blindness. As currently planned, the Orion I visual prosthesis system will be based on technology that we utilize in our Argus II system.

We believe we can further expand our market to include nearly all profoundly blind individuals, other than those who are blind due to preventable diseases or due to brain damage, by developing a visual cortical prosthesis. We refer to this product as the Orion<sup>TM</sup> I visual prosthesis system. Our objective in designing and developing the Orion I visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for vision. We intend to develop the Orion I visual prosthesis by leveraging the Argus II system and plan to begin clinical trials of the Orion I visual prosthesis system in the first half of 2017. We estimate that there are about 575,900 people in the US, 1.13 million in Europe, and about 5.8 million worldwide who are legally blind due to causes other than preventable conditions, RP or AMD. If approved for marketing, the FDA will determine the subset of these patients who are eligible for the Orion I.

**Our Competition**

The US life sciences industry is highly competitive and well-positioned for future growth. 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.
- **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 with wet AMD was recently implanted in London with an embryonic stem cell line. No data is yet available as to safety or efficacy of this implantation.
- **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 recently announced phase 3 data for a 21 patient study with a median age of 11 for a gene that affects a very small percentage of retinitis pigmentosa patients, RPE65. They met their primary endpoint (completing a maze test) but did not improve visual acuity. They are expected to apply for FDA approval in 2016. Should this product garner FDA approval, we believe that there is essentially no overlap with our current market since our patients are generally older (Argus II is indicated for an age minimum of 25 in the US). That study involved injecting better sighted patients in attempting to show an improvement in residual vision rather than restoring vision that is completely lost which is the objective of the Argus II treatment.
- **Optogenetics Therapy:** aimed at bypassing compromised photoreceptors and inducing light sensitivity in other retinal cells. 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.
- **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.
- **The BrainPort® V100, by Wicab, Inc.,** 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. Wicab reports that The Brain Port V100 is currently commercially available in the US, EU and Hong Kong.
- There are currently no 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.
- Pharmaceutical 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 German company that is developing the Alpha IMS, a wireless sub-retinal implant. Although this company had obtained CE Mark and was expected to begin commercialization during 2015 in the EU, to our knowledge this product is not generally available to commercial patients. Furthermore, there was a recent report of two clinical trial patients recently implanted in the UK. To our knowledge, Retina Implant has not applied for or obtained FDA approval to begin a clinical trial in the US as of March 11, 2016. Retina Implant has announced it raised 26 million euros for the purpose of establishing additional centers and initiating reimbursement applications.
- Pixium Vision S.A.: A French company that is developing the IRIS (Intelligent Retinal Implant System) that is surgically placed into the eye and attached to the surface of the retina. Similar to our Argus II technology, its system uses a camera and a wireless transmitter. Pixium is in clinical studies with IRIS (announced their first human IRIS II implant, which they plan to commercialize, in February 2016) and has submitted a CE mark application in 2015 and plans to begin commercialization of its product during 2016 in EU. To our knowledge, Pixium Vision has not applied for or obtained FDA approval to begin a clinical trial in the US as of the date of this Annual Report on Form 10-K.
- 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), Stanford University (preclinical), and Monash Vision Group (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.

No other retinal prosthesis to our knowledge has been successful in long-term human trials, currently making the Argus II System the sole implant generally available to commercial patients for treating RP in the US, Canada, EU, and Saudi Arabia. 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 \$1.1 million as of December 31, 2015, which we believe to be adequate.

#### **Our Manufacturing and Quality Assurance**

We have a single manufacturing facility, located at our principal office in Sylmar, 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. At present less than half of this space is being used for Argus II implant production. At the same site are 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 fulfillment 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 supplier sources before experiencing any such disruptions.

As of December 31, 2015 our manufacturing department had 39 employees and the quality assurance department had an additional nine members. We operate a day shift and smaller swing shift, and at this staffing level we can manufacture up to 10 devices per month. To support future growth of the sales of the Argus II System, 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 approximately 100 devices per month.

## **Employees**

As of December 31, 2015, we had 118 employees, including approximately 48 in operations; 17 in selling, marketing and distribution; 34 in clinical and regulatory and research and development; and 19 in administration. Of these employees, we employed 102 in the United States and 16 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.

## **Available Information**

Our website address is [www.secondsight.com](http://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 could decline, and you may lose all or part of your investment in our shares.*

### **Risks Related to Our Dependence on the Argus II System**

*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 I visual prosthesis (a modified version of the Argus II System), to treat other diseases causing 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 both RP and AMD. We believe our expanded growth will depend on the further development, regulatory approval and commercialization of the Orion I 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 I 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 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 U.S. and by regional, or national funding agencies in Europe. Our business could be materially adversely affected if the Medicare program, local Medicare Administrative Contractors or fiscal intermediaries were to make such a determination and deny, restrict or limit the reimbursement of Argus II System. For instance, on October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) released the final rule to update the reimbursement amount for the Argus II for calendar year 2016. The changes will apply to outpatient services provided on or after January 1, 2016. To date, all Argus II implants in the United States have been done on an outpatient basis. In the rule, CMS specified a payment rate of \$95,000 for the implant procedure and the Argus II Retinal Prosthesis System. If CMS does not revise its decision, the new reimbursement rate would have a material negative impact on our short- and medium-term cash flow, financial position and results of operations. In the longer term, it is uncertain how much the new reimbursement rate would affect our financial position and results of operations, as it is uncertain when and by what amount the reimbursement rate may change in the future and also the extent, if at all, to which the revised rates set by CMS will influence other payors in the United States. If a \$95,000 reimbursement rate for calendar year 2016 were to remain the same beyond 2016 and affect the rates that other U.S. payors are willing to pay for the implant procedure, it could have a material negative impact on our long-term cash flow, financial position and results of operations.

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 the Argus II System 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, both in the US and 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 IMS product but has not yet sold it to our knowledge, and to our knowledge neither Retina Implant nor Pixium has filed for market approval with the FDA, nor to our knowledge has either company obtained an Investigational Device Exemption to begin the required clinical trials in the US. 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 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 I visual prosthesis and obtain government and private insurance reimbursement. As of December 31, 2015 we have total stockholders' equity of \$20.3 million and an accumulated deficit of \$(172.7) 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,
- adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations and the healthcare expenditure of domestic or foreign nations.

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

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

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

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

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

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

The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the disease or condition to be treated, the jurisdiction in which we are seeking approval and the regulations applicable to that particular medical device. Regulatory agencies, including those in the 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.

***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 2012 the European Commission proposed a new regulatory scheme. It is anticipated that the proposals which are currently being discussed by the Council of the European Union, will impose significant additional obligations on medical device companies. We expect that these proposals will be adopted in 2016, and if so, the new regulations on medical devices would become effective at that time. Devices with a current CE marking may have to comply with additional, more challenging regulatory obligations, the details of which are not yet clarified. We expect changes being made to regulations will 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. Additionally we anticipate that the new regulations will require clinical evidence as well as analytical performance levels, the details of which are yet to be provided. If the additional provisions proposed by the European Parliament are adopted, this could lead to the involvement of the European Medicines Agency (EMA) 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 proposed revisions would impose enhanced competence requirements for NBs and "special notified bodies" (SNBs) for specific categories of devices, such as implantable devices. This could result in stricter conformity assessment procedures. Although the extent of the new regulations is currently uncertain 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 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 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 initial 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.

***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 the Argus II System 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 and obtain indication expansion for the next generation of the Argus II System and for new product candidates 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.

***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.

***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 ophthalmic, regulatory industry, sales and marketing, operational, and/or corporate finance experience. The loss of any senior 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.

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

As of December 31, 2015, we had federal and state of California income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately \$119.1 million and \$93.2 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 2023 through 2035 for federal net operating losses and from 2015 through 2035 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 have experienced ownership changes in the past. We may experience additional ownership changes as a result of shifts in our stock ownership, including shifts in our stock ownership that are outside of our control. As a result, our ability to use our pre-change NOL carryforwards to offset taxable income may be subject to limitations. In addition, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited under state tax law. For these reasons, we may not be able to utilize and benefit from a material portion of our NOL carryforwards and other tax attributes.

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

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We have adopted 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.

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 has filed oppositions in the European Patent Office (EPO) challenging the validity of 13 European patents owned or exclusively licensed by Second Sight. Retina Implant has joined in one of the 13 oppositions. Two of the patents are owned by Johns Hopkins University (JHU) and exclusively licensed to Second Sight. Eleven of the patents are owned by Second Sight. Second Sight was successful in the Opposition Division in the two JHU cases. However, in the Appellate Division one of the JHU patents was preserved and one of JHU patents was invalidated. In the third proceeding Pixium was successful in the Opposition Division, and we have appealed. In the fourth case we were successful in the Opposition Division. In the fifth case, Pixium was successful in the Opposition Division and we have appealed. The sixth through eleventh of these opposition cases have not reached a hearing in the opposition division. We have opposed one Pixium patent. The patent was successfully opposed and significantly narrowed. These challenges to our patent portfolio, if successful, may affect our ability to block competitors from utilizing this particular intellectual property in Europe, but in our view have no material effect on our ability to make and sell the Argus II System or otherwise have any material effect upon us. Of the 13 patents contested, two have reached final resolution with no further appeal available within in the EPO. These patents represent possible improvements that we, or a competitor, may wish to use in the future. Remaining at issue are nine out of over 340 patents we have to protect our technology. These EPO proceedings involving us and Pixium include:

- EP 1061874 *Visual Prosthesis* — upheld by the opposition and appellate divisions. No further appeal is available in the EPO.
- EP 1061996 *Apparatus for Preferential Outer Retinal Stimulation* — upheld by the opposition division, lost in the appellate division. No further appeal is available in the EPO.
- EP 1171188 *Retinal Color Prosthesis for Color Sight Restoration* — successfully opposed in the opposition division, pending before the Appellate Division.
- EP2219728 *Electrode Array for Even Neural Pressure Having Multiple Attachment Points* — successfully upheld in the Opposition Division, Pixium has appealed.
- EP1937352 *Sub-threshold Stimulation to Precondition Neurons for Supra-threshold Stimulation* — successfully opposed in the Opposition Division, pending appeal.
- EP2192949 — *Return Electrode for a Flexible Circuit Electrode Array* — successfully opposed in the opposition division and we have appealed.
- EP1949437 — *Implantable Microelectronic Device and Method of Manufacture* — opposition filed.
- EP1945835 — *Platinum Electrode Surface Coating and Method for Manufacturing the Same* — opposition filed.
- EP2061549 — *Package for an Implantable Neural Stimulation Device* — opposition filed.
- EP1497483 — *Platinum Electrode* – opposition filed.
- EP1562672 — *Field Focusing and Mapping in an Electrode Array* – opposition filed.
- EP2077892 — *Automatic Fitting for a Visual Prosthesis* – opposition filed.
- EP2114514 — *Flexible Circuit Electrode Array with Wire or Film Support* – opposition and response filed.
- EP1986733 (Pixium) — *Device with Flexible Multilayer System for Contacting or Electro-stimulation of Living Tissue Cells or Nerves* — successfully opposed and significantly narrowed. Pixium has appealed.

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.

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 exclusive licenses from Johns Hopkins University, Duke University, and the Doheny Eye Institute to intellectual property relating to the Argus II visual prosthesis. These licenses impose various commercialization, milestone payment, profit sharing, insurance and other obligations on us. If we fail to comply with any material obligations, the licensor will have the right to terminate the applicable license, which covers part of the system of the eye implant and thus will be a barrier to manufacture the Argus II System and impair our ability to sell the Argus II. The existing or future patents to which we have rights based on our agreements with Johns Hopkins University, Duke University and the Doheny Eye Institute may be too narrow to prevent third-parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of the license agreement. Each license expires with the expiration of the last of the licensed patents. In the case of JHU, the license will expire March 13, 2018, unless extended by additional patents. While the JHU agreement includes a patent which is a significant obstacle to our competitors, it is one of many other patents which in our view present material obstacles to our competitors. The DEI license includes ongoing research, making the expiration date indeterminate, but in any event the expiration date is no earlier than August 8, 2033. The total aggregate royalty on both agreements does not exceed 3.25% of Argus II System net sales. All of the patents in the DEI agreement are co-owned with the Doheny Eye Institute. We license the Doheny Eye Institute'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 confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third-parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their medical device development activities for us.

***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. As of March 1, 2016 we have 347 issued patents and 156 pending patent applications on a worldwide basis. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around our intellectual property and in that event we may lose competitive advantage and our business may suffer.

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

***Third-party claims of intellectual property infringement may prevent or delay our commercialization efforts for Argus II and our development and commercialization activities for other product candidates.***

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 eye 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 that covers our clinical trials and commercial sales, our aggregate coverage limit under these insurance policies for an amount 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.

***CE Marking does not absolve us from strict conformity with all applicable European Union legislation and member state regulation where the product is offered and if we do not adhere to these directive and regulations we may incur fines and other penalties that will prevent or delay market penetration of our products.***

The CE (European Conformity) marking is a symbol that manufacturers affix to products to indicate that a product conforms to all relevant EU rules and regulations and that the manufacturer has performed all necessary evaluation procedures. Although the CE mark allows manufacturers to place products on the market and permits free movement of goods, it is not a mark of approval by the EU. The manufacturer and its authorized representative in EU are responsible for all aspects of the product assessment, testing, documentation, declaration of conformity and CE marking, even where a formal processing agent, the notified body, is required, as in the case of non-European based manufacturers. In all cases the manufacturer and representative assume the full responsibility and liability even when using the services of a consultant or test laboratory. Liability is not transferrable to third parties, including the notified body which is required for processing the certification. Generally, there is strict liability applied to medical devices subject to the CE marking by directive 85/374/EEC, and testing and reporting does not change or reduce this liability.

***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, or PPACA, 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 are likely, and we expect ongoing initiatives in the U.S. and Europe. These reforms could have an adverse effect on our ability to obtain timely regulatory approval for new products and on anticipated revenues from the Argus II System and other product candidates, both of which may affect our overall financial condition.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance requirements.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ, have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will be required to devote a substantial amount of time to these compliance requirements. Moreover, these rules and regulations substantially increase our legal and financial compliance costs and will make some activities more time consuming and costly. These rules and regulations make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

***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 so long as we are an “emerging growth company,” which could be as long as five years following the completion of our IPO. 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 will be 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 will be required to furnish a report by our management on our internal control over financial reporting the year following our first annual report required to be filed with the SEC. The report will contain, 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 Additional 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 commercial success of the Argus II System,
- our ability to obtain regulatory approval of the Argus II System in additional jurisdictions,
- our ability to obtain regulatory approval of the Argus II System for treatment of AMD,
- the emergence of products that compete with our product candidates,
- 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,
- regulatory developments affecting our product candidates or those of our competitors, and
- our ability to obtain adequate reimbursement from government or private payers.

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 growth. Additional capital, may be difficult to obtain restricting our operations and resulting in additional dilution to our stockholders.***

We raised net proceeds of approximately \$34.2 million from the IPO we completed in November 2014. Our business requires additional capital to fund our operations over approximately the next 12 months. However, the actual amount of funds that we will need for our business development 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 commercialization of the 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 I visual prosthesis, marketing and general and administrative expenses, and
- regulatory changes and technological developments in our markets.

As we require additional funds, we may seek to fund our operations through the sale of equity securities, additional 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 to others, 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, or to cease operations entirely.

#### **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 price of our common stock may 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 underlying 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 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 the company 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.

*Sales of substantial amounts of our common stock in the public 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 market, or the perception that these sales could occur, as well as sales of shares by directors or officers, 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.

***Certain of our stockholders have the ability to control the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.***

As of December 31, 2015 our executive officers, key employees, directors and their affiliates beneficially own in the aggregate approximately 62% of the outstanding shares of our common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. They may also have interests that differ from yours and may vote in a manner that is adverse to your interests. This concentration of voting power may have the effect of deterring, delaying or impeding actions that could be beneficial to you, including actions that may be supported by our board of directors, and deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

***Holders of common stock who purchased shares in the IPO, but who do not register and continuously hold shares in their name for two years will lose the Long Term Investor Right and opportunity to receive additional shares from us if those Long Term Investor Rights are triggered.***

We granted each purchaser of shares in the IPO the Long Term Investor Right to receive for no additional investment or payment up to one additional share for each share purchased in the offering if the requirements have been met including:

- the purchaser registers those shares in its name, either in certificate or book entry form, within 90 days following the closing date of the IPO,
- the purchaser continuously holds those shares in its name until the second anniversary date of the closing date of the IPO, and
- the price per share of our common stock does not trade at \$18.00, which is 200% of the offering price, or greater for any five consecutive trading days during the two year period after the closing date of this offering.

If the holder of the shares has timely registered the shares purchased in the IPO but does not hold the shares continuously for the two years after the closing date of the offering in November 2014, or if the price per share of our common stock trades at 200% of the offering price, or greater for any five consecutive trading days during the two year period after the closing date of the offering, the Long Term Investor Right will terminate and the holder will lose the opportunity to benefit from receipt of shares if this Long Term Investor Right is triggered.

***Holders who have perfected their LTIRs and are keeping those shares registered in their names, may experience delays in their ability to dispose of those shares which could cause partial or full loss of their investment in the event of a rapid decline in our share price.***

Our shares are susceptible to financial market volatility and other financial and business related risks that can cause the value of our shares to decline drastically within a short period of time. Holders who have perfected their LTIRs and maintain those shares registered in their names may experience delays in their ability timely to dispose of those shares which can result in partial or full loss of their investment.

***If the Long Term Investor Right is triggered we will become obligated to deliver additional shares according to a formula limited to no more than one share for each share acquired in this offering which may still lead to partial or substantial loss of investment for those holders who have perfected their LTIRs.***

If the Long Term Investor Right is triggered for the delivery of up to one share for each share held by a holder who has perfected and retained his LTIR on the two years anniversary of the closing date of our IPO, holders cannot be assured that they will recover their investment or avoid incurring a loss when the additional shares under the Long Term Investor Right are delivered to you. In the event the Long Term Investor Right is triggered our other stockholders will incur dilution and may experience a decline in the value of their shares. As of December 31, 2015 there were 400,057 shares of common stock issuable under outstanding Long Term Investor Rights.

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

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

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

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

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

We completed our initial public offering in November 2014. Since that time, our shares closing prices have ranged from \$3.78 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 \$33,100 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 originally rented these premises from Mann Biomedical Park LLC, an entity affiliated with our former Chairman of the Board, Alfred E. Mann. 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. In November 2014, the industrial center in which these premises are located was sold to an independent third party.

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 currently about \$8,200 per month. Our lease is currently monthly with a six month notice required for termination, with the Foundation for the Innovation Park at EPFL.

### Item 3. Legal Proceedings

We are not a party to 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. Reserved

## 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

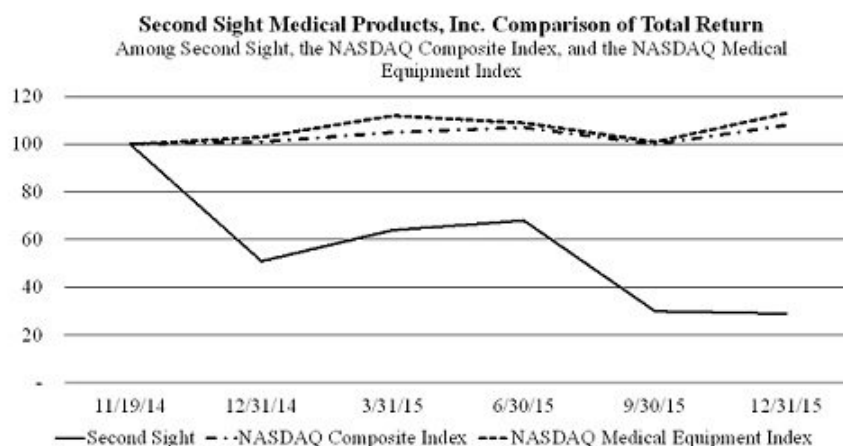
Second Sight’s common stock is traded on the NASDAQ Capital Market under the symbol “EYES.” The following table sets forth the high and low closing sales prices of our common stock as reported on the NASDAQ Capital Market for the following time periods.

	<u>High</u>	<u>Low</u>
<u>Fiscal Year Ended December 31, 2015</u>		
First quarter	\$ 17.44	\$ 8.43
Second quarter	\$ 16.28	\$ 11.56
Third quarter	\$ 14.45	\$ 5.93
Fourth quarter	\$ 8.07	\$ 4.70
<u>Fiscal Year Ended December 31, 2014</u>		
Fourth quarter	\$ 23.60	\$ 10.15

On March 8, 2016, the closing sales price reported for our common stock was \$5.34 per share, and as of that date there were approximately 179 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.

This chart compares the cumulative total stockholder return on our common stock with that of the NASDAQ Composite index and the NASDAQ Medical Equipment index. The chart assumes \$100 was invested at the close of the market on November 19, 2014 (the date our common stock first commenced trading on NASDAQ) in our common stock, the NASDAQ Composite index and the NASDAQ Medical Equipment index. The comparison assumes reinvestment of dividends. The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



	11/19/2014	12/31/2014	3/31/2015	6/30/2015	9/30/2015	12/31/2015
NASDAQ Composite Index	100	101	105	107	100	108
NASDAQ Medical Equipment Index	100	103	112	109	101	113
Second Sight	100	51	64	68	30	29

#### Use of Proceeds from Initial Public Offering

On November 18, 2014, we sold 4,025,000 shares of common stock in our IPO, including 525,000 shares sold upon exercise of the underwriter's over-allotment option pursuant to a registration statement (File No. 333-198073) that we initially filed with the Securities and Exchange Commission in August 2014. Our net proceeds totaled approximately \$34.2 million, after offering costs of approximately \$5.0 million, including approximately \$2.9 million in fair value of warrants and shares of common stock issued in connection with the underwriting and other services rendered for the IPO. In addition to funding our ongoing business operations, we have invested the proceeds of the IPO in our business to expand sales and marketing efforts, enhance our current Argus II product, gain regulatory approvals for additional indications, and continue research and development into next generation technology. Through December 31, 2015, approximately \$20.4 million of the net proceeds from the IPO were used to fund ongoing business operations and approximately \$13.8 million remained deposited in various cash and money market funds. None of the proceeds was used for construction of plant, building and facilities, the purchase of real estate, or the acquisition of any business.

**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, 2015, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015 and 2014 are derived from, and are qualified in their entirety by reference to, the Company’s audited consolidated financial statements included elsewhere in this Form 10-K. The consolidated balance sheet data as of December 31, 2013 is derived from the audited consolidated financial statements not included herein, but which were previously filed with the Securities and Exchange Commission.

(in thousands, except per share data)	<b>Fiscal Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net sales	\$ 8,950	\$ 3,398	\$ 1,565
Cost of sales	5,293	3,558	5,629
Gross profit (loss)	<u>3,657</u>	<u>(160)</u>	<u>(4,064)</u>
<b>Operating expenses:</b>			
Research and development, net of grants	3,036	5,041	3,249
Clinical and regulatory	3,510	2,622	3,215
Selling and marketing	8,935	6,845	3,302
General and administrative	8,223	6,565	4,168
Total operating expenses	<u>23,704</u>	<u>21,073</u>	<u>13,934</u>
Loss from operations	(20,047)	(21,233)	(17,998)
Interest income	2	9	8
Other income, net	27	12	35
Interest expense on convertible promissory notes and loan payable	—	(1,957)	(1,589)
Amortization of discount on convertible promissory notes	—	(5,077)	(3,425)
Write-off of unamortized discount on conversion of convertible promissory notes	—	(6,955)	—
Net loss	<u>\$ (20,018)</u>	<u>\$ (35,201)</u>	<u>\$ (22,969)</u>
Net loss per common share – Basic and diluted	\$ (0.56)	\$ (1.41)	\$ (1.02)
Weighted average shares outstanding – Basic and diluted	35,637	25,053	22,521

(in thousands)	<b>As of December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Cash	\$ 239	\$ 619	\$ 63
Money market funds	\$ 15,721	\$ 34,000	\$ 8,612
Working capital	\$ 18,782	\$ 33,525	\$ 9,104
Total assets	\$ 28,245	\$ 43,069	\$ 12,673
Convertible promissory notes payable	\$ —	\$ —	\$ 19,211
Stockholders’ equity (deficiency)	\$ 20,263	\$ 34,618	\$ (9,221)

## 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, 2015, 2014 and 2013 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

We were founded in 1998 with a mission to develop, manufacture, and market prosthetic devices that restore vision to the blind. Our principal offices are located in Sylmar, California, approximately 25 miles northwest of downtown Los Angeles. We also have an office in Lausanne, Switzerland that manages our commercial and clinical operations in Europe and the Middle East.

Our first commercial product, the Argus II System, is a retinal prosthesis that can provide some functional vision to individuals blinded by retinitis pigmentosa (RP). The Argus II System is an implantable neurostimulation device that uses electrical stimulation of the retina (based on a wireless video camera feed) to replace the function of the defunct photo-receptors in RP patients.

Our major corporate, clinical and regulatory milestones include:

- In 1998, we were founded.
- In 2002, we commenced clinical trials for our prototype product, the Argus I retinal prosthesis.
- In 2006, we commenced clinical trials for the Argus II System, which later became our first commercial product.
- In 2007, we commenced clinical trials in the US for the Argus II System, which later became our first commercial product.
- In 2011, we received marketing approval in Europe (CE Mark) for the Argus II System.
- In 2013, we received marketing approval in the United States (FDA) for the Argus II System.
- In 2014, we completed our initial public offering and began trading on NASDAQ under the symbol "EYES."
- In 2015, we commenced a clinical trial in the UK for an expanded indication for the Argus II System in individuals with dry AMD.

We began selling the Argus II System in Europe at the end of 2011, in Saudi Arabia in 2012, and in the United States and Canada in 2014, and in Turkey in 2015. We have limited regulatory approval in Canada and Saudi Arabia, and we are currently applying for full approval. To date, all of our sales have been made by our direct sales force, but we plan to add partners and distributors to enhance our coverage of existing and future markets. In 2014, we entered into our first distribution agreements, that cover the countries of Spain and Turkey, and we are at various stages of negotiations with a number of other distributors for countries in Europe and the Middle East.

### Going Concern

From inception, our operations have been funded primarily through the sales of our common stock, as well as from the issuance of convertible debt, research and clinical grants, and product revenue generated by the sale of our Argus II System. During the years ended December 31, 2015, 2014 and 2013, we funded our business primarily through:

- Revenue of \$8.9 million, \$3.4 million, and \$1.6 million in 2015, 2014 and 2013, respectively, generated by sales of our Argus II System,
- Issuance of convertible debt with the face value of \$19.5 million in 2013,
- A \$4.1 million grant under Joint Research and Development Agreement with The Johns Hopkins University Applied Physics Laboratory in 2014,
- Issuance of common stock in a private placements aggregating \$9.1 million and \$2.4 million in 2014 and 2013, respectively, and
- Issuance of common stock in our initial public offering in November 2014, which generated net proceeds of \$34.2 million of cash after offering expenses.



Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. 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. As a result, management has concluded that there is substantial doubt about our ability to continue as a going concern, and our independent registered public accounting firm, in its report on our 2015 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern.

On January 25, 2016, we filed a registration statement with the Securities and Exchange Commission to conduct a registered rights offering as of a future record date to allow the holders of our common stock to purchase newly-issued shares of common stock. The shares will be offered at the lower of \$4.25 per share or 85% of the closing price of the Company's common stock as reported by Nasdaq on the last day of the offering period. Assuming full subscription and a closing stock price of between \$4.00 and \$6.00 per share on the last day of the offering period, we expect to sell between 4.6 million and 5.8 million shares of common stock for gross proceeds of approximately \$19.8 million. The actual number of shares sold and proceeds raised will depend on, among other factors, the extent to which current shareholders participate in the rights offering and the final price per share at which we sell our common stock. We intend to use the proceeds from this rights offering to invest in our business to expand sales and marketing efforts, enhance current products, gain regulatory approvals for additional indications, and continue research and development into next generation technology.

We have received verbal assurances from two shareholders, one of whom is currently a director of the Company, and the other of whom is an affiliate of an early investor in the Company, that they will each exercise their subscription rights in full. In addition, to the extent that other shareholders do not exercise their subscription rights in full, these two shareholders have also provided verbal assurances to us that they will exercise their respective over-subscription privileges at the subscription price, to allow these shareholders to make an aggregate investment in us of up to \$12.75 million. Accordingly, the rights offering is expected to raise a minimum of \$12.75 million and a maximum of approximately \$19.8 million in gross proceeds. We expect that the rights offering may close during the second quarter of 2016. The director/shareholder has also been granted the right, but not the obligation, to provide all of the remaining unsubscribed amounts, up to the aggregate balance of the amount not taken up in the rights offering by our other shareholders. We believe that these two shareholders have the financial capability to meet these financial commitments to us as described herein.

No assurances can be given that we will ultimately be successful in completing this rights offering, or if unsuccessful, that we will be able to raise sufficient funds through other means so as to be able to continue operating our business at current levels beyond the fourth quarter of fiscal 2016.

#### *Insurance Reimbursement*

Obtaining reimbursement from governmental and private insurance companies is critical to our future 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. 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. As of March 1, 2016, five of 12 MACs (17 states, Puerto Rico and US Virgin Islands) have made positive coverage decisions for the Argus II. Effective January 1, 2016, the Centers for Medicare & Medicaid Services (CMS) established a New Technology Ambulatory Payment Class (APC) 1599, Level 48, with a payment rate of \$95,000 for both the procedure and the Argus II Retinal Prosthesis System. From October 1, 2013 through December 31, 2015, the Argus II was classified as having pass-through payment status and the device was paid separately from the procedure.

- **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 Medicare Advantage 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. In 2015, 93% or 13 of 14 Medicare Advantage pre-authorization requests were granted.
- **Commercially insured patients** – Commercial insurance plans make coverage and payment rate decisions independent of Medicare decisions and contracts are individually negotiated with facility and physician providers.

In 2015, 32 individuals in the US and Canada received and were implanted with the Argus II technology. Of these, nine were Medicare FFS patients, 13 were Medicare Advantage patients and three were commercially insured patients. The remaining seven patients were covered by private pay, Veteran's Administration, or other insurers.

A significant focus for 2016, and beyond, will be expanding US reimbursement coverage and working with Centers for Medicare and Medicaid Services (CMS) to establish Medicare hospital outpatient and ambulatory surgery center payment rates that are in line with facility costs. We have individuals working at Second Sight dedicated to reimbursement and employ a variety of consultants with expertise in this field. Currently, five MACs that oversee 17 states and two US Territories have agreed to cover the Argus II System when medically necessary for the FDA approved indications. The MACs now covering the Argus II include First Coast Service Options (covers on a case-by-case basis for Florida, Puerto Rico and US Virgin Islands), CGS Administrators, LLC (for the states of Ohio and Kentucky), Palmetto GBA (for the states of North and South Carolina, West Virginia and Virginia, other than the counties of Arlington and Fairfax in Virginia and the City of Arlington in Virginia), National Government Services, Inc. (NGS), Jurisdiction 6 (for the states of Illinois, Minnesota and Wisconsin), and NGS, Jurisdiction K (for the states of Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont). We are actively engaged with the remaining MACs and are committed to providing them with clinical evidence to support our requests for coverage. We expect that additional positive coverage decisions will be issued over time but cannot predict timing or ultimate success with each MAC.

We are actively engaged with CMS concerning the outpatient payment rate for Medicare FFS patients. As discussed above, the 2016 Medicare hospital outpatient payment rate for the Argus procedure is \$95,000. Based on available cost information, the Medicare hospital outpatient payment rate should be at least \$150,000 to fully cover the hospitals' costs for the device and procedure (with physician fees being billed and reimbursed separately). Our efforts have been focused on changing the 2016 payment rate to be more reflective of hospitals' actual costs. As of March 1, 2016, we are operating our business with the belief that the US outpatient payment rate will remain \$95,000 in 2016. In parallel, the company is focused on obtaining a 2017 outpatient payment rate that adequately covers hospital costs. Several paths exist to accomplishing this goal including continued education of hospitals concerning the importance of properly coding, billing and submitting Argus II Medicare claims. This activity is important to establish an accurate claims data base that CMS will use to set future payment rates. Finally, the company is exploring other options for changes to Medicare payment policy that may facilitate appropriate reimbursement. No assurance can be given that the company will be successful in any of these endeavors.

Within Europe, we have obtained reimbursement approval in Germany, France and two regions of Italy. We also are seeking reimbursement approval in other countries including the United Kingdom, Belgium, Netherlands, Switzerland and Turkey. In France, Second Sight was 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, Second Sight is conducting a post-market study in France which will enroll a total of 18 subjects and follow them for two years. The French program will fund implantation of up to 18 additional patients that will not be part of the post-market study. After review of the study's results, we expect 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 continue to fund the Argus II after the first 36 implants.

To date, we have not faced traditional sales challenges in any of our markets, largely due to the currently unmet clinical need and the lack of any other available device or competitive treatment for RP-caused profound blindness. 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 US, our efforts in 2016 will focus on presenting media ads dedicated to RP patients and their families. These ads will be placed in geographic areas where we have proven implanting centers and established reimbursement. Based on pilot efforts we conducted in 2015 we believe this may be a cost-efficient method to connect qualified patients with Argus II implanting centers. As of March 1, 2016 as a result of these efforts the Company had a patient interest list with over 150 conditionally qualified individuals.

#### *Product and Clinical Development Plans*

We are currently working on new external hardware and software for our Argus II System, which we believe may improve the performance characteristics, ease of use and resolution of the system. In the first half of 2016, we plan to introduce new clinical software to be used for adjusting the Argus II that we believe will help clinicians with the initial programming and follow up training of patients. In early 2017, we plan to introduce new eyewear and a new VPU that will allow us to implement some software enhancements that may improve the performance of the Argus II System. For example, improving the resolution of the system may enhance the user experience and increase our potential market size. Improved image resolution may be achieved by enhanced image processing, including contrast enhancement and electronic zooming.

Currently, our Argus II System is approved for persons suffering from RP. We believe we may be able to expand the market for the Argus II System beyond RP to patients with severe to profound vision loss due to dry age-related macular degeneration, or AMD. We are currently enrolling and implanting patients in a pilot study, of about five patients, to evaluate the safety and benefit of the Argus II System for use in persons suffering from AMD. Based on the results from this study, we could begin a larger scale efficacy trial. The size and timing of the pivotal study are dependent on multiple factors including the actual subset of AMD patients we target and whether we decide to modify the Argus II system prior to commencing a pivotal study. The subset of patients will influence the regulatory and reimbursement pathways, the size of the study and the length of time required to enroll the study. The company is also evaluating the potential benefits of system changes optimized for AMD. No assurance can be given that we will be successful in any of these endeavors. If the Argus II System is successfully developed and approved for sale to treat AMD, as to which there can be no assurances, we believe that the potential addressable market opportunity for that device will significantly exceed our existing RP markets for the Argus II System.

We are also conducting preclinical development, including animal studies, of a product for cortical stimulation that we refer to as the Orion I visual cortical prosthesis (or “Orion I”), which we expect will be able to provide some vision restoration to individuals with almost all unpreventable forms of blindness. Our objective in designing and developing the Orion I is to bypass the retina and optic nerve and to directly stimulate the visual cortex region of the brain. Human clinical testing is likely to take the form of a feasibility study followed by a premarket approval pivotal trial. The details of these trials will be determined collaboratively with the FDA at that time. We cannot accurately estimate the timing or exact cost of these trials at this time. If the Orion I is successfully developed and approved for sale, as to which there can be no assurances, we believe that the potential addressable market opportunity for that device will greatly exceed our existing RP markets for the Argus II System.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB’s Exposure Draft Update issued on April 29, 2015, and approved in July 2015, Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date, ASU 2014-09 is now effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company is evaluating ASU 2014-9, and has not yet determined its impact to the Company’s financial statements, nor decided the transition approach it will take.

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 provides 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 financial statements for each annual and interim reporting period, an entity’s management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have any impact on the Company’s financial statement presentation and disclosures.

In January 2015, the FASB issued Accounting Standards Update No. 2015-01 (ASU 2015-01), Income Statement – Extraordinary and Unusual Items (Subtopic 225-20). ASU 2015-01 eliminates from GAAP the concept of extraordinary items. Subtopic 225-20, Income Statement – Extraordinary and Unusual Items, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. Paragraph 225-20-45-2 contains the following criteria that must both be met for extraordinary classification: (1) Unusual nature. The underlying event or transaction should possess a high degree of abnormality and be of a type clearly unrelated to, or only incidentally related to, the ordinary and typical activities of the entity, taking into account the environment in which the entity operates. (2) Infrequency of occurrence. The underlying event or transaction should be of a type that would not reasonably be expected to recur in the foreseeable future, taking into account the environment in which the entity operates. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the guidance prospectively. A reporting entity also may apply the guidance retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU 2015-01 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In February 2015, the FASB issued Accounting Standards Update No. 2015-02 (ASU 2015-02), Consolidation (Topic 810) . ASU 2015-02 changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. All legal entities are subject to reevaluation under the revised consolidation mode. ASU 2015-02 affects the following areas: (1) limited partnerships and similar legal entities; (2) evaluating fees paid to a decision maker or a service provider as a variable interest; (3) the effect of fee arrangements on the primary beneficiary determination; (4) the effect of related parties on the primary beneficiary determination; and (5) certain investment funds. ASU 2015-02 is effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. A reporting entity may apply the amendments in this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. A reporting entity also may apply the amendments retrospectively. The adoption of ASU 2015-02 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 (ASU 2015-03), Interest – Imputation of Interest (Subtopic 835-30). ASU 2015-03 simplifies the presentation of debt issuance costs and requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the new guidance. ASU 2015-3 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within that fiscal year. Early adoption is permitted for financial statements that have not been previously issued. An entity is required to apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented is adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The adoption of ASU 2015-03 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17 (ASU 2015-17), Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The adoption of ASU 2015-17 is not expected to have any impact on Company’s financial statement presentation or disclosures.

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02 regarding leases. The new standard requires lessee recognition on the balance sheet of a right-of-use asset and a lease liability, initially measured at the present value of the lease payments. It further requires recognition in the income statement of a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. Finally, it requires classification of all cash payments within operating activities in the statement of cash flows. It is effective for fiscal years commencing after December 15, 2018 and early adoption is permitted. Management has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company’s financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's 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.* The Company's revenue is derived primarily from the sale of its Argus II retinal implant, which is implanted during retinal surgery to restore some functional vision to patients blinded by Retinitis Pigmentosa. The Company sells to a variety of customers including university hospitals, large medical centers and distributors.

Revenue is recognized when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collectability is probable, and delivery has occurred.

Revenue is generated under sales agreements with multiple deliverables (multiple-element arrangements), comprising the following deliverables:

- Hospital start up kits (one per site),
- Surgical support,
- Training, and
- The Argus II System

The deliverables may vary by transaction.

The Company evaluates each deliverable in a multiple-element arrangement to determine whether it represents a separate unit of accounting. An element constitutes a separate unit of accounting when the delivered item has standalone value and delivery of the undelivered element is probable and within the Company's control. The Company has determined that the elements listed above do not have standalone value to the customer until delivery of all components has occurred. Accordingly, revenue from multiple-element arrangements is recognized when delivery of all of deliverables has taken place and all other revenue recognition criteria have been met. Generally, revenue recognition occurs at the time of implantation, but revenue recognition can be delayed if certain training has not been delivered to the implanting sites, or if other revenue recognition criteria have not been met.

In the United States, the amount of revenue recognized per unit has been limited in some situations due to the uncertainties of the reimbursement environment and payment terms. In such cases, revenue is not recognized until the consideration becomes fixed, generally when paid to the Company.

In order to determine whether collection is reasonably assured, the Company assesses a number of factors, including creditworthiness of the customer and medical insurance coverage. The Company may periodically grant extended payment terms to customers. In such situations, the Company defers the recognition of revenue until collection becomes probable, which is generally upon receipt of payment.

The Company also sells surgical supplies to customers and recognizes revenue on these products when they are shipped and other revenue recognition criteria have been met.

The Company sells through distributors in certain countries. The Company provides these distributors with clinical start-up kits, surgical supplies and the Argus II System, as well as training them to provide pre- and post-surgical support. The Company monitors the surgery. Other than surgical support which is provided by the Company, the distributor is responsible for delivering products and services to its customers. In the past, the Company has allowed distributors to return or exchange products in certain situations. Due to the Company's continuing involvement and its returns policy, the Company recognizes revenue from distributors when the implantation procedure has been performed by the distributor's customer, and all other revenue recognition criteria between the Company and the distributor have been met.

*Stock-Based Compensation.* Pursuant to Financial Accounting Standards Board ("FASB") ASC 718 Share-Based Payment ("ASC 718"), the Company records stock-based compensation expense for all stock-based awards. Under ASC 718, the Company estimates 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, with certain exceptions, is determined based on the estimated fair value of the shares at the date of grant.
- The risk free interest rate for periods within the contractual life of the option is based on the U.S. treasury yield in effect at the time of grant.
- As permitted by SAB 107, due to the Company's insufficient history of option activity, management utilizes the simplified approach to estimate the options expected term, which represents the period of time that options granted are expected to be outstanding.
- Volatility is determined based on 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. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

*Patent Costs.* The Company has over 345 domestic and foreign patents. Due to the uncertainty associated with the successful development of one or more commercially viable products based on Company's 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.

*Convertible Promissory Notes and Warrants .* The warrants and embedded beneficial conversion feature of convertible promissory notes are classified as equity under FASB ASC Topic 815-40 "Derivatives and Hedging — Contracts in Entity's Own Equity". The Company allocates the proceeds of the convertible promissory notes between convertible promissory notes and the financial instruments related to warrants associated with convertible promissory notes based on their relative fair values at the commitment date. The fair value of the financial instruments related to warrants associated with convertible promissory notes is determined utilizing the Black-Scholes option pricing model and the respective allocated proceeds to the warrants is recorded in additional paid-in capital. The Company utilized the Black-Scholes option valuation model using the same valuation assumptions as described herein for Stock Based Compensation. The embedded beneficial conversion feature associated with convertible promissory notes is recognized and measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital in accordance with ASC Topic 470-20 "Debt — Debt with Conversion and Other Options." The portion of debt discount resulting from the allocation of proceeds to the financial instruments related to warrants associated with convertible promissory notes is being amortized over the life of the convertible promissory notes. For the portion of debt discount resulting from the allocation of proceeds to the beneficial conversion feature, it is amortized over the term of the notes from the respective dates of issuance.

*Long Term Investor Right .* Each beneficial owner ("IPO Shareholder") of the Company's common stock, who purchased shares directly in the offering ("IPO Shares"), may qualify to receive up to one additional share of common stock from the Company for each share purchased in the offering ("IPO Supplemental Shares") pursuant to the Long Term Investor Right that was included with each IPO Share. To qualify for receipt of IPO Supplemental Shares, an IPO Shareholder was required to become the direct registered owner of its IPO Shares within 90 days following the closing date of the offering, or by February 22, 2015. Furthermore, IPO Shareholders are required to hold their IPO Shares in their own name and not place them in "street name" or trade them at any time during the 24 month period immediately following the IPO closing date. This Long Term Investors Right is non-detachable and transferable only in limited circumstances.

The Company will issue IPO Supplemental Shares to IPO Shareholders who have not otherwise forfeited their Long Term Investor Right if, during the two-year period immediately following the IPO closing date, the Company's common stock does not trade at or above \$18.00 per share (200% of the IPO price per share) for any five consecutive day period. If the Company's common stock trades on its principal exchange at 200% of the IPO price per share or greater on five consecutive trading days during the two years after the IPO closing date, the Long Term Investor Right will terminate.

The formula to determine the number of IPO Supplemental Shares to be issued on a trigger of the Long Term Investor Right will be: (i) \$18.00 minus (ii) the average of the highest consecutive closing prices in any 90 day trading period on the principal exchange during the two years after the Closing Date (the "Measurement Average") divided by the Measurement Average. Fractional shares issuable to a qualifying IPO Shareholder resulting from the calculation will be rounded up to the next whole share of common stock, taking into account the aggregate number of Long Term Investor Rights of a holder. As an illustrative example, if the highest average of consecutive closing prices over any 90 calendar day period is \$10.00 per share, each Long-Term Investor Right will be entitled to 0.80 additional shares of common stock, which is calculated as:  $(\$18.00 - \$10.00)/\$10.00$ .

The IPO offering price for purposes of the calculation of the amount of common stock to be issued on a Long Term Investor Right will be subject to adjustment in the event of a reorganization, recapitalization or split-up of the Company's shares, the issuance of a stock dividend or any similar event. The amount of IPO Supplemental Shares, if any, to be issued will be computed by an independent public accountant as soon as practicable following the second anniversary of the Closing Date. The determination by such independent public accountant will be final and binding on the Company and on all qualifying IPO Shareholders and the Company will within about 15 days after receipt of written determination deliver to shareholders certificates evidencing the additional shares.

The Company has identified and will track IPO Investors who have perfected their Rights on a quarterly basis. At the end of each reporting period, the Company will disclose the potential dilutive effect of the Right, including the number of common shares that would be issuable on such date, based on the actual share price movements since the IPO.

The Right is an equity instrument that is accounted for as a component of the actual price per common share paid by the investor in the IPO. For basic earnings per share, the common shares associated with the Right are treated as contingently issuable shares and will not be included in basic earnings per share until the actual number of shares can be calculated and the shares have been issued.

## Results of Operations

*Net sales.* Our net sales are derived primarily from the sale of our Argus II System. We began selling our products in Europe in 2011, Saudi Arabia in 2012, in the United States and Canada in 2014, and in Turkey in 2015. Our objective is to increase our product revenue over the next several years as we pursue commercialization of our product, as our product becomes more well-known and accepted in the market, and as insurance coverage becomes more widespread.

*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 Sylmar, California facility. Historically, our cost of sales has been greater than our revenues, which has resulted in gross losses. However, in the third and fourth quarters of fiscal 2014 and for all of fiscal 2015, due to higher revenues and increased manufacturing output and efficiencies, we generated a positive gross margin. Our product involves new and technologically complex materials and processes. As we move from making small quantities of our product for clinical trials to larger quantities for commercial distribution, we are developing new manufacturing techniques and processes that we expect to allow us to scale production. We are currently experiencing low yields on our manufacturing process, but we expect that over the next few years we will be able to refine our processes and improve our manufacturing yields. Accordingly, as we produce in quantities sufficient to support our commercial efforts, we expect that we will generate a positive gross profit.

*Operating Expenses.* We generally recognize our operating expenses as we incur them 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 deferred stock-based compensation allocated to 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 offsets to the costs as they are incurred to complete the related work.

- 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 I 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 assess the safety and efficacy of enhancements to our current Argus II System, seek to expand the indications for the Argus II System, such as AMD, and prepare to initiate clinical studies of potential future products, such as the Orion I 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. 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 System 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 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.

*Interest expense on convertible promissory notes.* Interest expense was a non-cash expense associated with the Company's convertible promissory notes. Simple interest was accrued at 7.5% per annum based on the face value of the convertible promissory notes outstanding during the year. The accrued interest was added to the amount of outstanding debt, but does not earn additional interest. The terms of the convertible promissory notes provided for automatic conversion of principal and accrued interest into equity on our IPO, at \$5.00 per share. Accordingly, subsequent to our IPO in the fourth quarter of 2014, the Company no longer incurred interest expense on the convertible promissory notes.

*Amortization of discount on convertible promissory notes.* As discussed more fully above, our convertible promissory notes issued during 2012 and 2013 were issued with detachable warrants and an embedded beneficial conversion feature, which were recorded as an issuance discount with an offsetting credit to additional paid-in capital. This issuance discount was amortized as a non-cash charge over the term of the convertible promissory note. The terms of the convertible promissory notes provided for conversion into equity on an IPO, at \$5.00 per share. At December 31, 2013, the unamortized issuance cost related to our convertible promissory notes was \$12.0 million. As a result of our IPO in November 2014, \$7.0 million of unamortized issuance costs were charged to income due to the automatic conversion of all outstanding convertible promissory notes into common stock.

#### **Comparison of the Years Ended December 31, 2015 and 2014**

*Net Sales.* Our net sales increased from \$3.4 million in 2014 to \$8.9 million in 2015, an increase of \$5.5 million, or 162%. This increase in net sales was primarily due to selling 75 Argus II systems that were implanted in 2015 compared to 29 in 2014. Average revenue recognized per implant was fairly constant at approximately \$119,000 in 2015 compared to \$117,000 in 2014. In 2015, there were 43 implants in Europe and the Middle East (EMEA) compared to 13 implants in the prior year. The increase in implants in EMEA is primarily attributable to reimbursement programs in France and Italy, which combined accounted for 31 implants in 2015 compared to three in the 2014. In the United States and Canada (North America), implants increased to 32 in 2015 compared to 16 in 2014. We began selling the Argus II in North America in 2014, and the growth in 2015 represents the positive results of our ongoing commercial efforts.

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 EMEA and North America, 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 recent CMS pricing decision discussed above, we made the determination in late February 2016 to temporarily discount the Argus device in the US to approximately \$92,000 compared to the \$144,000 we sold the product for in 2015. Accordingly, we expect that our average revenue per implant will be lower in 2016 than it was in 2015. The actual impact of this pricing decision on our average revenue will depend on the number of US patients implanted with the Argus II in a given period. Beyond 2016, our average revenue per implant may increase if we are successful in negotiating with CMS to increase the Medicare FFS reimbursement rate for the Argus II System. No assurance can be given, however, that we will be successful in doing so.

Prior to offering these discounts, our business was negatively impacted during the first two months of 2016 by the difference between our selling price and the 2016 payment rate for Medicare patients. More specifically, we believe several Medicare cases and one planned implanting center opening were delayed due to reimbursement concerns. Given these reimbursement concerns in the U.S. and the inherent variability in our results, we now expect our Q1 2016 implants will be in a range of between 10 and 14 implants worldwide. This expected range is down from the 19 worldwide implants reported in the first quarter of 2015. Most of this expected shortfall is attributable to the US market. With U.S. discounts in place, we should see implant levels rebound in upcoming quarters as we open new centers, qualify more patients and benefit from expanded reimbursement coverage.

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 increased from \$3.6 million in 2014 to \$5.3 million in 2015, an increase of \$1.7 million or 47%. This increase is primarily due to increasing our production volume and yields in 2015 relative to 2014, resulting in more finished goods and sub-assemblies being accepted into inventory and a lower level of scrapped product being expensed. As we manufacture more products, our manufacturing overhead is spread over more units and our cost per unit produced decreases. Also, as our yields improve and we accept more units into inventory, the amount of scrapped product that is written off to cost of sales decreases. We will continue to invest in improving our manufacturing processes. However, if we produce fewer units in 2016, our cost per unit produced could increase. Additionally, our lower expected revenue per implant in 2016, as discussed above, will most likely lead to lower gross margins being recognized in 2016 than in 2015.



*Research and development expense.* Research and development expense decreased from \$5.0 million in 2014 to \$3.0 million in 2015, a decrease of \$2.0 million, or 40%. The decrease is primarily attributable to utilizing \$1.9 million of grant funding from The Johns Hopkins University Applied Physics Laboratory to offset labor, consulting and overhead costs incurred during 2015 compared to no grant funding in the prior year. To date, we have recognized \$1.9 million out of a total \$4.1 million related to this grant. We expect research and development costs to increase in the future as we pursue further enhancements of our existing product and develop technology for our potential future cortical implant product.

*Clinical and regulatory expense.* Clinical and regulatory expense increased from \$2.6 million in 2014 to \$3.5 million in 2015, an increase of \$0.9 million, or 35%. This increase is primarily attributable to the cost of post-market and other clinical trials to assess the safety and efficacy of our current product, to assess possible enhancements to our existing product, and to assess the efficacy of our technology for treating blindness due to Age-Related Macular Degeneration.

*Selling and marketing expense.* Selling and marketing expense increased from \$6.8 million in 2014 to \$8.9 million in 2015, an increase of \$2.1 million or 31%. This increase in costs is attributable to an increase in personnel, as well as higher costs for marketing and customer awareness programs, as we increased our efforts to commercialize the Argus II System. Beginning in 2014, we began selling our product in the United States, Canada and Spain. These costs increased as we intensified our selling and marketing efforts to accelerate the commercialization of our product, but we expect selling and marketing expense to decrease over time when expressed as a percentage of product revenue.

*General and administrative expense.* General and administrative expense increased from \$6.6 million in 2014 to \$8.2 million in 2015, an increase of \$1.6 million, or 24%. This increase is primarily attributable to \$0.8 million of higher stock-based compensation charges in 2015, \$0.5 million in higher compensation costs, as well as higher legal, accounting, insurance and regulatory costs associated with being a public company.

*Interest expense on the convertible promissory notes.* Interest expense on the convertible promissory notes decreased from \$2.0 million in 2014 to \$0 in 2015. This decrease is due to the Company's IPO, effective November 18, 2014, when all of the Company's convertible promissory notes were converted into common stock. After the IPO, the Company did not incur interest expense on the convertible promissory notes.

*Amortization of issuance discount on convertible promissory notes.* Amortization of issuance discount on convertible promissory notes decreased from \$5.1 million in 2014 to \$0 in 2015. This decrease is due to the Company's IPO, effective November 18, 2014, when all of the Company's convertible promissory notes were converted into common stock. After the IPO, the Company did not incur the amortization of issuance discount on the convertible promissory notes.

*Write-off of unamortized discount on conversion of convertible promissory notes.* The original terms of the Company's convertible promissory notes specified that the notes automatically converted into common stock of the Company in the event, among other things, of an IPO. Accordingly, as of the IPO date, the Company wrote off \$7.0 million of deferred issuance costs related to the convertible promissory notes that converted into common stock.

*Net loss.* The net loss was \$35.2 million in 2014, as compared to \$20.0 million in 2015. The \$15.2 million reduction in net loss from 2014 to 2015 was primarily attributable to approximately \$14.1 million of non-cash charges related to convertible debt and the conversion of convertible debt into common stock as a result of the Company's IPO in November 2014. These expenses include approximately \$2.0 million in non-cash interest expense, \$5.1 million for the amortization of debt issuance discounts, and \$7.0 million related to the write-off of unamortized debt issuance discounts.

### **Comparison of the Years Ended December 31, 2014 and 2013**

*Net Sales.* Our net sales increased from \$1.6 million in 2013 to \$3.4 million in 2014, an increase of \$1.8 million or 113%. This increase in product revenue was due to selling more implants in 2014 and attaining a higher average selling price for implanted devices. We sold 29 Argus II Systems that were implanted in 2014, compared to 22 in the prior year. In 2013, all implants were in Europe and the Middle East, whereas in 2014, there were 16 implants in the United States and Canada and 13 in Europe and the Middle East. The decrease in implants in Europe and the Middle East during 2014, as compared to 2013, is primarily due to sites in Italy and Saudi Arabia, which together accounted for 10 implants in 2013, performing no implants in the first three quarters of fiscal 2014, before resuming activity with a combined 4 implants in the fourth quarter of 2014. The increase in average selling price in 2014 was primarily due to establishing a higher selling price on the introduction of the Argus II system in the United States and Canada, combined with a lower level of discounting and free goods in Europe in comparison to 2013.

*Cost of sales.* Cost of sales decreased from \$5.6 million in 2013 to \$3.6 million in 2014, a decrease of \$2.0 million, or 36%. This decrease is primarily due to increasing our production volume and yields in 2014 relative to 2013, resulting in more finished goods and sub-assemblies being accepted into inventory and a lower level of scrapped product being expenses. As we manufacture more products, our manufacturing overhead is spread over more units and our cost per unit produced decreases. Also, as our yields improve and we accept more units into inventory, the amount of scrapped product that is written off to cost of sales decreases. We will continue to invest in improving our manufacturing processes, and we expect that manufacturing yields will improve and cost of sales will decrease relative to our revenues over the next few years, although we expect significant fluctuations on a quarter to quarter basis.

*Research and development expense.* Research and development expense increased from \$3.2 million in 2013 to \$5.0 million in 2014, an increase of \$1.8 million, or 56%. This increase in expense is primarily related to work developing our next generation externals, which includes new eyewear and a new video processing unit. In 2014, we spent \$0.9 million more on salaries and other compensation costs than in 2013, and we spent \$0.3 million more on materials, consulting services and other supplies to make and evaluate prototypes. We expect research and development costs to increase in the future as we pursue further enhancements of our existing product and develop technology for our potential future cortical implant product.

*Clinical and regulatory expense.* Clinical and regulatory expense decreased from \$3.2 million in 2013 to \$2.6 million in 2014, a decrease of \$0.6 million, or 19%. This decrease is primarily attributable to lower levels of staffing in 2014 compared to 2013. We expect clinical and regulatory costs to increase in the future as we conduct clinical trials to assess possible enhancements to our existing product, and to assess the safety and efficacy of our current product for treating blindness due to age related macular degeneration.

*Selling and marketing expense.* Selling and marketing expense increased from \$3.3 million in 2013 to \$6.8 million in 2014, an increase of \$3.5 million, or 106%. This increase in costs is attributable to an increase in personnel, as well as higher costs for marketing and customer awareness programs, as we increased our efforts to commercialize the Argus II System as, beginning in 2014, we began selling our product in the United States, Canada and Spain. While we expect these costs to increase in the future as we increase our selling and marketing resources to accelerate the commercialization of our product, we expect selling and marketing expense to decrease over time when expressed as a percentage of product revenue.

*General and administrative expense.* General and administrative expense increased from \$4.2 million in 2013 to \$6.6 million in 2014, an increase of \$2.4 million or 57%. This increase is primarily attributable to \$0.8 million of higher stock-based compensation charges in 2014, \$0.8 million in higher compensation costs, which includes \$0.4 million due to forgiveness of a loan receivable to an officer to finance stock options, \$0.2 million of expense related to a stock award to the Company's Chairman, as well as higher spending on patent and audit related fees. The stock-based compensation charge in 2014 includes \$0.6 million related to option grants to our chief executive officer. After we become a public company, we expect our general and administrative costs to increase as we incur the additional costs of being a public company, including higher legal, accounting, insurance, exchange listing, and other costs.

*Interest expense on the convertible promissory notes.* Interest expense on the convertible promissory notes increased from \$1.6 million in 2013 to \$2.0 million in 2014, an increase of \$0.4 million, or 25%. This increase is due to the higher average level of debt outstanding during 2014 compared to 2013, although the debt was only outstanding for ten and one-half months in 2014. As a result of the Company's IPO, effective November 18, 2014, all of the Company's convertible promissory notes were converted into common stock. After the IPO, the Company no longer incurred interest expense on the convertible promissory notes.

*Amortization of issuance discount on convertible promissory notes.* Amortization of issuance discount on convertible promissory notes increased from \$3.4 million in 2013 to \$5.1 million in 2014, an increase of \$1.7 million or 50%. This increase is due to the higher average level of debt outstanding during 2014 compared to 2013, although the debt was only outstanding for ten and one-half months in 2014, and to higher value attributed to the beneficial conversion feature associated with promissory notes issued during 2013, but which was only outstanding for a part of 2013. As a result of the Company's IPO, effective November 18, 2014, all of the Company's convertible promissory notes were converted into common stock. After the IPO, the Company will no longer incur the amortization of issuance discount on convertible promissory notes.

*Write-off of unamortized discount on conversion of convertible promissory notes.* The original terms of the Company's convertible promissory notes specified that the notes automatically converted into common stock of the Company in the event, among other things, of an IPO. Accordingly, as of the IPO date, the Company wrote off \$7.0 million of deferred issuance costs related to the convertible promissory notes that converted into common stock.

*Net loss.* The net loss was \$23.0 million in 2013, as compared to \$35.2 million in 2014.

## **Liquidity and Capital Resources**

Our company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. 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. As a result, our independent registered public accounting firm, in its current report on our 2015 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern (see "Going Concern" above).

On November 18, 2014, we sold 4,025,000 shares of common stock in an IPO, including 525,000 shares sold upon exercise of the underwriter's over-allotment option, at a price of \$9.00 per share. Our net proceeds totaled \$34.2 million after cash offering costs of \$2.0 million, and excluding non-cash costs of \$2.9 million for the fair value of warrants and common stock issued in connections with services rendered.

In accordance with the original terms of the Company's convertible promissory notes, the notes converted into the Company's common stock upon the Company's IPO. In November 2014, convertible promissory notes with a face value of \$29.5 million, plus accrued interest of \$3.7 million, converted into 6.6 million shares of common stock.

Working capital was \$18.8 million at December 31, 2015, as compared to \$33.5 million at December 31, 2014, a decrease of \$14.7 million or 44.0%. Working capital was \$33.5 million at December 31, 2014, as compared to \$9.1 million at December 31, 2013, an increase of \$24.4 million or 268%. We use our cash, money market funds and working capital to fund our operating activities.

### *Cash Flows from Operating Activities*

During 2015, we used \$20.6 million of cash in operating activities, consisting primarily of a net loss of \$20.0 million, offset by non-cash charges of \$3.3 million for depreciation and amortization of property and equipment, stock-based compensation, and common stock issuable and decreased by a net change in operating assets and liabilities of \$3.9 million. This compares to 2014, when we used \$17.1 million of cash in operating activities, consisting of a net loss of \$35.2 million, offset by a non-cash charge of \$6.9 million for the write off of unamortized issuance costs related to the automatic conversion of convertible debt triggered by our IPO, reduced by non-cash charges of \$9.6 million for amortization of discount on convertible notes payable, non-cash interest accrued on convertible notes payable, depreciation and amortization of property and equipment, stock-based compensation, a stock grant to a related party, common stock issued for services, and common stock issuable and decreased by a net change in operating assets and liabilities of \$1.6 million.

During 2014, we used \$17.1 million of cash in operating activities, consisting primarily of a net loss of \$35.2 million, offset by non-cash charges of \$6.9 million for the write off of unamortized issuance costs related to the automatic conversion of convertible debt triggered by our IPO, \$9.6 million for amortization of discount on convertible notes payable, non-cash interest accrued on convertible notes payable, depreciation and amortization of property and equipment, stock-based compensation, a stock grant to a related party, common stock issued for services, and common stock issuable and decreased by a net change in operating assets and liabilities of \$1.6 million. This compares to 2013, when we used \$17.4 million of cash in operating activities, consisting of a net loss of \$23.0 million, reduced by non-cash charges of \$6.1 million for depreciation and amortization of property and equipment, stock-based compensation, amortization of discount on convertible notes payable, and non-cash interest accrued on convertible notes payable, and increased by a net change in operating assets and liabilities of \$0.5 million.

### *Cash Flows from Investing Activities*

Investing activities in 2015 provided \$17.5 million of cash, reflecting \$18.3 million in proceeds from money market investments offset by \$0.8 million for the purchase of equipment.

Investing activities in 2014 used \$25.9 million of cash, reflecting \$25.4 million in purchases of money market investments and \$0.5 million for the purchase of equipment.

Investing activities in 2013 used \$4.5 million of cash, reflecting \$4.3 million in purchases of money market investments and \$0.2 million used to purchase property and equipment in 2013.

### Cash Flows from Financing Activities

Financing activities provided \$2.8 million of cash in 2015, including \$2.7 million from stock option and warrant exercises, issuance of common stock for ESPP purchases of \$0.2 million offset by \$0.1 million for payment of employment taxes related to stock option exercises. Financing activities provided \$43.8 million of cash in 2014, including of \$34.2 million net proceeds from our IPO, \$9.1 million from the issuance of 1.3 million shares of common stock at \$7.00 per share in a private placement, and \$0.5 million from stock option and warrant exercises

Financing activities provided \$43.8 million of cash in 2014, including of \$34.2 million net proceeds from our IPO, \$9.1 million from the issuance of 1.3 million shares of common stock at \$7.00 per share in a private placement, and \$0.5 million from stock option and warrant exercises. Financing activities provided \$21.9 million of cash in 2013, including \$19.5 million from the issuance of convertible promissory notes primarily to existing investors and \$2.4 million from the issuance of 0.3 million shares of common stock to new investors at \$7.00 per share to new investors and \$0.1 million from stock option exercises, offset by a convertible note repayment of \$0.1 million.

### Financial Commitments

Effective August 2012, we entered into a lease agreement (the "Sylmar Lease") with a Company owned by the major stockholder of the Company for office space for a term of five years that was to expire on February 28, 2017. The Sylmar 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 Sylmar 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 Company's 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 \$8,200) per month.

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

Years	Amount
2016	\$ 808
2017	833
2018	858
2019	884
2020	910
Thereafter	1,095
Total	<u>\$ 5,388</u>

### Off-Balance Sheet Arrangements

At December 31, 2015, the Company 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, 2015, our cash equivalents consisted solely of money market funds.

## **Exchange Rate Sensitivity**

During 2015, approximately 46% of our revenue was denominated in U.S. dollars, 49% in Euros, and 5% in Canadian dollars. This compares with 2014 when approximately 48% of our revenue was denominated in U.S. dollars, 42% in Euros, and 10% in Canadian dollars. For 2015 and 2014, the majority of our operating expenses were denominated in U.S. dollars. We have not entered into foreign currency forward contracts to hedge our operating expense exposure to foreign currencies, but we may do so in the future.

## **Item 8. Financial Statements and Supplementary Data**

Our financial statements and supplementary data required by this Item are provided in the consolidated financial statements of the Company 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**

### **Disclosure of Controls and Procedures**

Our management carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this report.

The design of any system of control is based upon certain assumptions about the likelihood of future events, and 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.

### **Management's Report on Internal Control over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **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 2016 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 2016 Proxy Statement, which we expect to file with the SEC no later than April 30, 2016.

#### **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 our 2016 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 our 2016 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 our 2016 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 our 2016 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 our 2016 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.

**SIG NATURE S**

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 11, 2016

Second Sight Medical Products, Inc.

/s/ JONATHAN WILL MCGUIRE

Jonathan Will McGuire

Chief Executive Officer

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JONATHAN WILL MCGUIRE</u> Jonathan Will McGuire	Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2016
<u>/s/ THOMAS B. MILLER</u> Thomas B. Miller	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2016
<u>/s/ ROBERT J. GREENBERG</u> Robert J. Greenberg, M.D.	Chairman of the Board	March 11, 2016
<u>/s/ WILLIAM J. LINK</u> William J. Link	Director	March 7, 2016
<u>/s/ AARON MENDELSON</u> Aaron Mendelsohn	Director	March 7, 2016
<u>/s/ GREGG WILLIAMS</u> Gregg Williams	Director	March 7, 2016
<u>/s/ MATTHEW PFEFFER</u> Matthew Pfeffer	Director	March 7, 2016



**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Second Sight Medical Products, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended December 31, 2015. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 1 to the consolidated financial statements, the Company is subject to the risks and uncertainties associated with a new business and has incurred significant losses from operations since inception. The Company's operations are dependent upon it raising additional funds through an equity offering or debt financing. The Company has no committed sources of capital and is not certain whether additional financing will be available when needed on terms that are acceptable, if at all. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Gumbiner Savett Inc.

March 11, 2016

Santa Monica, California

**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

**Consolidated Balance Sheets  
(In thousands)**

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 239	\$ 619
Money market funds	15,721	34,000
Accounts receivable	1,501	708
Inventories, net	8,209	5,722
Prepaid expenses and other current assets	1,094	927
<b>Total current assets</b>	<b>26,764</b>	<b>41,976</b>
Property and equipment, net	1,432	1,005
Deposits and other assets	49	88
<b>Total assets</b>	<b>\$ 28,245</b>	<b>\$ 43,069</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 710	\$ 513
Accrued expenses	2,068	1,412
Accrued compensation expense	2,069	1,362
Accrued clinical trial expense	616	489
Deferred revenue	322	600
Deferred grant revenue	2,197	4,075
<b>Total current liabilities</b>	<b>7,982</b>	<b>8,451</b>
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: 35,942 and 35,241 at December 31, 2015 and December 31, 2014, respectively	166,049	163,171
Common stock to be issued	205	166
Additional paid-in capital	27,277	24,590
Notes receivable to finance stock option exercises	(5)	(171)
Accumulated other comprehensive loss	(581)	(474)
Accumulated deficit	(172,682)	(152,664)
<b>Total stockholders' equity</b>	<b>20,263</b>	<b>34,618</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 28,245</b>	<b>\$ 43,069</b>

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,		
	2015	2014	2013
Net sales	\$ 8,950	\$ 3,398	\$ 1,565
Cost of sales	5,293	3,558	5,629
Gross profit (loss)	<u>3,657</u>	<u>(160)</u>	<u>(4,064)</u>
Operating expenses:			
Research and development, net of grants	3,036	5,041	3,249
Clinical and regulatory	3,510	2,622	3,215
Selling and marketing	8,935	6,845	3,302
General and administrative	8,223	6,565	4,168
Total operating expenses	<u>23,704</u>	<u>21,073</u>	<u>13,934</u>
Loss from operations	(20,047)	(21,233)	(17,998)
Interest income	2	9	8
Other income, net	27	12	35
Interest expense on convertible promissory notes and loan payable	—	(1,957)	(1,589)
Amortization of discount on convertible promissory notes	—	(5,077)	(3,425)
Write-off of unamortized discount on conversion of convertible promissory notes	—	(6,955)	—
Net loss	<u>\$ (20,018)</u>	<u>\$ (35,201)</u>	<u>\$ (22,969)</u>
Net loss per common share – basic and diluted	<u>\$ (0.56)</u>	<u>\$ (1.41)</u>	<u>\$ (1.02)</u>
Weighted average shares outstanding – basic and diluted	35,637	25,053	22,521

See accompanying notes to consolidated financial statements.

**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

**Consolidated Statements of Comprehensive Loss  
(In thousands)**

	<b>Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (20,018)	\$ (35,201)	\$ (22,969)
Other comprehensive loss:			
Foreign currency translation adjustments	(107)	(207)	(82)
Comprehensive loss	<u>\$ (20,125)</u>	<u>\$ (35,408)</u>	<u>\$ (23,051)</u>

See accompanying notes to consolidated financial statements.

**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

**Consolidated Statements of Stockholders' Equity (Deficiency)  
(In thousands)**

	<u>Common Stock</u>		<u>Common Stock Issuable</u>		<u>Additional Paid-in Capital</u>	<u>Notes Receivable for Stock Option Exercises</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficiency)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balance, December 31, 2012	22,375	\$ 85,566	—	\$ —	\$ 6,420	\$ (351)	\$ (185)	\$ (94,494)	\$ (3,044)
Issuance of shares of common stock in connection with private placement	343	2,400	—	—	—	—	—	—	2,400
Fair value of warrants issued in connection with convertible promissory notes	—	—	—	—	3,107	—	—	—	3,107
Fair value of beneficial conversion feature in connection with convertible promissory notes	—	—	—	—	10,488	—	—	—	10,488
Exercise of stock options	332	345	—	—	—	—	—	—	345
Stock-based compensation expense	—	—	—	—	770	—	—	—	770
Notes receivable, including amount due from officer of \$100 for stock option exercises, net	—	—	—	—	—	(236)	—	—	(236)
Comprehensive loss	—	—	—	—	—	—	—	(22,969)	(22,969)
Net loss	—	—	—	—	—	—	—	(22,969)	(22,969)
Foreign currency translation adjustment	—	—	—	—	—	—	(82)	—	(82)
Comprehensive loss	—	—	—	—	—	—	(82)	(22,969)	(23,051)
Balance, December 31, 2013	23,050	\$ 88,311	—	\$ —	\$ 20,785	\$ (587)	\$ (267)	\$ (117,463)	\$ (9,221)
Issuance of common stock in connection with initial public offering	4,025	36,225	—	—	—	—	—	—	36,225
Issuance costs of initial public offering	—	(4,971)	—	—	—	—	—	—	(4,971)
Fair value of warrants issued in connection with initial public offering	—	—	—	—	2,772	—	—	—	2,772
Issuance of common stock in connection with conversion of convertible promissory notes	6,639	33,196	—	—	—	—	—	—	33,196
Issuance of common stock in connection with warrant exercise	2	10	—	—	—	—	—	—	10
Issuance of common stock in connection with private placement	1,300	9,099	—	—	—	—	—	—	9,099
Finders' fee paid on private placement	64	451	—	—	(451)	—	—	—	—
Exercise of stock options	115	506	—	—	—	—	—	—	506
Stock-based compensation expense	—	—	—	—	1,475	—	—	—	1,475
Common stock cancelled	(1)	(9)	—	—	9	—	—	—	—
Stock issued in connection with professional services	22	178	—	—	—	—	—	—	178
Common stock issuable for services	—	—	16	166	—	—	—	—	166
Stock grant in connection with services by a director	25	175	—	—	—	—	—	—	175
Repayment of notes receivable for stock option exercises, net	—	—	—	—	—	(7)	—	—	(7)
Forgiveness of notes receivable from an officer for stock option exercises	—	—	—	—	—	423	—	—	423
Comprehensive loss	—	—	—	—	—	—	—	(35,201)	(35,201)
Net loss	—	—	—	—	—	—	—	(35,201)	(35,201)
Foreign currency translation adjustment	—	—	—	—	—	—	(207)	—	(207)
Comprehensive loss	—	—	—	—	—	—	(207)	(35,201)	(35,408)
Balance, December 31, 2014	35,241	\$ 163,171	16	\$ 166	\$ 24,590	\$ (171)	\$ (474)	\$ (152,664)	\$ 34,618

**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

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

	<u>Common Stock</u>		<u>Common Stock Issuable</u>		<u>Additional Paid-in Capital</u>	<u>Notes Receivable for Stock Option Exercises</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficiency)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Issuance of common stock in connection with cashless exercise of warrants	1	—	—	—	—	—	—	—	—
Issuance of common stock in connection with warrant exercise	140	702	—	—	—	—	—	—	702
Issuance of common stock in connection with Employee Stock Purchase Plan	53	226	—	—	—	—	—	—	226
Exercise of stock options	574	2,782	—	—	—	—	—	—	2,782
Stock-based compensation expense	—	—	—	—	2,687	—	—	—	2,687
Common stock tendered to exercise stock options	(78)	(993)	—	—	—	—	—	—	(993)
Stock issued or issuable in connection with professional services	23	285	17	39	—	—	—	—	324
Common stock tendered to pay taxes on stock option exercise	(12)	(124)	—	—	—	—	—	—	(124)
Repayment of notes receivable for stock option exercises, net	—	—	—	—	—	166	—	—	166
Comprehensive loss	—	—	—	—	—	—	—	(20,018)	(20,018)
Net loss	—	—	—	—	—	—	—	(107)	(107)
Foreign currency translation adjustment	—	—	—	—	—	—	(107)	—	(107)
Comprehensive loss	—	—	—	—	—	—	(107)	(20,018)	(20,125)
Balance, December 31, 2015	35,942	\$ 166,049	33	\$ 205	\$ 27,277	\$ (5)	\$ (581)	\$ (172,682)	\$ 20,263

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,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	\$ (20,018)	\$ (35,201)	\$ (22,969)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	335	279	316
Stock-based compensation	2,687	1,475	770
Stock grant in connection with services by a director	—	175	—
Forgiveness of notes receivable related to stock option exercise	—	423	—
Amortization of discount on convertible notes payable	—	5,077	3,425
Non-cash interest accrued on convertible notes payable	—	1,952	1,589
Write off of unamortized discount on conversion of convertible promissory notes	—	6,955	—
Common stock issued for research and development agreement	—	9	—
Common stock issuable for services	324	166	—
Changes in operating assets and liabilities:			
Restricted cash	—	—	163
Accounts receivable	(793)	(239)	(148)
Grants receivable	—	—	47
Inventories	(2,488)	(3,375)	(560)
Prepaid expenses and other assets	(127)	(556)	(34)
Accounts payable	197	199	(417)
Accrued expenses	656	749	176
Accrued compensation expenses	707	216	284
Accrued clinical trial expenses	127	(2)	29
Deferred revenue	(278)	531	(98)
Deferred grant revenue	(1,878)	4,075	—
Net cash used in operating activities	<u>(20,549)</u>	<u>(17,092)</u>	<u>(17,427)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(762)	(560)	(246)
Proceeds (investment) in money market funds	18,279	(25,388)	(4,302)
Net cash provided (used) in investing activities	<u>17,517</u>	<u>(25,948)</u>	<u>(4,548)</u>
Cash flows from financing activities:			
Proceeds from sale of common stock	—	43,295	2,400
Proceeds from exercise of options, warrants and employee stock purchase plan options	2,883	509	109
Repayment of convertible promissory note	—	—	(54)
Proceeds from issuance of convertible notes payable	—	—	19,519
Payment of employment taxes related to stock option exercises	(124)	—	—
Net cash provided by financing activities	<u>2,759</u>	<u>43,804</u>	<u>21,974</u>
Effect of exchange rate changes on cash	<u>(107)</u>	<u>(207)</u>	<u>(82)</u>
Cash:			
Net increase (decrease)	(380)	557	(83)
Balance at beginning of year	619	62	145
Balance at end of year	<u>\$ 239</u>	<u>\$ 619</u>	<u>\$ 62</u>

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,		
	2015	2014	2013
<b>Supplemental cash flow information:</b>			
<b>Non-cash financing and investing activities:</b>			
Fair value of warrants issued in connection with convertible promissory notes	\$ —	\$ —	\$ 3,107
Fair value of warrant issued as part of underwriting fee for the Company's initial public offering	\$ —	\$ 2,772	\$ —
Fair value of beneficial conversion feature issued in connection with convertible promissory notes	\$ —	\$ —	\$ 10,488
Employee exercise of stock options through secured promissory notes	\$ —	\$ —	\$ 252
Principal and accrued interest on notes payable converted to common stock	\$ —	\$ 33,196	\$ —
Common stock issued in connection with finder fees paid on private placements	\$ —	\$ 451	\$ —
Common stock issued for professional services rendered in connection with initial public offering	\$ —	\$ 170	\$ —

See accompanying notes to consolidated financial statements.

**SECOND SIGHT MEDICAL PRODUCTS, INC.  
AND SUBSIDIARY**

**Notes to Consolidated Financial Statements**

**1. Organization and Business Operations**

Second Sight Medical Products, Inc. (“Second Sight” or “the Company”), formerly Second Sight LLC, was founded in 1998 as a limited liability company and was subsequently incorporated in the State of California in 2003. Second Sight develops, manufactures and markets implantable prosthetic devices that can restore some functional vision to patients blinded by outer retinal degenerations, such as Retinitis Pigmentosa.

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

The Company’s 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. The Company began selling its product in Europe in 2011, in Saudi Arabia in 2013, in the United States and Canada in 2014, and in Turkey in 2015.

**Going Concern**

From inception, the Company’s operations have been funded primarily through the sales of its common stock, as well as from the issuance of convertible debt, research and clinical grants, and product revenue generated by the sale of its Argus II System. During the years ended December 31, 2015, 2014 and 2013, the Company funded its business primarily through:

- Revenue of \$8.9 million, \$3.4 million, and \$1.6 million in 2015, 2014 and 2013, respectively, generated by sales of the Company’s Argus II System,
- Issuance of convertible debt with the face value of \$19.5 million in 2013,
- A \$4.1 million grant under Joint Research and Development Agreement with The Johns Hopkins University Applied Physics Laboratory in 2014,
- Issuance of common stock in a private placements aggregating \$9.1 million and \$2.4 million in 2014 and 2013, respectively, and
- Issuance of common stock in the Company’s initial public offering in November 2014, which generated net proceeds of \$34.2 million of cash after offering expenses.

The Company’s financial statements have been presented on the basis that its business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company is subject to the risks and uncertainties associated with a business with one product line and limited commercial product revenues, including limitations on the Company’s operating capital resources and uncertain demand for its products. The Company has incurred recurring operating losses and negative operating cash flows since inception, and it expects to continue to incur operating losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern, and the Company’s independent registered public accounting firm, in its report on the Company’s 2015 consolidated financial statements, has raised substantial doubt about the Company’s ability to continue as a going concern.

On January 25, 2016, the Company filed a registration statement with the Securities and Exchange Commission to conduct a registered rights offering as of a future record date to allow the holders of its common stock to purchase newly-issued shares of common stock. The shares will be offered at the lower of \$4.25 per share or 85% of the closing price of the Company’s common stock as reported by Nasdaq on the last day of the offering period. Assuming full subscription and a closing stock price of between \$4.00 and \$6.00 per share on the last day of the offering period, the Company expects to sell between 4.6 million and 5.8 million shares of common stock for gross proceeds of approximately \$19.8 million. The actual number of shares sold and proceeds raised will depend on, among other factors, the extent to which current shareholders participate in the rights offering and the final price per share at which the Company sells its common stock. The Company intends to use the proceeds from this rights offering to invest in its business to expand sales and marketing efforts, enhance current products, gain regulatory approvals for additional indications, and continue research and development into next generation technology.

However, there can be no assurances that the Company will ultimately be successful in completing this rights offering, or if unsuccessful, that the Company will be able to raise sufficient funds through other means so as to be able to continue to operate its business beyond the fourth quarter of fiscal 2016.

## **2. Summary of Significant Accounting Policies**

### **Principles of Consolidation**

The accompanying consolidated financial statements include the financial statements of Second Sight and Second Sight Switzerland. Intercompany balances and transactions have been eliminated in consolidation.

### **Accounts receivable**

Trade accounts receivable are stated net of an allowance for doubtful accounts. The Company performs ongoing credit evaluations of its customers' financial condition and generally requires no collateral from its customers or interest on past due amounts. Management estimates 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. There was no allowance for doubtful accounts at December 31, 2015 and 2014.

### **Inventories**

Inventories are stated at the lower of cost or market, 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. The Company establishes a reserve to mark down its 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 cost 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	1 – 5 years or the term of the lease, if shorter
Furniture, fixtures and equipment	5 – 10 years

The Company reviews its 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 2015 and 2014.

Depreciation and amortization of property and equipment amounted to \$335,000, \$279,000 and \$316,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

### **Research and Development**

Research and development costs are charged to operations in the period incurred and amounted to \$3.0 million, \$5.0 million and \$3.2 million net of grant revenue, for the years ended December 31, 2015, 2014 and 2013, respectively.

## Patent Costs

The Company has over 345 domestic and foreign patents. Due to the uncertainty associated with the successful development of one or more commercially viable products based on Company's 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 \$679,000, \$666,000 and \$669,000 for the years ended December 31, 2015, 2014 and 2013, respectively, and are included in general and administrative expenses in the consolidated statements of operations.

## Revenue Recognition

The Company's revenue is derived primarily from the sale of its Argus II retinal implant, which is implanted during retinal surgery to restore some functional vision to patients blinded by Retinitis Pigmentosa. The Company sells to a variety of customers including university hospitals, large medical centers and distributors.

Revenue is recognized when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collectability is probable, and delivery has occurred.

Revenue is generated under sales agreements with multiple deliverables (multiple-element arrangements), comprising the following deliverables:

- Hospital start up kits (one per site),
- Surgical support,
- Training, and
- The Argus II System

The deliverables may vary by transaction.

The Company evaluates each deliverable in a multiple-element arrangement to determine whether it represents a separate unit of accounting. An element constitutes a separate unit of accounting when the delivered item has standalone value and delivery of the undelivered element is probable and within the Company's control. The Company has determined that the elements listed above do not have standalone value to the customer until delivery of all components has occurred. Accordingly, revenue from multiple-element arrangements is recognized when delivery of all of deliverables has taken place and all other revenue recognition criteria have been met. Generally, revenue recognition occurs at the time of implantation, but revenue recognition can be delayed if certain training has not been delivered to the implanting sites, or if other revenue recognition criteria have not been met.

In the United States, the amount of revenue recognized per unit has been limited in some situations due to the uncertainties of the reimbursement environment and payment terms. In such cases, revenue is not recognized until the consideration becomes fixed, generally when paid to the Company.

In order to determine whether collection is reasonably assured, the Company assesses a number of factors, including creditworthiness of the customer and medical insurance coverage. The Company may periodically grant extended payment terms to customers. In such situations, the Company defers the recognition of revenue until collection becomes probable, which is generally upon receipt of payment.

The Company also sells surgical supplies to customers and recognizes revenue on these products when they are shipped and other revenue recognition criteria have been met.

The Company sells through distributors in certain countries. The Company provides these distributors with clinical start-up kits, surgical supplies and the Argus II System, as well as training them to provide pre- and post-surgical support. The Company monitors the surgery. Other than surgical support which is provided by the Company, the distributor is responsible for delivering products and services to its customers. In the past, the Company has allowed distributors to return or exchange products in certain situations. Due to the Company's continuing involvement and its returns policy, the Company recognizes revenue from distributors when the implantation procedure has been performed by the distributor's customer, and all other revenue recognition criteria between the Company and the distributor have been met.

## Grant Receipts and Liabilities

From time to time, the Company receives 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, 2015, 2014 and 2013 grants offset against operating expenses were \$1,878,000, \$19,000 and \$175,000, respectively.

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts could differ materially from those estimates.

## Concentration of Risk

### *Credit Risk*

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash, money market funds, and trade accounts receivable. The Company maintains 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. The Company extends differing levels of credit to customers, and typically does not require collateral.

The Company also maintains 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*

During the years ended December 31, 2015, 2014 and 2013, the following customers comprised more than 10% of revenues :

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Customer 1	14%	7%	0%
Customer 2	7%	21%	0%
Customer 3	4%	10%	0%
Customer 4	0%	6%	13%
Customer 5	0%	0%	31%
Customer 6	0%	3%	13%
Customer 7	0%	0%	12%

As of December 31, 2015 and 2014, the following customers comprised more than 10% accounts receivable:

	<u>2015</u>	<u>2014</u>
Customer 1	19%	0%
Customer 2	17%	32%
Customer 3	10%	2%
Customer 4	10%	0%
Customer 5	10%	0%
Customer 6	4%	13%
Customer 7	0%	13%
Customer 8	0%	20%

### *Geographic Concentration*

During the years ended December 31, 2015, 2014 and 2013, regional revenue, based on customer locations which comprised more than 10% of revenues, consisted of the following:

	<u>2015</u>	<u>2014</u>	<u>2013</u>
United States	46%	47%	0%
Italy	20%	8%	18%
France	16%	3%	7%
Germany	6%	16%	32%
Canada	5%	10%	0%
Saudi Arabia	0%	3%	31%
Netherlands	0%	0%	13%

### *Sources of Supply*

Several of the components, materials and services used in the Company's 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 the Company's sole source suppliers could result in a delay or interruption in the supply of components to the Company until that supplier cures the problem or an alternative source of the component is located and qualified. Even where the Company 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 the Company's abilities to deliver its products as may be timely required to meet demand.

### **Foreign Operations**

The accompanying consolidated financial statements as of December 31, 2015 and 2014 include assets amounting to approximately \$3.0 million and \$2.1 million, respectively, relating to operations of the Company in Switzerland. It is always possible unanticipated events in foreign countries could disrupt the Company's 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 the Company has 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.

The Company determines 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, the Company performs an analysis of the assets and liabilities at each reporting period end.

Money market funds are the only financial instrument that is measured and recorded at fair value on the Company's balance sheet, and they are considered Level 1 valuation securities in both 2015 and 2014.

### **Stock-Based Compensation**

Pursuant to Financial Accounting Standards Board ("FASB") ASC 718 Share-Based Payment ("ASC 718"), the Company records stock-based compensation expense for all stock-based awards.

Under ASC 718, the Company estimates 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, with certain exceptions, is determined based on the estimated fair value of the shares at the date of grant.

- The risk free interest rate for periods within the contractual life of the option is based on the U.S. treasury yield in effect at the time of grant.
- As permitted by SAB 107, due to the Company's insufficient history of option activity, management utilizes the simplified approach to estimate the options expected term, which represents the period of time that options granted are expected to be outstanding.
- Volatility is determined based on 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. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

### **Long Term Investor Right**

Each beneficial owner ("IPO Shareholder") of the Company's common stock, who purchased shares directly in the offering ("IPO Shares"), may qualify to receive up to one additional share of common stock from the Company for each share purchased in the offering ("IPO Supplemental Shares") pursuant to the Long Term Investor Right that was included with each IPO Share. To receive IPO Supplemental Shares, within 90 days following the closing date of the offering, or by February 22, 2015, an IPO Shareholder was required to take action to become the direct registered owner of its IPO Shares. Furthermore, IPO Shareholders are required to hold their IPO Shares in their own name and not place them in "street name" or trade them at any time during the 24 month period immediately following the IPO closing date. This Long Term Investors Right is non-detachable and transferable only in limited circumstances.

The Company will issue IPO Supplemental Shares to IPO Shareholders who have not otherwise forfeited their Long Term Investor Right if, during the two-year period immediately following the IPO closing date, the Company's common stock does not trade at or above \$18.00 per share (200% of the IPO price per share) for any five consecutive day period. If the Company's common stock trades on its principal exchange at 200% of the IPO price per share or greater on five consecutive trading days during the two years after the IPO closing date, the Long Term Investor Right will terminate.

The formula to determine the number of IPO Supplemental Shares to be issued on a trigger of the Long Term Investor Right will be: (i) \$18.00 minus (ii) the average of the highest consecutive closing prices in any 90 day trading period on the principal exchange during the two years after the Closing Date (the "Measurement Average") divided by the Measurement Average. Fractional shares issuable to a qualifying IPO Shareholder resulting from the calculation will be rounded up to the next whole share of Common Stock, taking into account the aggregate number of Long Term Investor Rights of a holder. As an illustrative example, if the highest average of consecutive closing prices over any 90 calendar day period is \$10.00 per share, each Long-Term Investor Right will be entitled to 0.80 additional shares of common stock, which is calculated as:  $(\$18.00 - \$10.00)/\$10.00$ .

The IPO offering price for purposes of the calculation of the amount of common stock to be issued on a Long Term Investor Right will be subject to adjustment in the event of a reorganization, recapitalization or split-up of the Company's shares, the issuance of a stock dividend or any similar event. The amount of IPO Supplemental Shares, if any, to be issued will be computed by an independent public accountant as soon as practicable following the second anniversary of the Closing Date. The determination by such independent public accountant will be final and binding on the Company and on all qualifying IPO Shareholders and the Company will within 15 days after receipt of written determination deliver to shareholders certificates evidencing the additional shares.

The Company has identified and will track IPO Investors who have perfected their Long Term Investor Rights on a quarterly basis. At the end of each reporting period, the Company will disclose the potential dilutive effect of the Long Term Investor Rights, including the number of common shares that would be issuable on such date, based on the actual share price movements since the IPO.

The Long Term Investor Right is an equity instrument that is accounted for as a component of the actual price per common share paid by the investor in the IPO. For basic earnings per share, the common shares associated with the Long Term Investor Right are treated as contingently issuable shares and will not be included in basic earnings per share until the actual number of shares can be calculated and the shares have been issued.

As of December 31, 2015 there were 400,057 shares of common stock issuable under outstanding Long Term Investor Rights.

## **Convertible Promissory Notes and Warrants**

The warrants and embedded beneficial conversion feature of convertible promissory notes are classified as equity under FASB ASC Topic 815-40 “Derivatives and Hedging — Contracts in Entity’s Own Equity”. The Company allocates the proceeds of the convertible promissory notes between convertible promissory notes and the financial instruments related to warrants associated with convertible promissory notes based on their relative fair values at the commitment date. The fair value of the financial instruments related to warrants associated with convertible promissory notes is determined utilizing the Black-Scholes option pricing model and the respective allocated proceeds to the warrants is recorded in additional paid-in capital. The Company utilized the Black-Scholes option valuation model using the same valuation assumptions as described herein for Stock Based Compensation. The embedded beneficial conversion feature associated with convertible promissory notes is recognized and measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital in accordance with ASC Topic 470-20 “Debt — Debt with Conversion and Other Options.” The portion of debt discount resulting from the allocation of proceeds to the financial instruments related to warrants associated with convertible promissory notes is being amortized over the life of the convertible promissory notes. For the portion of debt discount resulting from the allocation of proceeds to the beneficial conversion feature, it is amortized over the term of the notes from the respective dates of issuance.

## **Comprehensive Income or Loss**

The Company complies 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, 2015, 2014 and 2013 comprehensive income (loss) is the total of net income (loss) and other comprehensive income (loss) which, for the Company, 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, 2015, 2014 and 2013.

## **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 U.S. GAAP. Assets and liabilities of those operations are translated at exchange rates in effect at the balance sheet date. The resulting gains and losses from translating foreign currency financial statements are recorded as other comprehensive income (loss). Revenues and expenses are translated at the average exchange rate for the reporting period. Foreign currency translation 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**

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its 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. The Company has incurred losses for tax purposes since inception and has significant tax losses and tax credit carryforwards. These amounts are subject to valuation allowances as it is not likely that they will be realized in the next few years.

## **Product Warranties**

The Company’s policy is to warrant all shipped products against defects in materials and workmanship for two years by replacing failed parts. The Company also provides 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. The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Although any such adjustments were not material in the years ended December 31, 2015, 2014 and 2013, 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

The Company collects value added tax on its sales in Europe and certain states in the United States impose a sales tax on the Company's sales to nonexempt customers. The Company collects that value added and sales tax from customers and remits the entire amount to the respective authorities. The Company's accounting policy is to exclude the tax collected and remitted to the authorities from revenues and cost of revenues.

## Net Loss per Share

The Company's 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 convertible notes payable, common stock warrants and common stock options outstanding were anti-dilutive.

At December 31, 2015, 2014 and 2013, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to ultimately acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Long Term Investor Rights	400,057	1,021,021	—
Underwriter's warrants	802,000	805,000	—
Convertible notes payable	—	—	6,248,652
Warrants associated with convertible debt	1,038,403	1,178,707	1,180,766
Common stock options	3,472,146	3,251,627	2,240,568
Restricted stock units	190,000	—	—
Employee stock purchase plan	93,000	—	—
Total	<u>5,995,606</u>	<u>6,256,355</u>	<u>9,669,986</u>

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB's Exposure Draft Update issued on April 29, 2015, and approved in July 2015, Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date, ASU 2014-09 is now effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company is evaluating ASU 2014-9, and has not yet determined its impact to the Company's financial statements, nor decided the transition approach it will take.

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 provides 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 financial statements for each annual and interim reporting period, an entity’s management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have any impact on the Company’s financial statement presentation and disclosures.

In January 2015, the FASB issued Accounting Standards Update No. 2015-01 (ASU 2015-01), Income Statement – Extraordinary and Unusual Items (Subtopic 225-20). ASU 2015-01 eliminates from GAAP the concept of extraordinary items. Subtopic 225-20, Income Statement – Extraordinary and Unusual Items, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. Paragraph 225-20-45-2 contains the following criteria that must both be met for extraordinary classification: (1) Unusual nature. The underlying event or transaction should possess a high degree of abnormality and be of a type clearly unrelated to, or only incidentally related to, the ordinary and typical activities of the entity, taking into account the environment in which the entity operates. (2) Infrequency of occurrence. The underlying event or transaction should be of a type that would not reasonably be expected to recur in the foreseeable future, taking into account the environment in which the entity operates. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the guidance prospectively. A reporting entity also may apply the guidance retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU 2015-01 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In February 2015, the FASB issued Accounting Standards Update No. 2015-02 (ASU 2015-02), Consolidation (Topic 810) . ASU 2015-02 changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. All legal entities are subject to reevaluation under the revised consolidation mode. ASU 2015-02 affects the following areas: (1) limited partnerships and similar legal entities; (2) evaluating fees paid to a decision maker or a service provider as a variable interest; (3) the effect of fee arrangements on the primary beneficiary determination; (4) the effect of related parties on the primary beneficiary determination; and (5) certain investment funds. ASU 2015-02 is effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. A reporting entity may apply the amendments in this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. A reporting entity also may apply the amendments retrospectively. The adoption of ASU 2015-02 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 (ASU 2015-03), Interest – Imputation of Interest (Subtopic 835-30). ASU 2015-03 simplifies the presentation of debt issuance costs and requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the new guidance. ASU 2015-3 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within that fiscal year. Early adoption is permitted for financial statements that have not been previously issued. An entity is required to apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented is adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The adoption of ASU 2015-03 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17 (ASU 2015-17), Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The adoption of ASU 2015-17 is not expected to have any impact on Company’s financial statement presentation or disclosures.

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02 regarding leases. The new standard requires lessee recognition on the balance sheet of a right-of-use asset and a lease liability, initially measured at the present value of the lease payments. It further requires recognition in the income statement of a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. Finally, it requires classification of all cash payments within operating activities in the statement of cash flows. It is effective for fiscal years commencing after December 15, 2018 and early adoption is permitted. Management has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

### 3. Money Market Funds

Money market funds at December 31, 2015 totaled \$15,721,000 and consisted of \$555,000 in the City National Rochdale Government Fund Class S, \$14,948,000 in the FFI Institutional Fund, and \$218,000 held in a deposit account in Switzerland as security for the performance of contracts. Money market funds at December 31, 2014 totaled \$34,000,000 and consisted of \$268,000 in the City National Rochdale Government Fund Class S, \$1,024,000 in a Preferred Deposit, \$7,000 in the BBIF Money Fund Class 4, \$32,645,000 in the FFI Institutional Fund, and \$56,000 held in a deposit account in Switzerland as security for the performance of a contract.

The investment objective of the City National Rochdale Government Money Market Fund is to preserve principal and maintain a high degree of liquidity while providing current income through a portfolio of liquid, high quality, short-term U.S. Government bonds and notes, at least 80% of which is in U.S. Government securities. The City National Rochdale Government Money Market Fund is managed by City National Rochdale, LLC. The Preferred Business Deposit Fund is managed by Merrill Lynch and is designed to provide liquidity, safety and competitive yields. The investment objective of the BBIF Money Fund is to seek current income, preservation of capital and liquidity through a diversified portfolio of U.S. dollar-denominated short-term securities with maturities of not more than 397 days (13 months). The BBIF Money Fund is managed by BlackRock Advisors, LLC. The investment objective of the FFI Institutional Fund is to seek maximum current income consistent with liquidity and the maintenance of a portfolio of high-quality, short-term money market securities. The FFI Institutional Fund is managed by BlackRock Advisors, LLC.

The following table presents money market funds at their level within the fair value hierarchy at December 31, 2015 and 2014 (in thousands).

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>December 31, 2015:</b>				
Money market funds	\$ 15,721	\$ 15,721	\$ —	\$ —
<b>December 31, 2014:</b>				
Money market funds	\$ 34,000	\$ 34,000	\$ —	\$ —

### 4. Selected Balance Sheet Detail

#### Inventories, net

Inventories consisted of the following at December 31, 2015 and 2014 (in thousands):

	<u>2015</u>	<u>2014</u>
Raw materials	\$ 575	\$ 611
Work in process	5,028	4,729
Finished goods	3,156	1,749
	8,759	7,089
Allowance for excess and obsolescence	(550)	(1,367)
Inventories, net	\$ 8,209	\$ 5,722

## Property and equipment, net of accumulated depreciation

Property and equipment consisted of the following at December 31, 2015 and 2014 (in thousands):

	2015	2014
Laboratory equipment	\$ 3,369	\$ 3,286
Computer hardware and software	1,960	1,701
Leasehold improvements	508	362
Furniture, fixtures and equipment	135	135
	<u>5,972</u>	<u>5,484</u>
Accumulated depreciation and amortization	(4,540)	(4,479)
Property and equipment, net	<u>\$ 1,432</u>	<u>\$ 1,005</u>

## 5. Related Party Transactions

As of December 31, 2013, three investors who at the time were members of the Company's Board of Directors and certain of their affiliates (collectively, the "Related Party Investors") held \$23.4 million in face value of the Company's convertible promissory notes. These convertible notes, which are more fully described in Note 7, entitled the Related Party Investors to (i) simple interest of 7.5% per annum accrued on the outstanding face value of convertible notes, (ii) warrants to purchase shares of the Company's common stock at \$5.00 per share, and (iii) the right to convert their convertible notes into shares of the Company's common stock at \$5.00 per share upon the occurrence of certain events, one of which was an initial public offering of the Company's common stock. In June 2014, an entity associated with one of these Related Party Investors assigned \$200,000 in face value of these convertible notes payable to unrelated parties. This assignment included all accrued interest pertaining to those notes and the related 8,000 warrants. As more fully described in Note 7, all of the Company's convertible promissory notes were converted into common stock upon the initial public offering of common stock. Accordingly, the Related Party Investors received 5.2 million shares of the Company's common stock upon conversion of their convertible promissory notes. As of December 31, 2013, the Related Party Investors held convertible promissory notes, including accrued interest, totaling \$24.7 million. As of December 31, 2015 and 2014, in connection with the issuance of these convertible notes, the Related Party Investors held warrants to purchase 927,152 shares of the Company's common stock. During the period January 1, 2014 to November 18, 2014 (the date the notes were converted to common stock of the Company), the Company recorded interest expense to the Related Party Investors of approximately \$1.5 million. During the year ended December 31, 2013, in connection with these convertible notes, the Company recorded interest expense to the Related Party Investors of approximately \$1.2 million. The Related Party Investors purchased these convertible notes on the same terms and conditions as the other investors in the convertible note financings. The Related Party Investors were also stockholders of the Company at the time that they purchased the convertible notes.

Alfred E. Mann, who was the largest stockholder and until August 2015 chairman of the Company, was also a substantial contributor to the Alfred E. Mann Foundation for Scientific Research (the "Foundation"). Beginning February 2007, an officer of the Company also became Chairman of the Board of the Foundation. The Company and the Foundation share certain limited administrative and engineering employees. The shared employees make an allocation of their time between the Company and the Foundation. There are also various other costs shared between the Company and the Foundation. In connection with these shared costs, the Company owed the Foundation \$1,000 as of December 31, 2015 and 2014.

On May 31, 2011, the Company's current Chairman, and then Chief Executive Officer, entered into a loan agreement with the Company to finance the exercise of stock options to purchase 100,000 shares for \$319,000, with a maturity date of May 31, 2016 and interest accruing at 2.26% per annum. On December 11, 2013, the same individual entered into a second loan agreement with the Company to finance the exercise of stock options to purchase 200,000 shares of common stock for \$100,000, with a maturity date of December 31, 2018 and interest accruing at 1.64% per annum. As of December 31, 2013, the balance outstanding pursuant to the two loans, including accrued interest, was \$423,000. These loans receivable were recorded in the Company's financial statements as an offset to stockholders' equity. In July 2014, the Company's Board of Directors approved forgiving this note receivable and related accrued interest of \$423,000, which amount is included in general and administrative expenses in the Company's statement of operations for the year ended December 31, 2014.

Prior to November 2014, the Company leased its office and laboratory space in Sylmar, California under an operating lease with Mann Biomedical Park, LLC (formerly Sylmar Biomedical Park, LLC), which was wholly owned by Alfred E. Mann, who at the time was a principal stockholder and Chairman of the Company (see Note 13). In November 2014, the Mann Biomedical Park, LLC was sold to an unrelated third party.

The Company entered into a loan agreement with an entity affiliated with Mr. Mann, who at the time was a principal stockholder and Chairman of the Company, to lend the Company up to \$3.0 million at an annualized interest rate of 1.5% on an unsecured basis. The Company borrowed \$2.0 million pursuant to this loan agreement on October 1, 2014, and repaid the loan on November 24, 2014, including \$4,000 of interest. As of December 31, 2014, no amounts were due or outstanding under this agreement.

## **6. Grants**

In April 2010, the Company was awarded a development and testing grant of \$3.0 million from the Department of Health and Human Services, National Institutes of Health (NIH). The grant was for three years commencing in May 2010. The grant included managing various subcontracts with designated individuals and their respective institutions. The grant reimburses research costs to develop technology for the prevention, cure and amelioration of the loss of eyesight and other neurologic applications. The Company recorded funding under the grant as an offset to research and development expenses. In 2015, 2014 and 2013, research and development expenses were offset by \$0, \$19,000 and \$175,000, respectively.

In September, 2014, the Company entered into a Joint Research and Development Agreement or JRDA with The Johns Hopkins University Applied Physics Laboratory or APL. The JRDA includes a subcontract to do research under a grant received by APL. Under the JRDA, the Company has agreed to perform research regarding integration of APL research in to a visual prosthesis system. In October, 2014, APL paid the Company \$4.1 million in one lump sum to conduct its portion of the research. The JRDA also includes a license from APL to the Company, 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, the Company issued 1,000 shares of its common stock to APL, has agreed to pay APL patent prosecution costs, and to pay APL a royalty of .25% of net sales of licensed products. The Company recorded funding under the grant as an offset to research and development expenses of \$1.9 million in 2015.

## **7. Convertible Promissory Notes and Warrants**

During 2010 and 2011, the Company borrowed money in a series of financing rounds by issuing \$15.4 million of convertible notes (the "2010 - 2011 Notes") primarily to existing stockholders. The notes accrued interest at 7.5% per annum and had a variety of maturity dates. During 2011, all but two of the 2010 and 2011 Notes, with a combined face value \$47,000, were converted into 3.2 million shares of the Company's common stock at \$5.00 per share. In March 2013, the Company redeemed the remaining two notes for \$54,000 in cash.

During 2012 and 2013, the Company borrowed money primarily from existing investors in three separate rounds through the issuance of convertible promissory notes (collectively, the "Convertible Notes") totaling \$29.5 million. The first round of Convertible Notes in the amount of \$5.0 million was issued from July through November 2012 (the "July 2012 Notes"). The second round of Convertible Notes in the amount of \$5.0 million was issued from October through December 2012 (the "October 2012 Notes"). The third round of Convertible Notes in the amount of \$19.5 million was issued from February through December 2013 (the "February 2013 Notes"). There were no placement fees associated with the Convertible Notes, and other administrative costs were nominal and were expensed as incurred. The July 2012 Notes and the October 2012 Notes had maturity dates of July 31, 2015. The February 2013 Notes had a maturity date of February 28, 2016. The Convertible Notes accrued interest at the rate of 7.5% per annum, which is added to the principal amounts. For the year ended December 31, 2014, the annualized effective interest rate on the July 2012 Notes, the October 2012 Notes and the February 2013 Notes were 18.6%, 19.2%, and 63.3%, respectively. For the year ended December 31, 2013, the annualized effective interest rates on the July 2012 Notes, the October 2012 Notes, and the February 2013 Notes were 14.5%, 14.9% and 33.3%, respectively.

The Convertible Notes were due on their respective maturity dates or convertible into the Company's common stock upon the occurrence of a "capital event," which is defined as (i) a sale of stock to a third party, excluding existing shareholders, of not less than \$15.0 million, (ii) an initial public offering, or (iii) a "qualifying reorganization event" as defined in the Convertible Promissory Note agreement. The Convertible Promissory Note agreement contained a beneficial conversion feature that provided that if the notes were converted due to a capital event then all outstanding principal and interest would be converted into shares of common stock at the lower of the purchase price paid pursuant to the capital event, or at \$5.00 per share. If no capital event occurred before the maturity date, the Convertible Promissory Note agreement provided that, at the election of the holder, all outstanding principal and interest could be converted to shares of common stock at \$5.00 per share. During 2013, the debt issuance discount recorded in connection with this beneficial conversion feature was \$10.5 million.

In connection with the Convertible Notes, the Company issued warrants to purchase 1,180,766 shares of the Company's common stock. The warrants grant the holder the right to purchase additional shares of common stock of the Company equal to the product of (a) twenty percent, multiplied by (b) the face amount of the convertible note divided by \$5.00. The exercise price for each share purchased under the warrant is \$5.00. Until their expiration date, the warrants may be exercised at any time, and from time to time, in whole or in part. As originally issued, the warrants expired on the earlier of their expiration dates, upon a change in control event, or within 30 days of prior written notice of a pending IPO. In June 2014, the board of directors amended the warrants to provide that they will not expire on the occurrence of an IPO. The warrants associated with the July 2012 Notes and the October 2012 Notes have an expiration date of July 31, 2017. The warrants associated with the February 2013 Notes have an expiration date of February 28, 2018. During 2013 the debt issuance discount recorded in connection with the fair value of warrants issued was \$3,107,000.

As of December 31, 2015, there were outstanding warrants associated with the Convertible Notes to purchase 1,038,403 shares of the Company's common stock, with a weighted average remaining contractual life of 1.96 years.

During the fourth quarter of 2014, because of the successful completion of the Company's IPO, the Company's Convertible Notes were automatically converted into 6,639,137 shares of the Company's common stock, and the unamortized discount on the Convertible Notes of approximately \$7.0 million was written off.

The calculated value of the warrants associated with the Convertible Notes was estimated on the respective dates of grant using the Black-Scholes option-pricing model with the following assumptions:

	<u>2013</u>
Risk-free interest rate	0.65% – 1.68%
Expected dividend yield	0%
Expected volatility	57.5%
Expected term	4.2 – 5.0 years
Weighted-average grant date calculated fair value	\$3.98

A summary of warrant activity for the years ended December 31, 2015, 2014, and 2013 is presented below:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Warrants outstanding at December 31, 2012	400,000	\$ 5.00	
Granted	780,766	5.00	
Exercised	—	—	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2013	<u>1,180,766</u>	\$ 5.00	
Granted	805,000	11.25	
Exercised	(2,059)	5.00	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2014	<u>1,983,707</u>	\$ 7.54	
Granted	—	11.25	
Exercised	(143,304)	5.13	
Forfeited or expired	—	—	
Warrants outstanding at December 31, 2015	<u>1,840,403</u>	\$ 7.72	2.80
Warrants exercisable at December 31, 2015	<u>1,840,403</u>	\$ 7.72	2.80

The estimated aggregate intrinsic value of warrants exercisable at December 31, 2015 and 2014 was approximately \$924,000 and \$6,200,000, respectively.

## 8. Employee Benefit Plans

The Company has 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, 2015, 2014 and 2013, employer contributions to the Plan totaled \$137,000, \$127,000 and \$110,000, respectively.

The Company is required to contribute to a government-sponsored pension plan for the employees of its Switzerland-based subsidiary. For the years ended December 31, 2015, 2014 and 2013, the employer's portion of the amounts contributed to the subsidiary's pension plan on behalf of those employees was \$134,000, \$101,000 and \$94,000, respectively.

## 9. Equity Securities

In June 2014, the Company's 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 Company's consolidated financial statements have been retroactively restated to reflect this amendment. 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.

### November 2014 IPO

On November 18, 2014, the Company sold 4,025,000 shares of common stock in an IPO, including 525,000 shares sold upon exercise of the underwriter's over-allotment option. Net proceeds to the Company totaled approximately \$34.2 million, net of offering costs of approximately \$5.0 million, including approximately \$2.9 million for the fair value of warrants and common stock issued in connections with services rendered. The proceeds from the IPO are expected to be used by the Company to invest in its business to expand sales and marketing efforts, enhance current product, gain regulatory approvals for additional indications, and continue research and development into next generation technology.

### Underwriter's Warrant

As a component of the IPO underwriting fee, the Company granted the underwriter a warrant to purchase 805,000 shares of the Company's 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. The fair value of the warrant issued as part of underwriting fee for the Company's IPO was estimated to be \$2,772,000, using the Black-Scholes option-pricing model with the following assumptions:

Risk-free rate of return	1.63%
Expected dividend yield	0%
Expected volatility	49.92%
Expected term	5 years

### Long Term Investor Right

As of December 31, 2015, the Company identified investors who had perfected and maintained Long Term Investor Rights in an aggregate of 1,382,218 shares of common stock that were acquired as part of the Company's IPO. The highest average closing price for the Company's common stock on NASDAQ during any consecutive 90 day period ended on or before December 31, 2015 was \$13.96. Based on this average closing stock price, an investor who purchased shares as part of the IPO, and who has perfected its Long Term Investor Right, would be entitled to 0.2894 shares for each share purchased in the IPO, rounded up to the next whole share, which represents an aggregate maximum of 400,057 shares that are potentially issuable by the Company pursuant to the Long Term Investor Right at such date. The actual number of common shares issuable pursuant to the Long Term Investor Right is dependent on the future stock price of the Company over the two year period subsequent to the November 24, 2014 closing date of the IPO, and could be as high as 400,057 shares and as low as zero shares.

The Long Term Investor Right is an equity instrument that is being accounted for as a component of the actual price per common share paid by the investor in the IPO. For basic earnings per share, the common shares associated with the Long Term Investor Right are treated as contingently issuable shares and are not included in basic earnings per share until the actual number of shares can be calculated and the shares have been issued.

## 2014 Private Placement

During 2014, the Company sold 1,299,853 shares of its common stock to new investors at \$7.00 per share in a private placement, raising a total of \$9.1 million. Related to this stock placement, the Company paid a finder's fee of 26,785 shares of common stock to Mendelsohn Investment Services, LLC, an entity affiliated with Aaron Mendelsohn, a member of the Company's Board of Directors. The Company paid an additional finder's fee of 37,599 shares of common stock to an existing shareholder in connection with this stock placement.

## 2013 Private Placement

From July 1, 2013 through December 31, 2013, the Company sold 342,955 shares of its common stock to new investors at \$7.00 per share in a private placement, raising a total of \$2.4 million. No costs were incurred in connection with these issuances.

## Common Stock Issuable

Beginning with services rendered in 2014, and with the first payment in June 2015, non-employee members of the Board of Directors will be paid for their services in common stock on June 1 of each year based on the average closing prices for the immediately preceding twenty trading days. For 2015, for these services the Company issued 23,136 shares with a value of \$285,000 and accrued \$205,000, which equates to 33,293 shares based on the average closing price of \$6.15 for the Company's common stock during last 20 trading days as of December 31, 2015. The shares, which have not yet been issued, are excluded from the calculation of weighted average common shares outstanding for EPS purposes. For 2014, the Company accrued \$166,000 for these services, which equates to 16,204 shares based on the \$10.26 closing price for the Company's common stock on December 31, 2014.

## 10. Stock-Based Compensation

Under the 2003 Plan, as restated in June 2011, the Company was authorized to issue options covering up to 3,500,000 common stock shares. Effective June 1, 2011, the Company adopted the 2011 Equity Incentive Plan (the "2011 Plan"). The maximum number of shares with respect to which options may be granted under the 2011 Plan is 6,000,000 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.

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

The Company recognized stock-based compensation cost of \$2,687,000, \$1,475,000 and \$770,000 during 2015, 2014 and 2013, 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:

	2015	2014	2013
Risk-free interest rate	1.93% – 2.21%	0.3% – 2.2%	1%
Expected dividend yield	0%	0%	0%
Expected volatility	47.5% – 50.4%	50.0% – 61.2%	61.2%
Expected term	6.25 – 6.5 years	1.5 – 6.5 years	6.5 years
Weighted-average grant date calculated fair value	\$ 6.17	\$ 4.73	\$ 1.58

As the Company has limited stock trading history, the expected volatility is based on the historical volatility of similar companies that have a trading history. The expected term represents the estimated average period of time that the options are expected to remain outstanding. Since the Company does not have sufficient historical data on the exercise of stock options, the expected term is based on the "simplified" method that measures the expected term as the average of the vesting period and the contractual term. The risk free rate of return reflects the grant date interest rate offered for zero coupon U.S. Treasury bonds over the expected term of the options.

A summary of stock option activity for the years ended December 31, 2015, 2014 and 2013 is presented below:



	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Options outstanding at December 31, 2012	2,727,503	\$ 4.32	
Granted	500	5.00	
Exercised	(331,871)	1.05	
Forfeited or expired	(155,564)	3.73	
Options outstanding at December 31, 2013	2,240,568	\$ 4.84	
Granted	1,377,978	7.62	
Exercised	(115,029)	4.40	
Forfeited or expired	(251,890)	4.44	
Options outstanding at December 31, 2014	3,251,627	\$ 6.07	
Granted	998,348	12.29	
Exercised	(573,792)	4.85	
Forfeited or expired	(204,037)	7.08	
Options outstanding at December 31, 2015	<u>3,472,146</u>	\$ 8.01	6.39
Options exercisable at December 31, 2015	<u>1,571,255</u>	\$ 5.44	3.62

The exercise prices of common stock options outstanding and exercisable are as follows at December 31, 2015:

<u>Exercise Price</u>	<u>Options Outstanding (Shares)</u>	<u>Options Exercisable (Shares)</u>
\$ 4.25	125,000	125,000
\$ 4.88	16,500	—
\$ 5.00	1,408,553	1,223,965
\$ 7.00	252,095	51,969
\$ 9.00	699,650	170,121
\$ 9.01	34,000	—
\$ 12.43	420,000	—
\$ 12.46	246,000	—
\$ 12.73	150,000	—
\$ 13.09	116,348	—
\$ 13.90	3,000	—
\$ 14.06	1,000	200
	<u>3,472,146</u>	<u>1,571,255</u>

The estimated aggregate intrinsic value of stock options exercisable at December 31, 2015 and 2014 was approximately \$1,294,000 and \$10,080,000, respectively. As of December 31, 2015, there was \$9,148,000 of total unrecognized compensation cost related to the outstanding stock options that will be recognized over a weighted average period of 3.17 years.

On January 1, 2015, the Company's current Chairman, who at that time was the Chief Executive Officer, exercised stock options expiring on that date on a cashless basis to purchase 59,063 shares of common stock at an exercise price of \$4.75 per share. Based on the closing market price of the Company's common stock of \$10.26 on December 31, 2014, the Chief Executive Officer tendered 27,344 shares of common stock that he owned to satisfy the aggregate exercise price and surrendered 12,055 shares of common stock to satisfy the related \$124,000 of income and payroll tax withholding amounts related to the transaction.

In June 2015 the Company's current Chairman, who at that time was the Chief Executive Officer, exercised stock options on a cashless basis to purchase 150,000 shares of common stock at an exercise price of \$4.75 per share. Related to these exercises, the Chief Executive Officer tendered 50,753 shares of common stock that he owned to satisfy the aggregate exercise price.

In January 2014, the Company granted a stock option to its current Chairman, who at that time was the Chief Executive Officer, to purchase 125,000 shares of common stock at an exercise price of \$4.25 per share, exercisable for a period of three years from the date of grant. The stock option grant was fully vested on the date of issuance and was intended to replace an earlier stock option grant with the same exercise price that had expired in January 2014. The stock option was not granted pursuant to the 2011 Plan. The grant date fair value of the stock option, calculated pursuant to the Black-Scholes option-pricing model utilizing a volatility factor of 50% and a dividend rate of 0%, was determined to be \$393,000, which was charged to operations as general and administrative expense in the year ended December 31, 2014.

During the year ended December 31, 2014, the Company recorded a charge of \$235,000 to extend the exercise period of 232,003 options for four employees who resigned and became consultants for the Company. All unvested options for employees were terminated when they ceased full-time employment with the Company.

On May 15, 2015 shareholders approved (1) an increase of 2,000,000 shares in the number of shares available for option awards under the 2011 Equity Incentive Plan, and (2) an Employee Stock Purchase Plan, with an initial 250,000 shares with annual increases of shares available equal to the lesser of (i) 1% of outstanding shares or (ii) 100,000 shares.

The Company adopted an employee stock purchase plan in June, 2015 for all eligible employees. Under the plan, shares of the Company's 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, 2015, 52,469 shares were issued under the plan.

The following table summarizes Restricted Stock Unit (RSU) activity for the year ended December 31, 2015:

	<u>Number of Awards</u>	<u>Weighted Average Grant Date Fair Value Per Share</u>
Outstanding as of December 31, 2014	-	\$ -
Awarded	190,000	12.43
Vested	-	-
Forfeited/canceled	-	-
Outstanding as of December 31, 2015	<u>190,000</u>	<u>\$ 12.43</u>

As of December 31, 2015, there was \$2,142,000 of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 3.63 years.

The total stock-based compensation recognized for stock-based awards granted in the consolidated statements of operations for the years ended December 31, 2015, 2014 and 2013 is as follows (in thousands):

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Cost of sales	\$ 279	\$ 192	\$ 153
Research and development	208	293	229
Clinical and regulatory	235	113	83
Selling and marketing	442	141	102
General and administrative	1,523	736	203
Total	<u>\$ 2,687</u>	<u>\$ 1,475</u>	<u>\$ 770</u>

From time to time, the Company has extended full-recourse loans to certain non-officer employees for the purpose of financing stock option exercises. These loans bear interest ranging from 1.27% to 1.91% per annum and are payable over three years in monthly installments of principal and interest. At December 31, 2015 and 2014, the outstanding balance of such loans, including accrued interest, was \$5,000 and \$109,000, respectively. These loans receivable are recorded in the Company's consolidated financial statements as an offset to stockholders' equity. Additionally at December 31, 2015 and 2014, the Company had a receivable in the amount of \$0 and \$10,000, respectively, from a non-officer employee for the exercise of options which has been recorded as an offset to stockholders' equity in the Company's consolidated financial statements.

On December 27, 2013, the Company extended a full-recourse loan totaling \$127,000 to a consultant for the purpose of financing the exercise of stock options. The loan bears interest at 1.64% per annum and is repayable in eight equal quarterly installments of \$16,000. This loan receivable is recorded in the Company's consolidated financial statements as an offset to stockholders' equity. At December 31, 2015 and 2014, the outstanding balance of this loan including accrued interest was \$0 and \$43,000, respectively.

#### Stock Awards

In July 2014, the Company awarded Alfred E. Mann, who at the time the Chairman of the Board of Directors, 25,000 shares of common stock in recognition of services rendered to the Company since inception. These shares were valued at \$175,000, or \$7.00 per share, and were charged to general and administrative expense in 2014.

In 2014, the Company awarded 21,215 shares to an outside attorney and his staff as part of the fee paid for drafting the Company's prospectus and S-1 filing. These shares were valued at \$170,000, with 10,715 shares valued at \$7.00 per shares and the balance valued at \$9.00 per share. The cost of these shares is treated as an issuance cost of the Company's initial public offering and was deducted from the gross proceeds from the offering.

#### Employment Agreement

On June 19, 2015 the Company entered into an at will employment agreement with Will McGuire to become the Company's President and Chief Executive Officer. The Company has agreed to pay Mr. McGuire an annual salary of \$390,000 and he will also be entitled to receive performance bonuses which will be based on performance standards and goals established by the Company's Board of Directors. Upon termination without cause, Mr. McGuire will be entitled to receive severance consisting of his salary for a period of 12 months following such termination and his pro-rated target bonus through the balance of the calendar year in which such termination occurs. As part of the agreement, the Company agreed to grant Mr. McGuire, effective on his official start date as an employee, options to purchase 420,000 shares of the Company's common stock, the fair value of which was determined to be \$2,574,000, of which \$240,000 was recognized during the year ended December 31, 2015 and 190,000 RSUs the fair value of which was determined to be \$2,362,000, of which \$220,000 was recognized during the year ended December 31, 2015. The fair value of the RSUs and the exercise price of the options were both marked at \$12.43 which was the closing price of the Company's stock on Nasdaq on August 17, 2015. The options and RSUs will vest over four years, with 25% vesting on the first anniversary of the grant date, and the remainder vesting thereafter in twelve equal installments of 6.25% on the quarterly anniversaries of the grant date.

#### 11. 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 the Company's deferred tax assets as of December 31, 2015 and 2014 are summarized below (in thousands):

	<u>2015</u>	<u>2014</u>
Stock-based compensation	\$ 2,825	\$ 2,489
Research credits	5,401	5,436
Depreciation	(12)	(13)
Net operating loss carryforwards	47,261	43,700
Inventory reserve	203	544
Other	845	492
Total deferred tax assets	<u>56,523</u>	<u>52,648</u>
Valuation allowance	(56,523)	(52,648)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>



In assessing the potential realization of these deferred tax assets, management considers 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 the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2015 and 2014, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized, and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

In accordance with the reporting requirements under ASC 718, the Company did not include excess windfall benefits resulting from stock option exercises as components of the Company's gross deferred tax assets and corresponding valuation allowance disclosures, as the tax attributes related to those windfall tax benefits should not be recognized until they result in a reduction of taxes payable. The tax-effected amount of gross unrealized net operating loss carryforwards excluded under ASC 718 was approximately \$1.1 million at December 31, 2015. When realized, those excess windfall benefits are credited to additional paid-in capital. The Company utilizes the with-and-without allocation method to determine when such net operating loss carryforwards have been realized.

No federal tax provision has been provided for the years ended December 31, 2015, 2014 and 2013 due to the losses incurred during such periods. The Company's effective tax rate is different from the federal statutory rate of 34% due primarily to operating losses that receive no tax benefit as a result of a valuation allowance recorded for such losses.

As of December 31, 2015, the Company had federal and state income tax net operating loss carryforwards, which may be applied to future taxable income, of approximately \$119.1 million and \$93.2 million, respectively. The federal net operating loss carryforwards will expire at various dates from 2023 through 2035. The state net operating loss carryforwards began to expire at various dates from 2015 through 2035. The Company also has a federal and state research and development tax credit carryforwards totaling approximately \$3,188,000 and \$3,353,000, respectively. The federal research and development tax credit carryforwards will expire at various dates from 2023 through 2035. The state research and development tax credit carryforwards do not expire.

Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company's net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within any three-year period since the last ownership change. The Company may have had a change in control under these Sections. However, the Company does not anticipate performing a complete analysis of the limitation on the annual use of the net operating loss and tax credit carryforwards until the time that it projects it will be able to utilize these tax attributes.

The Company files income tax returns in the U.S. federal jurisdiction and various states and is subject to income tax examinations by federal tax authorities for tax years ended 2012 and later and by state authorities for tax years ended 2011 and later. The Company currently is not under examination by any tax authority. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2015 and 2014, the Company has no accrued interest or penalties related to uncertain tax positions. Second Sight Switzerland, the Company's foreign subsidiary, has not had any taxable income in the prior and current years.

## 12. Product Warranties

A summary of activity in the Company's warranty liabilities, which are included in accrued expenses in the accompanying consolidated balance sheets, for the years ended December 31, 2015, 2014 and 2013 is presented below (in thousands):

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Balance, beginning of year	\$ 556	\$ 253	\$ 120
Additional accruals	991	415	139
Payments	(443)	(112)	(6)
Adjustments and other	(38)	—	—
Total	<u>\$ 1,066</u>	<u>\$ 556</u>	<u>\$ 253</u>

## 13. Commitments and Contingencies

### Lease Commitment

Effective August 2012, the Company entered into a lease agreement (the "Sylmar Lease") with a company owned by the major stockholder of the Company for office space for a term of five years that was initially set to expire on February 28, 2017. The Sylmar Lease included rental of additional space commencing January 1, 2013 and a five year option to renew. The lease requires the Company 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 Sylmar Lease was renegotiated with the term ending on February 28, 2022, and a five year option to renew. The new lease also requires the Company 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 Sylmar lease was sold to an unrelated party.

Second Sight Switzerland rents office space in Switzerland on a month-to-month basis for CHF 8,200 (approximately \$8,200, at December 31, 2015) per month.

Total rent expense was approximately \$954,000, \$1,007,000 and \$766,000 for the years ended December 31, 2015, 2014 and 2013, 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).

<b>Years</b>	<b>Amount</b>
2016	\$ 808
2017	833
2018	858
2019	884
2020	910
Thereafter	1,095
<b>Total</b>	<b>\$ 5,388</b>

### **License Agreements**

The Company has exclusive licensing agreements to utilize certain patents. These patents are related to the technology for visual prostheses. There are currently two such agreements that the Company has determined there is a reasonable likelihood of future royalty payments. The Company has agreed to pay the licensors' royalties for licensed products sold or leased by the Company. The royalty rates range from 0.5% to 3.25%, based on related net sales of the patented portion of licensed products, less a credit for royalties paid to others. The 3.25% rate reflects a .25% credit for royalties paid to others. Additional discounts may be possible if the Company enters into additional licenses.

One of the licensing agreements requires the Company to pay the licensors a \$5,000 annual maintenance fee for the first seven years and a \$10,000 annual maintenance fee each year thereafter for as long as the agreement has not been terminated by the Company. The second of these agreements has no stipulated fees. Pursuant to these agreements, the Company has incurred costs of approximately \$93,000, \$45,000 and \$28,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

### **Clinical Trial Agreements**

Based upon FDA approval, which was obtained in February 2013, the Company is required to collect follow-up data from subjects enrolled in its pre-approval trial for a period of up to ten years post-implant, which extends this trial through the year 2019. In addition, the Company is conducting three post-market studies to comply with US FDA, French, and European post-market surveillance regulations and requirements. The Company has 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, 2015, 2014 and 2013 were \$1,409,000, \$602,000 and \$481,000, respectively.

### **Litigation, Claims and Assessments**

Thirteen oppositions have been filed by a third-party in the European Patent Office, each challenging the validity of a European patent owned or exclusively licensed by the Company. The outcome of the challenges is not certain, however, if successful, they may affect the Company's ability to block competitors from utilizing its patented technology. Management of the Company does not believe a successful challenge will have a material effect on its ability to manufacture and sell its products, or otherwise have a material effect on its operations.

The Company is party to litigation arising in the ordinary course of business. It is management's opinion that the outcome of such matters will have not have a material effect on the Company's financial statements.

#### 14. Quarterly Financial Summary (unaudited)

(in thousands, except per share data)

	Quarters Ended			
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
Product sales	\$ 2,362	\$ 2,227	\$ 2,661	\$ 1,700
Gross profit	\$ 691	\$ 1,470	\$ 1,092	\$ 404
Operating loss	\$ (5,477)	\$ (4,662)	\$ (4,947)	\$ (4,961)
Net loss	\$ (5,474)	\$ (4,666)	\$ (4,922)	\$ (4,956)
Net loss per share – basic and diluted	\$ (0.15)	\$ (0.13)	\$ (0.14)	\$ (0.14)

	Quarters Ended			
	December 31, 2014(1)	September 30, 2014	June 30, 2014	March 31, 2014
Product sales	\$ 1,521	\$ 609	\$ 611	\$ 657
Gross profit (loss)	\$ 99	\$ 193	\$ (382)	\$ (70)
Operating loss	\$ (5,565)	\$ (5,649)	\$ (5,563)	\$ (4,456)
Net loss	\$ (13,577)	\$ (7,644)	\$ (7,541)	\$ (6,439)
Net loss per share – basic and diluted	\$ (0.46)	\$ (0.31)	\$ (0.32)	\$ (0.28)

(1) During the fourth quarter of 2014, the Company wrote-off the unamortized discount on convertible promissory notes of \$6,955 as a result of the automatic conversion of such notes into common stock upon the closing of the Company's IPO.

## EXHIBIT INDEX

Exhibit No.	Exhibit Description
1.1	Form of Underwriting Agreement. <sup>(1)</sup>
3.1	Restated Articles of Incorporation of the Registrant <sup>(1)</sup>
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect. <sup>(1)</sup>
4.1	Form of the Registrant's common stock certificate. <sup>(1)</sup>
4.2	Form of Underwriter's Warrant. <sup>(1)</sup>
10.1	Form of Indemnification Agreement between Registrant and each of its directors and officers. <sup>(1)+</sup>
10.2	2003 Equity Incentive Plan. <sup>(1)+</sup>
10.3	2003 Form of Employee Option Agreement. <sup>(1)+</sup>
10.4	2011 Equity Incentive Plan. <sup>(1)+</sup>
10.5	2011 Form of Employee Option Agreement. <sup>(1)+</sup>
10.6	2014 Option Issued to Robert Greenberg – Terms and Conditions. <sup>(1)+</sup>
10.7	2014 Executive Officer Option Agreement. <sup>(1)+</sup>
10.8	Form of Convertible Promissory Note. <sup>(1)</sup>
10.9	Form of Warrant, as amended. <sup>(1)</sup>
10.10	Standard Multi-Tenant Office Lease – Net, dated April 15, 2014, between Registrant and Mann Biomedical Park LLC. <sup>(1)</sup>
10.11	Exclusive License Agreement between Registrant and Johns Hopkins University and Duke University. <sup>(1)</sup>
10.12	Cost Reimbursement Consortium Research Agreement between Registrant and Doheny Eye Institute. <sup>(1)</sup>
10.13	Form of Lock Up Agreement. <sup>(1)</sup>
10.14	Shareholders' Agreement dated September 5, 2003. <sup>(1)</sup>
10.15	Offer Letter to Thomas Miller dated May 21, 2014. <sup>(1)+</sup>
10.16	Form of Loan Agreement dated September 30, 2014 between Mann Group LLC and Registrant for \$3,000,000, including form of promissory note as Exhibit A thereto. <sup>(1)</sup>
10.17	Joint Research and Development Agreement between Johns Hopkins University Applied Physics Laboratory and Registrant. <sup>(1)</sup>
10.18	Second Sight Medical Product, Inc. 2015 Employee Stock Purchase Plan <sup>(2)+</sup>
10.19	Executive Employment Agreement between Registrant and Will McGuire <sup>(3)+</sup>
21.1	List of subsidiaries of the Registrant <sup>(1)</sup>
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 registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 16, 2015.

(3) Incorporated by reference to registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 25, 2015.



**Certification of Principal Executive Officer Pursuant To  
Exchange Act Rules 13a-14(a) and 15d-14(a),  
As Adopted Pursuant To  
Section 302 of Sarbanes-Oxley Act of 2002**

I, Jonathan Will McGuire, 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 11, 2016

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

**Certification of Principal Financial Officer Pursuant To  
Exchange Act Rules 13a-14(a) and 15d-14(a),  
As Adopted Pursuant To  
Section 302 of Sarbanes-Oxley Act of 2002**

I, Thomas B. Miller, certify that:

1. I have reviewed this Annual Report on Form 10-Q 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 11, 2016

/s/ Thomas B. Miller  
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Thomas B. Miller  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**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 Thomas B. Miller, 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. Annual Report of the Company on Form 10-K (the "Report") for the fiscal year ended December 31, 2015, 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 at the dates and for periods indicated.

Date: March 11, 2016

/s/ Jonathan Will McGuire

Jonathan Will McGuire  
Chief Executive Officer  
*(Principal Executive Officer)*

/s/ Thomas B. Miller

Thomas B. Miller  
Chief Financial Officer  
*(Principal Financial and Accounting Officer)*