Invuity, Inc.
Form 10-K
March 25, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x 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

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-37417

Invuity, Inc.

(Exact name of Registrant as specified in its Charter)

| | |
|---|---|
| Delaware | 04-3803169 |
| (State or other jurisdiction of | (I.R.S. Employer |
| incorporation or organization) | Identification No.) |
| 444 De Haro Street | 94107 |

San Francisco, CA
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (415) 665-2100

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.001 Per Share; Common stock traded on the NASDAQ Stock Market

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 o NO x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES o NO x

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 x NO o

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 x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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. x

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 the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|---|---|---|---|
| Large accelerated filer | o | Accelerated filer | o |
| Non-accelerated filer | x (Do not check if a small reporting company) | Small reporting company | o |

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the NASDAQ Stock Market on March 22, 2016, was $79,741,646.

The number of shares of Registrant's Common Stock outstanding as of March 22, 2016 was 13,401,671.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to be held on May 19, 2016, are incorporated by reference into Part III of this Report.

Table of Contents

PART I

Some of the statements under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” and elsewhere in this Annual Report on Form 10-K are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company’s or our industry’s results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “focus,” “assume,” “goal,” “objective,” “will,” “may” “should,” “would,” “could,” “estimate,” “predict,” “potential,” “continue,” “enco negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in “Item 1A. Risk Factors” as well as those discussed elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

ITEM 1. BUSINESS.

Invuity, Inc. was incorporated in California in 2004 as Spotlight Surgical, Inc. We changed our name to Invuity, Inc. in 2007, and reincorporated in Delaware in May 2015. In June 2015, we closed an initial public offering (“IPO”) of 4,600,000 shares of our common stock at a public offering price of $12.00 per share, which includes 600,000 shares issued pursuant to the underwriters’ overallotment options, and received approximately $47.2 million in aggregate net proceeds, after underwriting discounts and commissions and offering costs incurred by the Company.

Overview of Our Company

We are a commercial-stage medical technology company pioneering the use of advanced photonics to provide surgeons with improved direct visualization of surgical cavities during minimally invasive and minimal access surgical procedures. We integrate our Intelligent Photonics technology platform into our single-use and reusable advanced surgical devices to address some of the critical intracavity illumination and visualization challenges facing surgeons today. We utilize this proprietary technology to develop optical waveguides that direct and shape thermally cool, brilliant light into broad, uniform and volumetric illumination of the surgical target. We believe that improving a surgeon’s ability to see critical anatomical structures can lead to better clinical and aesthetic outcomes, improved patient safety and reduced surgical time and healthcare costs. We sold our devices to approximately 530 hospitals in the fourth quarter of 2015, as compared to approximately 370 hospitals in the same quarter of 2014. Based on the number of single-use units we have shipped as of December 31, 2015, we estimate that our devices have been used in approximately 145,000 surgical procedures. We are also using our advanced photonics technology to develop new devices and modalities to broaden the application and adoption of open minimally invasive and minimal access procedures and enable new advanced surgical techniques.

Photonics is the science and technological applications of light. We have applied advanced principles of photonics to develop our Intelligent Photonics technology platform, which enables the transmission, management and manipulation of light in surgical procedures. Our initial application of this technology is integrated into our family of proprietary optical waveguides. Our waveguides are sophisticated devices that rely on the principles of optics to shape and direct light. They are coupled to a modified fiber optic cable and are designed to work with the standard xenon or LED light sources typically found and utilized in the operating room. Our optical waveguides are incorporated into surgical devices, including our customized line of illuminated surgical retractors, handheld illuminated aspiration devices and drop-in intracavity illuminators. Our handheld illuminated aspiration devices and drop-in intracavity illuminator are single-use products. Our retractors are reusable, but utilize a single-use optical waveguide with each procedure.

The fundamental attributes of our optical waveguides include a solid core optical-grade polymer, total internal reflection of light waves, light mixing and extraction by a complex geometry of refractive microstructures or microlenses. The solid core optical-grade polymer waveguide is coupled to a fiber optic cable in order to facilitate the efficient transfer of light. This unique coupling results in our waveguides capturing maximum light with minimal heat build-up. Our waveguides use critical angles and the properties of total internal reflection to retain and transmit maximum light as it travels through the device. In addition, each waveguide utilizes various novel optical methods to mix light during the total internal reflection transmission process to enable more uniform light extraction across its output surface. The output surface consists of a complex geometry of refractive microstructures or microlenses that extract, direct and shape volumetric illumination into the surgical cavity while virtually eliminating shadows and glare. This complex geometric structure extracts and directs light at numerous different angles to enable illumination of the surgical target, even if blood or debris accumulates on the surface of the waveguide. The uniform distribution of light extraction from the microstructures or microlenses throughout the entire output surface of the waveguide, as well as the proprietary solid core optical-grade polymer and patented design of our waveguides, results in thermally cool illumination.

Advances in medical technology have resulted in growing adoption of minimally invasive and minimal access surgical procedures. Minimally invasive surgery refers to surgeries performed through one or more small incisions, which offer several benefits over traditional invasive open surgery, such as fewer surgical target complications and infections, overall reduced trauma to the anatomy, less bleeding, shorter hospitalization time, less postoperative pain, faster recovery time and improved aesthetic outcomes. Some minimally invasive procedures, such as endoscopic, laparoscopic and arthroscopic procedures, use small tubes, tiny cameras and surgical instruments to access, visualize and perform the surgery. Other procedures also use smaller incisions than conventional open surgery, but still provide the surgeon with direct visualization of the surgical target and the ability to use traditional surgical instruments. We refer to these procedures as open minimally invasive and minimal access procedures. We estimate that approximately 40% of all surgical procedures in the United States are open minimally invasive and minimal access, and, based on the benefits of these procedures over conventional open surgery, we believe this percentage will continue to grow. We have initially targeted our sales and marketing efforts to surgeons in the following specialties: orthopedics, spine, breast, plastics, and thyroid. However, our current illuminated surgical devices have a broader indication for use and can be marketed to other specialties with limited or no additional regulatory clearance. We intend to target other surgical specialties including gynecology; colorectal; general surgery; trauma; cardiothoracic; neurosurgery and craniomaxilliofacial procedures. We currently estimate the annual total addressable market for our devices in these surgical specialties in the United States to be approximately $2.0 billion, based on the estimate of our average revenue per procedure.

In the last several years, we have transitioned from a focus on research and development to the commercialization of our device portfolio. As of December 31, 2015, we market nine families of illuminated surgical devices, consisting of over 40 devices. Our goal is to be the global leader in providing advanced photonics systems to surgeons across a broad array of surgical specialties, improving surgical precision and efficiency while improving patient safety. We market and sell our devices in the United States primarily through a direct sales force, which has grown from 39 as of December 31, 2014, to 59 as of December 31, 2015. We have plans to increase sales by further expanding this commercial organization. We believe this expansion will allow us to further penetrate and grow our market by demonstrating the benefits of our devices to additional surgeons, surgical specialties, and hospitals and expect to expand sales to Europe and other regions, both directly and through distributors.

Our Market Opportunity

Advances in medical technology have resulted in growing adoption of minimally invasive and minimal access surgical procedures. The increased utilization of these procedures by surgeons is primarily driven by their significant benefits compared to conventional open surgery including:

- smaller incisions resulting in less scarring and fewer complications;
- less trauma to the organs, muscles, nerves, and tissue;
- less bleeding and reduced need for blood transfusions;
- fewer surgical infections;
- shortened hospital stays, potentially reducing hospital costs;
- less postoperative pain and reduced need for associated narcotics;
- faster recovery time; and
- improved aesthetic outcomes.

Though some minimally invasive procedures, such as endoscopic, laparoscopic and arthroscopic procedures, have several of the benefits described above, surgeons are only able to view the surgical target through a tiny camera, which can cause reduced depth perception and field of vision, diminished hand-eye coordination, limited mobility of the surgical instruments, and reduced tactile feedback. These limitations can increase the cognitive and physical load on the surgeon and, consequently, increase the possibility of surgical error. We believe that open minimally invasive and minimal access procedures provide many of the benefits described above. However, the small incisions used in these procedures inherently reduce a surgeon’s ability to directly see the surgical target, particularly deep within the surgical cavity, which can impact surgical precision, procedural efficiency and patient safety.

Traditional Illumination Devices and Their Limitations

Lighting is a critical element of every open surgical procedure. Traditional surgical lighting options in the operating room include overhead lighting systems, surgical headlights and on-field fiber optic lighting systems. Our management is aware of various publications, some of which are several years old that identify limitations of these devices. The most common illumination method in the operating room setting today is overhead lighting systems. When used in open minimally invasive and minimal access procedures, overhead lighting systems can present numerous challenges. It can be difficult to maintain the required direct path of illumination

given changes of patient and surgeon positioning. Adjustments to the lighting position may be required which may inconvenience the surgeon, disrupt the surgical flow, increase operating procedure time, and increase risk of contamination given that overhead lighting systems are not sterile. Moreover, overhead lighting systems may be inadequate for surgery in deeper cavities due to the creation of shadows and the inability of the light to reach the depth of the incision.

Surgical headlights overcome some of the shortcomings of overhead lighting systems by bringing the light source closer to the surgical cavity, eliminating shadows caused by the surgeons head, and reducing the need to adjust the overhead lighting system. Despite these benefits, we believe headlights still present limitations. Use of headlights can cause head, neck and shoulder fatigue from the prolonged improper posture during their use. Because the source of light is still above the surgical cavity, we believe the use of headlights can create shadows and glare caused by hands, instruments and anatomy, which may limit visualization in deep surgical cavities. Headlights can also generate considerable amounts of heat during use, which can further limit comfort and can cause burns if an operator accidently mishandles the device.

Due to the limitations of overhead lighting systems and surgical headlights, on-field fiber optic lighting systems have been developed in an effort to provide intracavity lighting of the surgical field. On-field fiber optic lighting systems consist of a fiber optic cable attached to a fiber optic retractor. While traditional on-field fiber optic lighting systems can be effective at bringing the light source closer to the surgical field, we believe they also have inherent limitations and risks. Traditional on-field fiber optic lighting systems represent a thermal hazard in the operating room, creating the risk of burns to patients, surgeons and hospital staff, and operating room fires. The light generated by the xenon or LED light source is extremely powerful and can create temperatures exceeding 100°C. Thermal heat builds up whenever light is obstructed. We believe another limitation of traditional on-field fiber optic lighting systems is the potential for hot spots and glare. The general light output shape emanating from a fiber optic cable that resembles a cone and is circular, with a common center around the mechanical axis of the fiber bundle. Since this bright, narrow outlet of light exits the fiber in a straight line in the direction and orientation of the fiber, the light may be reflected back in the same direction, and can create glare in the line of vision of the surgeon. In an attempt to minimize this glare, the surgeon may be required to constantly reposition the fiber optic retractor during the procedure.

Market Need for Advanced Intracavity Illumination and Visualization Devices

Given the limitations of traditional surgical lighting options in the operating room, we believe there is a significant opportunity to enhance intracavity illumination and visualization during open minimally invasive and minimal access procedures. In addition, we believe that an advanced illumination and visualization technology could broaden the application and adoption of less invasive surgical techniques.

Our Solution

We utilize our Intelligent Photonics technology platform to develop surgical devices designed to overcome the significant limitations of traditional surgical lighting options in the operating room. Based on surgeon feedback, surgeon observation and bench testing, we believe our technology may provide the following benefits:

- Enhanced illumination and visualization of the surgical field. Our devices are designed to provide enhanced intracavity illumination and visualization of the surgical field during open minimally invasive and minimal access surgeries. The proprietary complex geometry of refractive microstructures or microlenses along the surface of our optical waveguides allow for the extraction of light in a manner that distributes light at different angles in a broad, uniform and volumetric pattern that is intended to reduce shadows, glare and excessive heat that are commonly associated with traditional surgical lighting options. In bench testing comparing light distribution and thermal profile of our Eikon retractor to a traditional fiber optic retractor, we found our Eikon retractor system had approximately five times the illumination area with a thermal profile that is below the risk of burn.

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Improved surgical precision during open minimally invasive and minimal access procedures. Our technology is designed to improve intracavity visualization to allow surgeons to identify, differentiate and avoid vital anatomical structures. We believe this enables surgeons to dissect with great precision, while also allowing them to differentiate tissue planes, identify and avoid nerves and blood vessels, and quickly locate and control bleeding vessels to achieve rapid hemostasis. With this precise visualization, we believe surgeons may be able to use smaller, and in some cases fewer, incisions.

- Reduced risks to patients and surgeons. Our technology is developed with design elements to help create thermally cool illumination as well as ergonomics to improve ease of use while performing a procedure. Our advanced surgical devices incorporate a solid core optical-grade polymer that facilitates efficient coupling to the surgical instrument to offer significantly improved light transfer while concurrently reducing heat transfer. We believe this is an important advancement over traditional on-field fiber optic lighting systems that do not efficiently transfer light through the fiber-to-fiber coupling, resulting in the generation of excess heat, which can increase the risk of burn to patients and surgical staff and create the potential for operating room fires. In addition, by improving visualization, our devices may also decrease risk of unintended retained foreign objects by improving the surgeon's ability to see and dispose of such objects that might have otherwise been left in the surgical cavity inadvertently. Finally, by being directly incorporated into a variety of illuminated surgical retractors, handheld illuminated aspiration devices, and drop-in intracavity illuminators, we believe our technology may help to decrease surgeon fatigue by reducing or eliminating the need for surgical headlights, thereby helping to reduce some of the associated head, neck and shoulder fatigue, frequent headaches, neck pain and injury to the cervical spine. In addition, our non-conductive Eikon LT retractors virtually eliminate the potential for burns due to arcing from electrosurgical devices coming in contact with traditional stainless steel retractors.
    - Enhanced operating room efficiency. We believe our technology improves operating room workflow by reducing the need for perioperative repositioning of traditional surgical lighting options. Overhead lighting systems and headlights require frequent readjustment, which may interrupt operating room workflow and extend surgical procedure time. Many open minimally invasive and minimal access procedures are time sensitive and the treatment area requires constant attention of the surgeon and operating team. Because our optical waveguides are directly connected to the surgical instrument that is used to access the deep surgical cavity, surgeons are able to clearly illuminate the surgical target and effectively focus on performing the procedure. As an example, in a survey we conducted with 12 surgeons that use our devices, each of whom is considered a leading breast surgeon, 11 of these surgeons reported that procedure time during nipple-sparing mastectomy procedures when using our devices was reduced by an average of 24%.
- Economic value proposition to healthcare systems. We believe our devices have the potential to substantially reduce procedure costs as well as create incremental revenue opportunities. We believe the improved efficiency of the operating room workflow and the related reduced procedure and anesthesia time can translate to meaningful cost savings for the hospital. In addition, we believe the reduction in procedure times also creates additional capacity in the operating room for surgeons to perform more procedures, which we believe can create incremental revenue for the hospital.

Our Intelligent Photonics Technology

Photonics is the science and technical application of light. We have applied advanced principles of photonics to develop our Intelligent Photonics technology platform, which enables the transmission, management and manipulation of light in surgical procedures. Our initial application of this technology is our family of proprietary optical waveguides. The fundamental attributes of our optical waveguides include a solid core optical-grade polymer, total internal reflection of light waves, light mixing and extraction by a complex geometry of refractive microstructures or microlenses.

Fundamental Attributes of Our Optical Waveguides

Solid Core Optical-Grade Polymer

Our optical waveguides are fabricated from a proprietary solid core optical-grade polymer, specifically selected for its key optical and mechanical characteristics, which enable the efficient transmission and management of light. These optical characteristics include the ability to mold the material into various complex geometries, which is of particular importance when molding ultra-precise structures. Certain mechanical properties of the polymer, such as structural integrity, hydrophobicity and thermal stability, are critical to its use during surgical procedures. In addition, our solid core design facilitates the coupling of the waveguide to the modified fiber optic cable in order to allow the efficient transfer of light into the solid core waveguide, while remaining thermally cool. All these characteristics are critical in order for the waveguide to function as an advanced illuminated surgical device.

Total Internal Reflection of Light Waves

One of the key aspects of the optical waveguide technology is the ability to transmit light in a highly efficient manner prior to its extraction. Light travels in waves. As a wave travels through a medium it will reach a boundary where there is a different medium on the other side of the boundary. At the point where the wave meets the boundary, three phenomena can occur: reflection, refraction or some combination of both. Reflection occurs when light bounces off the boundary and refraction occurs when waves pass through a boundary and change direction. The angle at which the wave hits the boundary is referred to as the angle of incidence. That angle is usually referenced to the line that is perpendicular to the boundary. A zero incidence angle means that the wave is traveling perpendicular to the boundary. At that angle most of the light will pass most of its energy through the boundary and will not refract as long as the index of refraction is less on the other side of the boundary than in the medium the light is traveling. As the angle of incidence increases, the wave will get split into two components: one portion will pass the boundary and refract and the other portion will reflect back into the medium in which the wave was originally traveling. As the angle increases, the amount of refraction will decrease and reflection will increase. The smallest angle where the light is completely reflected and not refracted is called the critical angle. At any angle of incidence greater than the critical angle, all of the light is reflected off the boundary with no refraction. This is referred to as total internal reflection. We designed the structural and material properties of our devices to maximize locations of total internal reflection as the light propagates along the central axis of the waveguide.

Light Mixing

Our optical waveguides utilize various novel optical methods to mix light, or randomize its reflections, during the total internal reflection transmission process. The design and shape of the optical stem, or area of the waveguide that is between the input of the waveguide and the array of refractive microstructures or microlenses, enhance the mixing of light waves, while maintaining total internal reflection. Our optical waveguides utilize light mixing before extraction to significantly reduce glare and bright spots, leading to a more uniform illumination profile across the surgical target while remaining thermally cool.

Complex Geometry of Refractive Microstructures and Microlenses

We designed a proprietary complex geometry of refractive microstructures and microlenses that are placed on the surface of the optical waveguide to extract light from the device in a manner that distributes light over the surgical target. This distribution of light from the waveguide also reduces the energy density in the device, thus reducing heat. Without the microstructures to extract the light uniformly on the surgical target, the waveguide would dissipate an energy density across its surface that is in excess of the amount that

5

the tissue could absorb without causing thermal injury. The surface of the waveguide contains a complex geometry of zones with corresponding refractive microstructures or microlenses at varying angles. These extraction zones allow the waveguide to direct the extracted light onto the surgical target and shape it into a broad, uniform and volumetric pattern. The ability to direct light is especially important when the waveguide is mounted on surgical retractors, because our device is able to push the light away from the retractor, thus maintaining its efficiency on the surgical target. We believe this is a significant advantage over traditional on-field fiber optic lighting systems, which lack the microstructures to direct light and instead direct light in a straight line in the shape of a cone from the end of the fiber. As a result, a portion of the illumination is obstructed and absorbed by the surgical retractors when the fiber is adjacent to the surgical instrument. The ability to shape light is also critical, as it reduces the focal intensity of light. With traditional fiber optic retractors, light is directed in a narrow beam, with intensity at a maximum in the center of the spot of light, and dropping off exponentially toward the edges. As a result, it typically does not illuminate the entire surgical cavity and heat builds up significantly in that focal zone. In contrast, our waveguides broaden this intensity of distribution, which allows the pattern of light to have uniform brightness across the surface of the surgical target, while minimizing the thermal profile.

Our waveguides are also designed to extract light from multiple zones, allowing the surgical target to be illuminated from various angles. As light is extracted across the waveguide at numerous different points along the surface at slightly different angles, if any of the features on the surface become blocked by an instrument, blood or tissue, there are multiple other microstructures from which light is extracted to provide illumination. This proprietary complex geometry also provides off-axis illumination on the surgical target, meaning that the light originates from a different angle than in direct orientation to the waveguide. As such, when light reflects off the tissue of the surgical target, instead of reflecting upwards towards the surgeon, the light is generally reflected onto the surface opposite the retractor. This feature of the waveguide is important because it allows the surgeon and operating staff much better visual perception of the surgical target with less shadows and glare.

Our Products

Our advanced photonics technology has allowed us to design multiple variations of our waveguides in order to target different illumination patterns for different shapes of surgical cavities. Because we can mold our solid core optical-grade polymer into different shapes, we are able to design waveguides that either direct the light narrowly for deep cavities, or broadly for larger blade cavities. Our waveguides also come in narrow or wide configurations to accommodate various retractor widths that are designed for varying patient anatomies. Our versatile design and manufacturing capabilities allow us to develop waveguides with a variety of extraction patterns. For example, our current retractor based waveguides utilize a complex geometry of refractive microstructures and microlenses, whereas as our handheld illuminated aspiration devices have integrated microlens arrays. Using advanced ray-trace software modeling programs, we are able to perform three-dimensional optical performance modeling of our waveguides, as well as an entire assembly including the retractor. We are capable of analyzing the entire optical performance of the assembly as we monitor various characteristics such as extracted light direction, uniformity on the target, glare to the user, as well as thermal profile. This ray-trace modeling process helps us develop illuminated surgical devices that are designed to provide optimal intracavity illumination.

We currently market nine families of illuminated surgical devices, consisting of over 40 devices. Our advanced photonics technology is integrated into each of these device families. Our device portfolio includes reusable illuminated surgical retractors that include a single-use waveguide, single-use handheld illuminated aspiration devices and single-use drop-in intracavity illuminators. Our optical waveguides are integrated into these customized devices to deliver improved visualization of the surgical cavity without generating excessive heat. Our accessories include sterilization trays and light cables.

| Product Family | Image | Description | Surgical Specialties |
|---|---|---|---|
| Eikon Illuminated Retractor System | | Illuminated surgical retractor with a low-profile design. Lightweight, radiolucent, anodized aluminum retractors provide electrical insulation from electrosurgical device preventing inadvertent thermal damage. Atraumatic and elevated tip for easy maneuverability, dissection and retraction. Available in multiple blade sizes for varying patient anatomies and surgeon preferences. | Breast Oncology / Oncoplastic Surgery / General Surgery / Orthopedics |
| Eikon LT Illuminated Retractor System | | Illuminated surgical retractor with a low-profile design. Lightweight, radiolucent, non-conductive retractors provide electrical insulation from electrosurgical device preventing inadvertent thermal damage. Atraumatic and elevated tip for easy maneuverability, dissection and retraction. Available in multiple blade sizes, with or without teeth, for varying patient anatomies, surgeon preferences, and surgical specialties. | Breast Oncology / Oncoplastic Surgery / General Surgery / Orthopedics |
| Saber Yankauer | | Handheld illuminator incorporated in a traditional Yankauer aspiration platform. Provides on-field illumination, aspiration, smoke evacuation, soft tissue retraction and blunt dissection in one device. Low-profile design enables surgeons to work efficiently in deep, dark cavities through smaller incisions. Available in multiple tip configurations (bulb, fin, taper and metal) for various surgical needs and in an optional pistol grip handle for improved ergonomics and visualization. | Orthopedic / Spine / Cardiothoracic / Breast / General Surgery |
| Saber Frazier | | Handheld illuminator incorporated in a traditional Frazier aspiration platform. Provides on-field illumination, aspiration, smoke evacuation, and soft tissue retraction in one device. Low-profile design enables surgeons to work efficiently in deep, dark cavities through smaller incisions. | Spine / Orthopedic / Neurosurgery |

| Product Family | Image | Description | Surgical Specialties |
|---|---|---|---|
| Eika Illuminated Retractor System | | Illuminated surgical retractor with a low-profile design. Self-retracting handle design enables either hands-free or manual retraction. Includes a handle slot for ideal cable management and placement. Available in multiple blade sizes for varying patient anatomies and surgeon preferences. Designed for anterior neck approaches, including thyroid and cervical spine surgeries. | Endocrine / Spine / Orthopedics |
| Breiten Illuminated Retractor System | | Illuminated surgical retractor with a low-profile design. Radiolucent to enable visibility during fluoroscopy. Color-coded for easy identification. Provides an offset hub for blade positioning. Available in multiple blade sizes and blade tips for varying patient anatomies and surgeon preferences. | Spine |
| Eipex Illuminated Retractor System | | Illuminated surgical retractor. Curved handle design enables either hands-free or manual retraction. Blade tip facilitates facet landing for added stability. Multiple cable management features for ideal cable placement. | Spine / Orthopedic |
| Eivector Illuminated Retractor System | | Illuminated surgical retractor with a low-profile design. Lightweight, radiolucent, anodized aluminum retractors provide electrical insulation from electrosurgical devices preventing inadvertent thermal damage. Attachable extension for added leverage in varying patient anatomies. Available in multiple blade sizes for varying patient anatomies and surgeon preferences. | Orthopedic |
| Eiberg Illuminated Retractor System | | Illuminated hohmann-style retractor with a low-profile design. Made of stainless steel, with an ergonomic design to be comfortable to hold. Designed with subtle curvatures and smooth edges to provide atraumatic, secure retraction. | Orthopedic |
| Waveguide XT System | | Drop-in intracavity illuminator with a low-profile design. Anchors to the incision wall providing a stand-alone, hands-free device. Minimal profile design is compatible with existing retractors and instrumentation and accommodates preferred surgical exposure techniques. | Spine |

Selected Surgical Applications

Our commercial strategy is initially focused on targeting open minimally invasive and minimal access procedures where there is a significant need for improved illumination and direct visualization. These procedures span a broad spectrum of surgical specialties including breast, orthopedic, spine, thyroid, plastic and general surgery. We believe our technology has enabled surgeons to perform procedures that were previously difficult to perform due to visualization and illumination challenges. The selected procedures discussed below illustrate some of the benefits of our technology.

Breast: Nipple Sparing Mastectomy

Surgical management of breast cancer has evolved dramatically over the past several decades. Surgeons have continuously looked for ways to improve oncologic outcomes while combining the techniques of oncoplastic surgery to maximize both the treatment of cancer and the aesthetic outcome with the optimal goal of preserving the nipple areola complex. Skin and nipple preservation during breast cancer surgery is essential to attain ideal aesthetic results.

A nipple sparing mastectomy, or NSM, is a procedure in which the cancerous breast tissue is removed but the breast skin and nipple are left intact. We believe the relatively limited adoption to date of the NSM procedure is attributed to a number of surgical limitations. Some of these limitations include limited access and visualization through smaller and distant incision location, and difficulty in maintaining consistent breast flap thickness and viability. We believe our advanced photonics technology can facilitate a surgeon's ability to:

- use a single infra-mammary fold incision in NSM to access and visualize deep into the surgical cavity;
- access and visualize the lymphatic tree without a second axillary incision in most cases; and
- assess the breast flap thickness and viability via trans-illumination.

Orthopedics: Total Hip Arthroplasty including the Anterior Approach

The growth of minimally invasive surgery in orthopedics has been dramatic worldwide, as clinical results indicate that patients who undergo these procedures typically experience improved clinical outcomes, shorter hospital stays, faster rehabilitation and improved aesthetic outcomes. Our technology has been used in a range of procedures including, among others, hip arthroplasty, within which the use of our technology has enabled a less invasive approach.

Traditional hip replacement, also known as hip arthroplasty, involves operating from the side or the back of the hip, which can create a significant disturbance of the muscles and tendons and an incision approximately 8 to 12 inches long. In comparison, the direct frontal, or anterior, approach requires an incision that is only 3 to 4 inches long and located at the front of the hip. In this position, the surgeon does not need to detach any of the muscles or tendons, but rather can move them aside along their natural tissue planes. This approach often results in faster recovery, less pain and more normal function after hip replacement. In addition, there is a lower risk of dislocating the new prosthesis when placed via the anterior approach, as the strength and integrity of the adjacent tendons and muscles surrounding the hip are maintained.

To date, we believe the less invasive anterior approach has been underutilized due, in part, to the visualization challenges associated with the procedure. More specifically, because the acetabulum and femoral canal are difficult to visualize using this approach, component positioning, sizing, and stability are more likely to be compromised, all of which are critical factors to yielding a successful and durable clinical outcome.

We believe the visualization provided by our devices can facilitate the surgeon's ability to:

- expose, prepare and seat the acetabular shell and liner within the acetabulum;
- place the acetabular screw;
- evaluate stability and impingement of the ball against the socket;
- prepare and mobilize the femur; and
- internally inspect the femoral canal.

Additional Applications

Our existing portfolio of devices is also eligible for use in, and could potentially improve the viability of, a multitude of additional surgical procedures. Importantly, our devices could be marketed and sold for a broad spectrum of surgical specialties without the need for any additional regulatory clearance. We believe our technology could help address the illumination and visualization challenges associated with various general surgery procedures, including appendectomy and herniorrhaphy; hysterectomy and other erological, gynecological and colorectal procedures;

thyroidectomy and parathyroidectomy and other ear, nose and throat procedures; cardiac, cardiothoracic and cardiovascular procedures; cranialmaxillofacial procedures and aesthetic plastic surgery.

We also continue to research and develop new devices, as well as pursue new clinical applications.

Sales and Marketing

We began selling our first FDA-cleared waveguide-based device in March 2009. As a result, we have limited experience marketing and selling our devices. We currently sell our devices through our direct sales representatives only in the United States. Our direct salesforce works with independent sales agents who assist us in educating targeted surgeons. While we primarily sell directly to hospitals, surgeons typically drive the purchasing decision. We sold our devices to approximately 530 hospitals in the fourth quarter of 2015. As of December 31, 2015, we had a sales and marketing team of 88 employees. Our sales team consisted of a Vice President of Sales, an Area Vice President, four Directors of Strategic Accounts and Business Development, six regional sales directors, two key account managers, a sales analyst, 59 direct sales representatives and 40 independent sales agents or agencies, whom we refer to as independent sales agents, all of whom had significant sales experience before joining our sales team. Additionally, we have eight marketing and six customer service employees. Over the past two years, we have significantly expanded our direct sales representatives to a total of 59 representatives at December 31, 2015. We plan to continue to expand our direct sales organization in the United States to help facilitate further adoption among existing hospital accounts, as well as to broaden awareness of our advanced photonics technology to new hospitals. Using our expanded direct sales force, we intend to continue to educate and train surgeons on the advantages of our advanced photonics technology compared to traditional operating room lighting options. We believe the benefits of our technology should also enable the broader application and adoption of open minimally invasive and minimal access surgical procedures by more surgeons. Our operating results are directly dependent upon the sales and marketing efforts of our employees.

Our marketing efforts are focused on developing a strong reputation with major teaching institutions and hospitals, as well as surgeons that we have identified as key opinion leaders based on their knowledge of our devices, clinical expertise and reputation. We developed the Invuity Hidden Scar™ Surgery program to train and certify surgeons on minimally invasive and minimal access surgical approaches and designate Centers of Excellence in Hidden Scar Surgery at hospitals and medical centers. Breast cancer surgery is our initial focus with the Hidden Scar Surgery program and we expect to expand into other specialties. We also use clinical education programs of several surgical system manufacturers, giving surgeons first-hand experience of the benefits of our devices.

We also sell and market to third-party medical device manufacturers. The majority of these sales have been to Zimmer Biomet, Inc. as part of its spinal implant surgical systems. Sales to Zimmer Biomet, Inc. or its predecessor in interest, Lanx, Inc., accounted for approximately 7%, 12%, and 12% of our total revenue in 2015, 2014, and 2013, respectively. In addition, sales to Medtronic, Inc. accounted for approximately 13% of our total revenue in 2013. There were no sales to any customer in excess of 10% of our total revenue for the fiscal year ended December 31, 2015.

Coverage and Reimbursement

Payment for patient care in the United States is generally made by third-party payors, including private insurers and government insurance programs. The reimbursement to the facility from third-party payors is intended to cover the overall cost of treatment, including the cost of our devices used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. We do not directly bill any third-party payors; instead, we receive payment from the hospital or surgical center for our devices. Failure by physicians, hospitals, ambulatory surgery centers and other users of our devices to obtain sufficient coverage and reimbursement from healthcare payors for procedures in which our devices are used, or adverse changes in government and private third-party payors' policies could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

In addition, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our devices

are used. Because the cost of our devices generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our devices. An example of such payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula. In the past, with respect to reimbursement for physician services under the Medicare Physician Fee Schedule, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions.

Any changes in coverage and reimbursement that lowers reimbursement for procedures using our devices could materially affect our business.

Competition

The medical device industry is highly competitive. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and devices for surgical illumination and visualization. We face significant competition from competitors that are based in the United States and internationally in the surgical illumination and visualization market, and we expect the intensity of competition will increase over time. Surgeons and hospitals typically use traditional overhead lighting, headlights and

fiber optic lighting products, and if we cannot convince surgeons and hospitals of the benefits of using our devices in addition to, or as an alternative to, traditional overhead lighting and headlights, or, of the benefits of using our devices instead of using competing fiber optic lighting products, our business may be harmed. Some of our main competitors are Lumitex, Inc., Scintillant (Engineered Medical Solutions Co. LLC), Stryker Corporation, TeDan Surgical Innovations, LLC, and Black & Black Surgical, Inc. and other general surgical instrument companies that supply traditional fiber optic retractors. Many of the companies developing or marketing competing products enjoy several competitive advantages, including:

- more established sales and marketing programs and distribution networks;
- long established relationships with surgeons and hospitals;
- contractual relationships with customers;
- products that have already received approval from the relevant VACs;
- greater financial and human resources for product development, sales and marketing;
- greater name recognition;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Any device we develop must compete for market acceptance and market share. We believe that the primary competitive factors in the surgical illumination and visualization market segment are clinical safety and effectiveness, price, surgeon experience and comfort with use of particular illumination systems, reliability and durability, ease of use, device support and service, sales force experience and relationships. Our success in selling our devices to hospitals is dependent on our ability to demonstrate that the clinical, qualitative and economic value delivered by our products outweighs their increase to the cost per procedure. Our ability to compete on price depends on our ability to demonstrate to surgeons, hospitals and surgery centers that the potential benefits of improved clinical outcomes and reduced procedure costs from the increased efficiency in the operating room workflow and related reduced procedure and anesthesia time using our medical devices outweigh the price of our devices compared to our competitors' products.

Intellectual Property

In order to remain competitive, we must protect the proprietary technology that we believe is important to our business, including seeking and, if granted, maintaining patents intended to cover our products and inventions that are commercially important to the development of our business. We also rely on trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights.

It is our policy to require our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using the proprietary rights of third parties in their work for us. We also require confidentiality agreements from third parties that receive our confidential data or materials.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. For more information, please see "Risk Factors—Risks Related to Our Intellectual Property."

As of December 31, 2015, we held 34 issued U.S. patents and had 40 U.S. utility patent applications and 9 Patent Cooperation Treaty (PCT) applications pending. As of December 31, 2015, we also had two issued patents from the Japan Patent Office, three issued patents from the Chinese patent office, and five patents from the European Patent Office which have effect in one or more of Germany, France, Great Britain and Italy. As of December 31, 2015, we

had 38 pending patent applications outside of the United States, including Europe, Japan, Korea, China, Australia and Canada. As we continue to research and develop our Intelligent Photonics technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and clinical uses of our illuminated devices and other products. Our issued patents expire between the years 2026 and 2035. Our pending patent applications and issued patents include claims directed to coupling of an illumination device with a light source or an instrument, as well as efficient and safe transmission of light through the illumination device.

As of December 31, 2015, we held one United States trademark registration, one United States trademark application, sixteen foreign trademark registrations, two foreign trademark applications and two international trademark registration, one of which is designated in two countries/regions and one of which is designated in eight countries/regions.

Manufacturing, Raw Materials and Quality Assurance

Our manufacturing involves the combined utilization of our internal manufacturing resources and expertise, approved suppliers and contract manufacturers. Our internal manufacturing activities, located in San Francisco, California, include the inspection, assembly and packaging of the waveguides, retractor systems, aspiration devices and accessories associated with each of our device families. We outsource the manufacture of components, subassemblies and certain finished devices that are produced to our specifications and shipped to our facilities for final assembly or inspection, and certification. Finished products are stored at and distributed from our facility. Quality control, risk management, efficiency and the ability to respond quickly to changing requirements are the primary goals of our manufacturing operations.

We have arrangements with our suppliers that allow us to adjust the delivery quantities of components, subassemblies and finished products, as well as delivery schedules, to match our changing requirements. The forecasts we use are based on historical trends, current utilization patterns and sales forecasts of future demand. Lead times for components, subassemblies and finished products may vary significantly depending on the size of the order, specific supplier requirements and current market demand for the components and subassemblies. Most of our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, the components used in our devices.

We obtain the optical polymer used in the manufacture of our waveguides and certain accessories from single suppliers, for which we attempt to mitigate risks through inventory management and purchase order commitments. While we believe alternate sources exist for the optical polymer, we have not qualified an alternate provider. Other products and components come from single suppliers, but alternate suppliers have been qualified or, we believe, can be readily identified and qualified. In addition, we rely on a single provider for sterilization of our devices that require sterilization. While we believe replacement suppliers exist for all components, materials and services we obtain from single sources, establishing additional or replacement suppliers for any of these components, materials or services, if required, may not be accomplished quickly. Even if we are able to find a replacement supplier, the replacement supplier may need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source components and materials used in our products, in the event of disruption, those inventories may not be sufficient. To date, we have not experienced material delays in obtaining any of our components, subassemblies or finished products, nor has the ready supply of finished products to our customers been adversely affected. To date, we have not experienced any material delays by our sterilization provider and will continue to evaluate the cost and benefit of qualifying a second sterilization provider.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on our business.

We have implemented a quality management system designed to comply with FDA regulations and International Standards Organization (“ISO”) standards governing medical device products. These regulations govern the design, manufacture, testing and release of diagnostic products as well as raw material receipt and control. We have received ISO 13485 certification as well as an EC Certificate under Directive 93/42/EEC on Medical Devices, Annex II, excluding section 4. Our key outsourcing partners are ISO-certified.

We use small quantities of common cleaning products in our manufacturing operations, which are lawfully disposed of through a normal waste management program. We do not forecast any material costs due to compliance with environmental laws or regulations.

Segment Reporting

We manage our operations as a single operating segment for the purposes of assessing performance and making operating decisions. All of our assets are maintained in the United States. We derive our revenue from sales to customers in the United States, based upon the billing address of the customer.

Government Regulation

Our products are medical devices and are therefore subject to extensive regulation by the FDA under the authority of the Federal Food, Drug and Cosmetic Act ("FDCA") and the regulations promulgated thereunder, as well as by corresponding state and international regulatory authorities. The regulations govern the following activities that we and our suppliers, licensors and partners engage in:

- product design and development;
- pre-clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- labeling and storage;
- pre-market clearance or approval; advertising and promotion;
- product sales and distribution;
- recalls and field safety corrective actions; and
- servicing and post-market surveillance.

Regulatory Clearances and Approvals. Unless an exemption applies, each medical device that we wish to commercially distribute in the United States will require either prior 510(k) clearance or PMA approval from the FDA. The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose low or moderate risk are placed in Classes I or II, which, unless subject to an exemption, requires the manufacturer to submit to FDA a 510(k) premarket notification requesting clearance for commercial distribution. Exempt Class I and II devices do not require submission of a 510(k) but are otherwise subject to general controls such as labeling, pre-market notification and adherence to the FDA's Quality System Regulation, or QSR, which cover manufacturers' methods and documentation of the design, testing, production, control quality assurance, labeling, packaging, sterilization, storage and shipping of products. Certain Class II devices are also subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling. Our waveguides, retractor and aspiration devices are marketed as Class I exempt devices. The fiber optic cables we supply as part of our illuminated retractor and aspiration systems are marketed as Class II exempt devices. The metal and plastic sterilization trays used by the customer to sterilize our reusable retractors and fiber optic cables are Class II 510(k) products.

To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 and for which the FDA has not yet called for the submission of PMAs. The FDA's 510(k) clearance pathway usually takes between three and 12 months from the date the notification is submitted, but can take considerably longer, depending on the extent of requests for additional information from the FDA and the amount of time a sponsor takes to fulfill them. FDA requests for additional information can include clinical data that the FDA determines is necessary to make a determination regarding substantial equivalence. We obtained 510(k) clearance for the BriteField McCulloch Retractor System, in April of 2009 and for the Eigr Surgical Illumination System in February of 2012. All of our other commercial products to date have been commercialized as Class I, Class II exempt or Class II devices.

After a device receives 510(k) clearance or is commercialized as a Class I or II exempt device, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this decision initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. We have made, and plan to continue to make, product enhancements that we believe do not require new 510(k) clearances. If the FDA requires us to seek 510(k) clearance or premarket approval for any such modifications to previously commercialized products, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval, and we

could be subject to significant regulatory fines or penalties.

A PMA must be submitted if a device cannot be cleared through the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data and labeling to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. None of our existing products are currently approved under a PMA, and we have no plans to develop products that would require a PMA.

Continuing FDA Regulation. Even after a device receives clearance or approval and is placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing with FDA;
- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations that prohibit the promotion of products for uncleared, unapproved or "off-label" uses, and impose other restrictions on labeling, advertising and promotional activities;
- Medical Device Reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and could be a risk to health; and
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

We and our contract manufacturers, specification developers and some suppliers of components or device accessories, also are required to manufacture our products in compliance with current Good Manufacturing Practice, or GMP, requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA and the California Food and Drug Branch evaluate compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA or the Food and Drug Branch believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- delays in clearing or refusal to clear future products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearances;
- product recall or seizure;
- interruption or total shutdown of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Fraud and Abuse Laws. There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, physician payment and privacy and security laws. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Federal Anti-Kickback Laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The definition of “remuneration” has been broadly interpreted to include anything of value, including such

items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. The Department of Health and Human Services, or HHS, has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of Inspector General.

The penalties for violating the Anti-Kickback Statute include imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items and services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, amends the intent requirement of the Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. The PPACA also provides that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

Federal False Claims Act. The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring “qui tam” whistleblower lawsuits against companies under the Federal False Claims Act. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

Civil Monetary Penalties Law. The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. A determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment. In addition, similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

Physician Payment Transparency Laws. There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. PPACA, among other things, imposes new reporting requirements on device manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Device manufacturers are required to submit reports to the government by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for “knowing failures”) for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Data Privacy and Security Laws. We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

U.S. Foreign Corrupt Practices Act. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries.

International Regulation

We may evaluate international expansion opportunities in the future. International sales of medical devices are subject to local government regulations, which may vary substantially from country to country. The time required to obtain approval in another country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Additional local requirements may apply on a country-by-country basis. Outside of the European Union, regulatory approval would need to be sought on a country-by-country basis in order for us to market our devices.

Research and Development

We have an experienced research and development team with the scientific, engineering and process talent that we believe is necessary to grow our business. As of December 31, 2015, we had 11 employees engaged in research and development. Our research and development team has the technical and engineering knowledge that we believe is necessary to develop next-generation technology, as well as the advanced educational backgrounds in physics, optics, biomedical and mechanical engineering to support innovation in these areas.

We expect to commit significant resources to developing new technologies and devices, improving product performance and reducing costs. We continually seek to enhance and iterate our existing devices. Our research and development expenses totaled $7.9 million, $5.2 million and $4.4 million in the years ended December 31, 2015, 2014 and 2013, respectively. We also expect to expand our technology to create next generation devices and new Intelligent Photonics technology platform. In addition, we are engaged in advanced research related to inclusion of illumination in other medical devices, as well as further improvements in visualization and tissue differentiation.

Seasonality

Traditionally, we have experienced seasonality in the first and fourth quarters of the year. Revenue tends to be the lowest in the first quarter as the result of the resetting of annual patient healthcare insurance plan deductibles and by hospitals and military facilities working off their inventories of products purchased in the fourth quarter. Revenue in the fourth quarter tends to be the highest as demand may be impacted by the desire of patients to spend their remaining balances in their flexible spending accounts or because they have met their annual deductibles under their health insurance plans. In addition, in the fourth quarter, our results can be impacted by the budgeting and buying patterns of hospitals and military facilities.

Employees

As of December 31, 2015, we had 148 full-time employees, which included 88 employees engaged in sales and marketing, 11 employees engaged in research and development, 34 employees engaged in manufacturing and quality assurance and 15 general and administrative employees. None of our employees are represented by collective bargaining agreement and we have never experienced any work stoppages. We believe that we have good relations with our employees.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act, as amended (the “Exchange Act”) are filed with the Securities and Exchange Commission (“SEC”). We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. Such reports and other information filed by us with the SEC are available free of charge on our website at www.investors.invuity.com when such reports are made available on the SEC’s website. The public may read and copy any materials filed by us with the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes thereto, before making a decision to invest in our common stock. The realization of any of the following risks could materially and adversely affect our business, financial condition, operating results and prospects. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business and Industry

We have a history of significant operating losses and expect to continue to incur losses in the future. If we do not achieve and sustain profitability, our financial condition and stock price could suffer.

We have experienced significant operating losses, and we expect to continue to incur operating losses for the next several years as we implement additional initiatives designed to grow our business, including, among other things, increasing sales and developing new devices. We incurred net losses of $37.6 million, $20.7 million, and $12.1 million for the years ended December 31, 2015, 2014, and 2013, respectively. As of December 31, 2015, our accumulated deficit was $105.6 million. Our prior losses, combined with expected future losses, have had and will

continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital. To date, we have financed our operations primarily through the sale of equity securities, certain debt-related financing arrangements and from sales of our approved devices. We have devoted substantially all of our resources to research and development of our devices, sales and marketing activities and certain clinical and quality assurance initiatives. Our ability to generate sufficient revenue from our existing devices or from any of our device candidates in development, and to transition to profitability and generate consistent positive cash flows, is uncertain. We will need to generate significant sales to achieve profitability, and we might not be able to do so. If our revenue grows more slowly than we anticipate, or if our operating expenses are higher than we expect, we may not be able to achieve profitability as anticipated, or ever, our financial condition will suffer and our stock price could decline. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

All of our revenue is generated from devices incorporating our Intelligent Photonics technology, and any decline in the sales of these devices or failure to gain market acceptance of these devices will negatively impact our business.

We have focused heavily on the development and commercialization of devices using our Intelligent Photonics technology platform for the illumination of certain open minimally invasive and minimal access surgeries. For the years ended December 31, 2015, 2014

and 2013, our revenues of $21.0 million, $13.1 million, and $7.2 million, respectively, were derived entirely from sales of devices incorporating our Intelligent Photonics technology. Because we expect our revenue to be derived entirely from sales of these devices for the foreseeable future, our ability to execute our growth strategy and become profitable will depend not only upon an increase in the number of hospitals using our devices, but also an increase in the number of specialties using our devices within those hospitals in which our devices are utilized. If our advanced photonics technology, and the devices that incorporate it, fail to achieve and maintain wide market acceptance for any reason, our business may be adversely affected, as we will be severely constrained in our ability to fund our operations and develop and commercialize improvements to existing and new product lines.

If we are unable to convince hospital facilities to approve the use of our devices, our sales may decrease.

In the United States, in order for surgeons to use our devices, the hospital facilities in which surgeons treat patients will typically require us to receive approval from the facility's value analysis committee, or VAC. VACs typically review the comparative effectiveness and cost of medical devices used in the facility. The makeup and evaluation processes for VACs vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant VAC. For example, even if we have an agreement with a hospital system for the purchase of our devices, in most cases, we must obtain VAC approval by each hospital within the system to sell at that particular hospital. Additionally, hospitals typically require separate VAC approval for each specialty in which our device is used, which may result in multiple VAC approval processes within the same hospital even if such device has already been approved for use by a different specialty group. We often need VAC approval for each different device to be used by surgeons in each discrete specialty. In addition, hospital facilities and group purchasing organizations, or GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchasing agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly, and time-consuming effort. If we do not receive access to hospital facilities in a timely manner, or at all, via these VAC and purchasing contract processes, or otherwise, or if we are unable to secure contracts in a timely manner, or at all, our operating costs will increase, our sales may decrease, and our operating results may be harmed. Furthermore, we may expend significant effort and still be unable to obtain VAC approval or a purchase contract from hospitals or GPOs.

We must demonstrate to surgeons and hospitals the merits of our devices in order to facilitate greater adoption of our devices.

Surgeons play a significant role in determining the devices used in the operating room and assisting in obtaining approval by the relevant VAC. Educating surgeons on the benefits of our devices requires a significant commitment by our marketing team and sales organization. Surgeons and hospitals may be slow to change their practices because of perceived risks arising from the use of new devices, lack of experience using new devices, lack of clinical data supporting the benefits of such devices or the cost of new devices. We cannot predict when, or if ever, there will be widespread adoption of our devices by surgeons and hospitals. If we are unable to educate surgeons and hospitals about the advantages of devices incorporating our advanced photonics technology as compared to other surgical illumination methods, which do not incorporate this technology, we may face challenges in obtaining approval by the relevant VAC, and we will not achieve significantly greater market acceptance of our devices, gain momentum in our sales activities, significantly grow our market share or grow our revenue, and our business and financial condition will be adversely affected.

If we fail to develop and retain our direct sales force and independent sales agents, our business could suffer.

We currently sell our devices through our direct sales representatives only in the United States. Our direct sales force works with independent sales agents or agencies, who assist us in educating targeted surgeons. Our operating results are dependent upon the sales and marketing efforts of our direct sales representatives. If our direct sales force fails to adequately promote, market and sell our devices, our sales may suffer.

As we launch new devices and increase our current marketing efforts with respect to existing devices and expand into new geographies, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales personnel with significant technical knowledge of our devices. We have made, and intend to continue to make, a significant investment in recruiting and training sales representatives. There is significant competition for sales personnel who are experienced in relevant medical device sales. Once hired, the training process is lengthy because of the significant education required to achieve the level of competency that surgeons expect from sales representatives with respect to understanding our devices. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, or if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non-competition provisions expire before deploying such personnel in restricted territories, or else incur costs to relocate personnel outside of such territories, and we may be subject to allegations that such new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information.

We operate in a highly competitive market segment. If our competitors are better able to market and develop devices than we are able to market or develop devices, our business will be adversely impacted.

The medical device industry is highly competitive. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and devices for surgical illumination and visualization. Any device we develop will have to compete for market acceptance and market share. We believe that the primary competitive factors in the surgical illumination and visualization market segment are clinical safety and effectiveness, price, surgeon experience and comfort with use of particular illumination systems, reliability and durability, ease of use, device support and service, sales force experience and relationships. We face significant competition from competitors based in the United States and internationally in the surgical illumination and visualization market, and we expect the intensity of competition will increase over time. Surgeons and hospitals typically use traditional overhead lighting, headlights and fiber-optic lighting products, and if we cannot convince surgeons and hospitals of the benefits of using our devices in addition to, or as an alternative to, traditional overhead lighting and headlights, or, of the benefits of using our devices instead of using competing fiber-optic lighting products, our business may be harmed. Many of the companies developing or marketing competing products enjoy several competitive advantages over us, including:

- more established sales and marketing programs and distribution networks;
- long established relationships with surgeons and hospitals;
- contractual relationships with customers;
- products that have already received approval from the relevant VACs;
- greater financial and human resources for product development, sales and marketing;
- greater name recognition;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or devices earlier than us, obtain regulatory clearance or approvals for competing devices more rapidly than us or develop more effective or less expensive devices or technologies that render our technology or devices obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel. If our competitors are more successful than us in these matters, our business may be harmed.

Our ability to sell our devices at prices necessary to support our current business strategies depends on demonstrating that the benefits of devices incorporating our Intelligent Photonics technology outweigh the increased cost of such devices compared to other surgical illumination methods.

Hospital and other healthcare provider customers that purchase our devices typically bill various third-party payors to cover all or a portion of the costs and fees associated with the surgical procedures in which our devices are used and bill patients for any deductibles or copayments. Supplies used in surgery, such as our devices, are typically not separately reimbursed by third-party payors, but are rather included in the overall reimbursement for the procedure involved. Because there is no separate reimbursement for medical devices and supplies used in surgical procedures, the additional cost associated with the use of our devices can impact the profit margin of the hospital or surgery center where the surgery is performed. If reimbursement is inadequate, hospitals may choose to use less expensive instruments or devices that do not include illumination. Some of our target customers may be unwilling to adopt our devices in light of the additional associated cost. Our success depends on our ability to convince such cost-restricted customers that the potential benefits of using our devices, such as reduced surgery time, reduced surgery blood transfusion, and reduced post-surgery complications, outweigh the additional cost of such devices.

It is difficult to forecast future performance and our financial results may vary from forecasts and may fluctuate from quarter to quarter.

Our limited operating history and commercial experience make it difficult for us to predict future performance and growth as such forecasts are limited and subject to a number of uncertainties, including our ability to market our devices successfully, our ability to maintain or obtain regulatory clearances, unexpected or serious complications related to our devices or other factors discussed in these risk factors. A number of factors over which we have limited control may contribute to fluctuations in our financial results. These factors include, without limitation:

- surgeon and hospital acceptance of our devices;
- the productivity of our sales representatives;
- the introduction of new devices and technologies or acquisitions by us or our competitors;

- fluctuations in our expenses associated with expanding our operations and operating as a public company;
- the timing, expense and results of research and development activities and obtaining future regulatory clearances and approvals;
- supplier, manufacturing or quality problems with our devices; and
- changes in our pricing policies or in the pricing policies of our competitors or suppliers.

Additionally, we may experience seasonal variations in revenue. For example, our revenue tends to be the lowest in the first quarter as the result of the resetting of annual patient healthcare insurance plan deductibles and by hospitals and military facilities working off their inventories of products purchased in the fourth quarter. Revenue in the fourth quarter tends to be the highest as demand may be impacted by the desire of patients to spend their remaining balances in their flexible spending accounts or because they have met their annual deductibles under their health insurance plans. In addition, in the fourth quarter, our results can be impacted by the budgeting and buying patterns of hospitals and military facilities.

The loss of one or more of our key customers could slow our revenue growth or cause our revenue to decline.

A material portion of our total revenue in any given period may come from a relatively small number of customers. Sales to one customer accounted for 12% of our total revenue in each of 2014 and 2013, and sales to another customer accounted for 13% of our total revenue in 2013. We do not expect sales to these customers to increase significantly in the future, and as our revenue increases, we expect sales to these customers to decrease as a percent of revenue. There were no sales to any customer in excess of 10% of our total revenue for the year ended December 31, 2015. However, the loss of any of our key customers for any reason, or a change in our relationship with any of our key customers may cause a significant decrease in our total revenue.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.

We rely on a number of suppliers who manufacture certain components of our devices, including specialty machining for our retractors and molding for our waveguides and handheld components. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we purchase components on a purchase order basis. Our suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for components;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our devices or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require device redesign and possibly premarket submission to the FDA;
- the failure of our suppliers to comply with strictly enforced regulatory requirements, which could result in disruption of supply and/or increased expenses;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect the supplier's ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

In addition, we rely on single- and limited-source suppliers for several of our components and sub-assemblies. For example, the optical molding for our waveguides is provided by one supplier. These components are critical to our

devices and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of these components or sub-assemblies used in our devices could involve significant time and cost.

Although we could temporarily assemble some of these components internally, we may incur greater costs, delay production or divert attention from other critical projects until we find an alternate source. Any interruption or delay in obtaining components from our

third-party suppliers, or our inability to obtain components from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing devices.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions. In addition, because of the broad choice of devices we offer the many surgeon specialists who use our devices, we must maintain sufficient inventory on hand to ensure each order is filled when received, and we provide our sales representatives with trunk stock inventory to allow them to demonstrate the breath of our offering. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory could become obsolete, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. We may need to write off inventory for other reasons as well.

We have limited clinical data to support the clinical and cost benefits of use of our devices, which could be a barrier to further surgeon adoption of our devices.

For FDA purposes, our devices are classified as Class I, Class II exempt or Class II devices. Class I and Class II exempt devices do not require a 510(k) premarket notification. Our Class II devices, which require a 510(k) premarket notification, are not in a category that requires clinical studies to obtain clearance for marketing. As a result the FDA has not required, and we have not developed, clinical data supporting the safety and efficacy of our devices. Therefore, we currently lack clinical data supporting the benefits and cost effectiveness of our devices compared to other illumination solutions. As a result, surgeons may be slow to adopt or recommend our devices, and we may encounter difficulty obtaining approval from VACs. Further, any clinical studies that we initiate or the clinical experience of surgeons may indicate that our devices do not provide advantages over our competitors' surgical illumination devices or that our devices do not deliver sufficient benefits to justify their cost. Such results could slow the adoption of our devices and significantly reduce our sales, which could harm our business and reputation.

We may need to conduct clinical studies in the future to support new device regulatory clearances or approvals, gain acceptance of our products in hospitals or to secure approval of the use of our devices in some foreign countries. Clinical testing is time-consuming and expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed or halted for numerous reasons. Moreover, we cannot assure you that the results of any clinical trials would support the promoted benefits of our devices. Failure or perceived failures in any clinical trials will delay and may prevent our device development and regulatory clearance or approval processes, damage our business prospects and negatively affect our reputation and competitive position.

Our long-term growth depends on our ability to develop and commercialize additional devices.

The medical device industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to enhance our device offerings and introduce new devices. Developing new devices is expensive and time-consuming and could divert management's attention away from our core business. Even if we are successful in developing additional devices, the success of any new device offering or enhancements to existing devices will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new devices or device enhancements in a timely manner;
- develop an effective and dedicated sales and marketing team;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new devices with data from preclinical studies and clinical trials;

- obtain the necessary regulatory clearances or approvals for new devices or device enhancements;
- be fully FDA-compliant with marketing of new devices or modified devices;
- provide adequate training to potential users of our devices; and
- receive adequate coverage and reimbursement for procedures performed with our devices.

If we are unsuccessful in developing and commercializing additional devices in other areas, our ability to increase our revenue may be impaired.

We may face product liability claims that could result in costly litigation and significant liabilities, and we may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Manufacturing and marketing of our commercial devices, and clinical testing of our devices under development, may expose us to product liability and other tort claims. Additionally, regardless of the merit or eventual outcome, product liability claims may result in:

- litigation costs;
- distraction of management's attention from our primary business;
- impairment of our business reputation;
- the inability to commercialize our devices;
- decreased demand for our devices or devices in development, if cleared or approved;
- device recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate, and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. If we are unable to obtain insurance in the future at an acceptable cost or on acceptable terms with adequate coverage, we will be exposed to significant liabilities.

Our ability to maintain our competitive position depends on our ability to attract, integrate and retain highly qualified personnel.

We believe that our continued success depends to a significant extent upon the efforts and abilities of our executive officers and other key personnel. Our executive officers and other key personnel are critical to the strategic direction and overall management of our company as well as our research and development process. All of our executive officers and other employees are at-will employees and, therefore, may terminate employment with us at any time with no advance notice. The loss of any of our executive officers and other key personnel could adversely affect our business, financial condition and operating results. Our former Chief Financial Officer, Michael Gandy, resigned effective August 21, 2015 and our new Chief Financial Officer, James Mackaness, began his service with us on August 24, 2015. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively.

We invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. Many of our competitors have greater resources than we have. We do not carry any "key person" insurance policies. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business.

In addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

If we fail to properly manage our anticipated growth, our business could suffer.

We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. For example, we increased the number of employees from 102 at December 31, 2014 to 148 at December 31, 2015. We intend to continue to grow and may experience periods of rapid growth and expansion. Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems and other operational infrastructure. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. To achieve our revenue goals, we must continue to hire, train, retain and motivate skilled personnel.

In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

We must also successfully increase production output to meet expected customer demand. In the future, we may experience difficulties with production yields and quality control, component supply, and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenues.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit manufacturing cost of our current devices and attain a low per unit manufacturing cost for our future devices.

Currently, the gross profit generated from the sale of our devices is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, reduce the per unit manufacturing cost of our current devices and attain low per unit manufacturing costs for our future devices. This cannot be achieved without improving manufacturing efficiency and increasing our manufacturing volume to leverage manufacturing overhead costs. If we are unable to improve manufacturing efficiency and reduce manufacturing overhead costs per unit, our ability to achieve profitability will be constrained. Any increase in manufacturing volumes is dependent upon a corresponding increase in sales. The occurrence of one or more factors that negatively impact the manufacturing or sales of our devices or reduce our manufacturing efficiency may prevent us from achieving our desired decrease in manufacturing costs, which would prevent us from attaining profitability.

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our devices and, as a result, there will be an adverse impact on our business until we are able to secure a new facility.

In the first quarter of 2015, we transitioned all of our internal manufacturing, development and management activities to a new single location in San Francisco, California. Our facility and equipment would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire, vandalism and power outages, which may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. While we have taken precautions to safeguard our facilities, including through insurance and health and safety protocols, the inability to perform those activities may result in the inability to continue manufacturing our devices during such periods and the loss of customers or harm to our reputation. We also possess insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We have no prior experience selling devices outside of the United States. If we commercialize any devices outside of the United States, a variety of risks associated with international operations could adversely impact our net sales, results of operations and financial condition.

We currently sell our devices in the United States, but expect to expand sales to Europe and other regions, both directly and through distributors, which will require us to identify and develop relationships with distributors who will focus on marketing our devices.

The sale and shipment of our devices across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign

Corrupt Practices Act and anti-boycott laws, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

Additionally, the countries into which we expand our sales in the future may have different practices than the United States regarding the use of disposable medical devices. In the United States, our single-use optical waveguides for use with reusable retractors, single-use handheld illuminated aspiration devices and single-use drop-in intracavity illuminators are not reused, whereas surgeons in some countries may reuse our single-use devices. Customers in these countries may be less willing to purchase our single-use devices as they were not designed to be reusable, or they may purchase fewer of our single-use devices than U.S.-based customers purchase, because they choose to reuse our devices rather than purchasing additional single-use devices from us.

International operations will expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing or defending intellectual property rights;
- pricing pressure that we may experience internationally;
- a shortage of high-quality sales people and distributors;
- third-party reimbursement policies that may require some of the patients who receive our devices to directly absorb medical costs or that may necessitate the reduction of the selling prices of our devices;
- competitive disadvantage with established businesses and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- foreign currency exchange rate fluctuations;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

If we experience any of these risks, our sales in international countries may be harmed and our results of operations would suffer.

Our operations involve the use of hazardous and toxic materials, and we must comply with environmental, health and safety laws and regulations, which can be expensive, and could have an adverse impact on our business.

Our operations use or generate small volumes of hazardous or toxic materials. We are, therefore, subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal and human exposure to hazardous and toxic materials. Liability under environmental laws can be joint and several and without regard to comparative fault, and environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could have an adverse impact on our business. Although we believe that our activities conform in all material respects with environmental, health and safety laws, there can be no assurance that violations of environmental, health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. The failure to comply with past, present or future laws could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws and regulations on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws and regulations, they will likely result in additional costs, and may require us to change how we manufacture our devices, which could have an adverse impact on our business.

We may acquire other companies or technologies, which could divert our management’s attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire or invest in companies or technologies that we believe could complement or expand our platform, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in

identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets, be successful in entering into an agreement with any particular target, or obtain the expected benefits of any acquisition or investment.

To date, the growth in our business has been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash or the incurrence of debt, which could harm our operating results. In addition, if an acquired company or technology fails to meet our expectations, or if we are unable to integrate any acquired company or technology, our operating results, business and financial condition may suffer.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. We are not aware of any breaches of our information technology infrastructure. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage or disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

Risks Related to Our Intellectual Property

If our intellectual property rights are not adequately protected, our business will be negatively affected.

Our success depends in large part on our intellectual property rights, including patents, trademarks, trade secrets, copyrights and know-how. The steps we have taken and may take in the future to protect our intellectual property may not adequately prevent misappropriation or ensure that others will not develop competitive technologies or devices. We cannot assure you that our competitors will not successfully challenge the validity or ownership of our patents or design products that avoid infringement of our proprietary rights with respect to our technology. There can be no assurance that other companies are not investigating or developing other similar technologies, that any patents will be issued from any application pending or filed by us, or that, if patents are issued, the issued claims will be sufficiently broad to deter or prohibit others from marketing similar devices. We may also not be able to detect infringement of our patents by third parties. In addition, we cannot assure you that any patents issued to us will not be challenged, invalidated or circumvented, or that the rights under those patents will provide a competitive advantage to us or that our devices and technology will be adequately covered by our patents and other intellectual property. Additionally, as our patents expire, we may be unsuccessful in extending their protection through adjustments in patent term. The expiration of, or the failure to maintain or extend our patents, could have a material adverse effect on us.

Furthermore, we do not have any patent rights in certain foreign countries in which a market may exist in the future, and the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. The scope of our patent claims may vary between countries, as individual countries have distinctive patent laws. Thus, we may not be able to stop a competitor from marketing and selling in certain foreign countries devices that are the same as or similar to our devices.

We also own trade secrets and confidential information that we try to protect by entering into invention assignment and confidentiality agreements with our employees and other parties. However, these agreements may not be honored or, if breached, we may not have sufficient remedies to protect our confidential or proprietary information. Further,

our competitors may independently learn our trade secrets and develop similar or superior technologies. To the extent that our consultants, key employees or others apply technological information to our projects that they develop independently or others develop, disputes may arise regarding the ownership of proprietary rights to such information, and such disputes may not be resolved in our favor. If we are unable to protect our intellectual property adequately, our business and commercial prospects will suffer.

The medical device industry is characterized by extensive patent litigation, and we could become subject to patent or other proprietary rights litigation that could be costly, result in the diversion of management's attention, require us to pay significant damages or royalty payments or prevent us from marketing and selling our existing or future devices.

Our success depends, in part, on not infringing the patents or violating the proprietary rights of others. Significant litigation regarding patent rights occurs in the medical device industry. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our devices. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability

to make, use and sell our devices. We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions related to other proprietary rights, the outcomes of which may not be known for prolonged periods of time. Such intellectual property litigation is typically costly and time-consuming. Litigation proceedings, if instituted against us, could divert our management's and technical team's attention and resources. Adverse determinations in any such litigation could result in significant liabilities to third parties or injunctions, or could require us to seek licenses from third parties and, if such licenses are not available on commercially reasonable terms, prevent us from manufacturing, selling or using certain devices, any one of which could have a material adverse effect on us. In addition, some licenses may be nonexclusive, which could provide our competitors access to the same technologies. Third parties could also obtain patents that may require us to either redesign products or, if possible, negotiate licenses from such third parties. Such licenses may materially increase our expenses.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to patents or other proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, or using devices that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, licensing, or using devices, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and
- redesign those devices that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

If any of the foregoing occurs, we may have to withdraw existing devices from the market or may be unable to commercialize one or more of our devices, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the industry grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may be required to indemnify our customers, distributors and OEM partners with respect to infringement by our devices of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors which may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the devices they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our devices.

Risks Related to Our Capital Structure

We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we seek to continue to grow our business and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization efforts and our efforts to develop new

technologies for surgical illumination and visualization, as well as technology complementary to our current devices. Our existing resources may not allow us to conduct all of these activities that we believe would be beneficial for our future growth. As a result, we may need to seek funds in the future and, if we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the year ended December 31, 2015, our net cash used in operating activities was $31.2 million, and was $19.8 million for the year ended December 31, 2014, respectively. As of December 31, 2015, following our recent IPO, we had working capital of $49.3 million, which included $46.3 million in cash and cash equivalents. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the results of our commercialization efforts for our existing and future devices, including international expansion;
- the rate at which we continue to grow our direct sales force and increase our marketing activities;

- the establishment of high volume manufacturing;
- the need for additional capital to fund future development programs;
- the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property; and
- our success in entering into collaborative relationships with other parties.

To finance these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary to relinquish some rights to our technologies or our devices, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have or are not able to obtain sufficient funds, we may have to reduce marketing, customer support or other resources devoted to our existing devices, delay development or commercialization of our devices in development, license to third parties the rights to commercialize devices or technologies that we would otherwise seek to commercialize or cease operations. Any of these actions could harm our operating results.

We may not be able to generate sufficient cash to service our indebtedness, which currently consists of our term loan with HealthCare Royalty Partners and line of credit with Silicon Valley Bank.

As of December 31, 2015, we owed an aggregate principal amount of $15.0 million to HealthCare Royalty Partners, a holder of more than 5% of our capital stock, pursuant to a term loan agreement, which we refer to as the HCRP loan agreement.

In addition, in February 2015, we entered into a $7.5 million loan and security agreement with Silicon Valley Bank, which we refer to as the SVB credit facility. SVB has a first priority security in our cash and cash equivalents, accounts receivable and inventory, and HCRP has a second priority security in these assets and a first priority interest in our remaining assets. As of December 31, 2015, we had not drawn down on the SVB credit facility. Pursuant to the terms of the SVB credit facility, we can borrow up to 80% of certain qualified accounts receivables at a per annum interest rate equal to the prime rate as published by the Wall Street Journal, plus 75 basis points. In addition, the credit facility states that if we maintain a net cash balance, defined as unrestricted cash held with SVB less any borrowings on the revolving line of credit, of more than $3.0 million, then all collections will be deposited in our operating account. If the net cash balance is below $3.0 million, then all collections will be held in an SVB-controlled account and applied to reduce the loan balance.

Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash balances and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We may be unable to maintain a level of cash balances or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. Our future working capital, borrowings or equity financing could be unavailable to repay or refinance the amounts outstanding under the loan agreements, and even if they were, these actions may be insufficient to permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of either the HCRP loan agreement or the SVB credit facility, we may not be allowed to draw additional amounts under the other agreement, and we may be required to repay any outstanding amounts earlier than

anticipated. In the event of a liquidation, HealthCare Royalty Partners and Silicon Valley Bank would be repaid all outstanding principal, premium, if any, and interest prior to distribution of assets to unsecured creditors, and the holders of our common stock would receive a portion of any liquidation proceeds only if all of our creditors, including HealthCare Royalty Partners and Silicon Valley Bank, were first repaid in full.

The HCRP loan agreement and the SVB credit facility each contain restrictive covenants that may limit our operating flexibility.

The HCRP loan agreement and the SVB credit facility each contain certain restrictive covenants that, among other things, either limit our ability to incur, or require a mandatory prepayment in the event we incur, additional indebtedness or liens, merge with or acquire other companies, consummate a change of control, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of our lenders or prepay the outstanding amounts under the HCRP loan agreement and SVB credit facility, which could require us to pay additional prepayment penalties.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations; in addition, we may be unable to use a substantial part of our net operating losses if we do not attain profitability in an amount necessary to offset such losses.

As of December 31, 2015, we had net operating loss, or NOL, carryforwards for federal and state income tax purposes of approximately $95.2 million and $61.0 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in the future, our ability to utilize NOLs could be further limited by Section 382. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Section 382. Furthermore, we may be unable to use a substantial part of our NOLs if we do not attain profitability in an amount sufficient to offset such losses. Any limitation on using NOLs could result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income and state tax reporting purposes, which could materially and adversely affect our results of operations.

Risks Related to Government Regulation

Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to introduce new or improved devices.

Our devices are medical devices and must comply with regulatory requirements imposed by the FDA in the United States and similar agencies in foreign jurisdictions. While our current devices are classified as Class I, Class II exempt, or Class II medical devices in the United States and, with respect to our Class I and Class I exempt devices, are not subject to premarket clearance or approval by the FDA, these requirements could change and new devices may be subject to more extensive regulation. Premarket clearance or approval has become more stringent overt time and can involve lengthy and detailed laboratory and clinical testing procedures and an extensive agency review process, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements depending on the complexity and novelty of the device. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

Government regulation may impede our ability to develop and manufacture our existing and future devices. Government regulation also could delay our marketing of new devices for a considerable period of time and impose costly procedures on our activities. The FDA and other regulatory agencies may not approve or clear any of our future devices on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals or clearances could negatively impact our marketing of any future devices and reduce our device revenues.

Our devices remain subject to strict regulatory controls on manufacturing, marketing and use. We may be forced to modify or recall a device after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material adverse effect on the reputation of our devices and on our business and financial position.

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our devices, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed.

Our devices are medical devices that are subject to extensive regulation by FDA in the United States and by regulatory agencies in other countries where we plan to do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- device design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance and approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for, an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device. Although we have obtained 510(k) clearance to market our sterilization trays, our clearance can be revoked if safety or efficacy problems develop.

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations, or MDRs, that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and sales of our devices may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. MDRs for our devices have been filed including one report in 2014 relating to tissue irritation and two reports in 2015, one for device breakage and one for melting of our waveguide due to a fiber optic cable malfunction. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. The only Correction and Removal report that we have submitted to the FDA is in connection with the discontinued reusable aspiration device that we voluntarily recalled in 2012.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our devices;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and

· criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

The misuse of our devices may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and FDA sanctions if we are deemed to have engaged in such promotion.

Surgeons may misuse our devices or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be

expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Our devices may, in the future, be subject to recalls or voluntary market withdrawals that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized devices in the event of material deficiencies or defects in the design, manufacture or labeling of the device that could affect patient safety or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. Further, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Manufacturers may, under their own initiative, conduct a device notification or recall to inform surgeons of changes to instructions for use or of a deficiency, or of a suspected deficiency, found in a device. For example, in 2012, we conducted a voluntary recall relating to a fiber optic aspiration device that we no longer sell. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues.

Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Recalls, which include certain notifications and corrections as well as removals, of any of our devices, could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenues.

Material modifications to our devices may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our devices until clearances or approvals are obtained.

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect it safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will make additional modifications in the future

that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties. Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. Specifically, on July 9, 2012, the FDA Safety and Innovation Act of 2012 was enacted which, among other requirements, obligates the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently submitted this report and suggested that manufacturers continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

If we or our suppliers fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be delayed or shut down and our sales could suffer.

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic announced and unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate and prompt corrective action in response to an adverse Quality System inspection could result in, among other things, a partial or total shut-down of our manufacturing operations, significant fines, consent decrees, injunctions, untitled letters, warning letters, injunctions, customer notifications or repair, replacement, refunds, recall, detention or seizure of our products, suspension of marketing clearances and approvals, seizures or recalls of our devices, operating restrictions, refusal to grant export approval for our products, refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products, withdrawing 510(k) clearances or pre-market approvals that have already been granted, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our devices and cause revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We passed the most recent audit by the Food and Drug Branch of CDHS in February 2015, and the inspection revealed no minor or major issues. However, we cannot assure you that we will pass future inspections or audits by the FDA or other regulatory bodies.

We may be subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

Our operations are, and will continue to be, directly and indirectly affected by various federal, state or foreign healthcare laws, including, but not limited to, those described below. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's

decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;
- the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which, pursuant to draft legislation being prepared by the German government, may make the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with surgeons and other healthcare providers, some of whom recommend, purchase and/or prescribe our devices, group purchasing organizations and our independent sales agents and distributors, could be subject to challenge under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, independent sales agents and distributors may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur

significant legal expenses and divert our management's attention from the operation of our business.

We may fail to obtain foreign regulatory approvals to market our devices in other countries.

We do not have any direct sales outside of the United States; our corporate partners, however, manufacture and sell certain of our devices outside of the United States and have already obtained the necessary regulatory approvals to manufacture and sell certain of our devices outside of the United States. Sales of our devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates the exports of medical devices from the United States. Complying with international regulatory requirements can be an expensive and a time-consuming process and clearance or approval is not certain. The time required to obtain clearances or approvals, if required by other countries, may be longer than that required for FDA clearances or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. In

certain countries we may rely upon third-party or third-party distributors to obtain all required regulatory clearances or approvals, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors in these countries may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications, which could increase the difficulty of attracting and retaining qualified distributors. If these distributors experience delays in receiving necessary qualifications, clearances or approvals to market our devices outside the United States, or if they fail to receive those qualifications, clearances or approvals, we may be unable to market our devices in certain international markets effectively, or at all, which will adversely affect our results of operations and financial condition generally.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

In March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA. Our operations are impacted by the federal Patient Protection and Affordable Care Act of 2010, which, as amended is known as the ACA. Effective January 1, 2013, we began to incur a 2.3% excise tax on sales of medical devices in the United States. Compliance with the ACA has imposed significant administrative and financial burdens on us. Such excise tax has been temporarily suspended effective January 1, 2016 through December 31, 2017.

In addition, other legislative changes have been proposed and adopted in the United States. On December 18, 2015, the President signed into law the Protecting Americans from Tax Hikes Act of 2015, which retroactively extends several expired tax provisions. Among the extended provisions is the Section 41 research credit for qualified research expenditures incurred through the end of 2015. The benefit of the reinstated credit impacted the income statement in the period of enactment, which was the fourth quarter of 2015 due to the reversal of the valuation allowance on federal research and development credit carryforwards.

On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare devices and services, which could result in reduced demand for our devices or additional pricing pressures.

Risks Related to our Common Stock

Our common stock has only recently become publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Our common stock has only recently become publicly traded, and we cannot be certain that an active trading market for our common stock will develop or be sustained. The lack of an active market may impair the value of your shares, or your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or products by using our shares as consideration. Although our common stock is listed on the NASDAQ Global Market, if we fail to satisfy the continued listing standards of the NASDAQ Global Market, we could be de-listed, which would negatively impact the price of our common stock.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially in response to, among other things, the risk factors described in this Annual Report on Form 10-K and other factors, many of which are beyond our control, including:

- actual or anticipated quarterly variations in our or our competitors' results of operations;
- variance in our financial performance from the financial projects we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- announcements of significant new devices or device enhancements by us or our competitors;
- changes in our pricing policies or the pricing policies of our competitors;

- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- legislation or regulatory policies, practices or actions affecting our business;
- lawsuits threatened or filed against us;
- the sale of our common stock or other securities in the future by us or our stockholders, including upon expiration of market standoff or contractual lock-up agreements;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announcements related to patents issued to us or our competitors and to litigation;
- recruitment or departure of key personnel, including changes in our board of directors and management;
- changes in market valuation or earnings of our competitors;
- the trading volume of our common stock;
- changes in the estimation of the future size and growth rate of our markets;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and
- developments in our industry.

In addition, the market prices of the stock of many new issuers in the medical device industry and of other companies with smaller market capitalizations like us have been volatile and from time to time have experienced significant share price and trading volume changes unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business, and adversely affect our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

A substantial number of additional shares may be sold into the public market in the near future, which may cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial amount of common stock in the public market, or the perception that these sales may occur, could adversely affect the market price of our common stock. As of December 31, 2015, we have 13,392,358 shares of common stock outstanding. This includes the 4,600,000 shares we sold in our IPO, which may be resold in the public market immediately.

The holders of 13,392,358 shares of common stock and holders of warrants to purchase 137,007 shares of common stock, based on shares outstanding as of December 31, 2015, have the right, subject to some conditions, to require us file registration statements under the Securities Act covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders pursuant to a stockholders agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired. These registration rights terminate in June 2022.

We filed a registration statement under the Securities Act to register all shares subject to options outstanding or reserved for future issuance under our equity incentive plans. Our 2015 Equity Incentive Plan provides for annual automatic increases in the shares reserved for issuance under the plan without stockholder approval, which would result in additional dilution to our stockholders. These shares can be freely sold in the public market upon issuance and vesting, subject to any applicable lock-up period or other restrictions provided under the terms of the applicable plan and/or the option agreements entered into with option holders.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2015, our directors and executive officers and stockholders holding more than 5% of our capital stock, and their affiliates, own a substantial majority of our outstanding common stock. To the extent our existing stockholders purchase additional shares, this ownership concentration would increase. As a result, if these stockholders were to choose to act together, they would be able to control the management and affairs of our company and most matters and exercise significant influence over most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger

or other sale of our company or its assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

If securities or industry analysts do not publish research or reports about our business, or if they issue a negative opinion regarding our common stock, the price of our common stock and trading volume could decline.

The trading market for our common stock will be influenced by the research reports and opinions that securities or industry analysts publish about our business, our market and our competitors. We are pioneering the use of advanced photonics in surgical illumination and thus, analysts may be less likely to publish reports and opinions about our industry. Therefore, we may be required to educate analysts on the nature of our industry in order to obtain research coverage, and such efforts may not be successful. We do not have any control over these analysts. Investors have numerous investment opportunities and may limit their investments to publicly traded companies that receive thorough research coverage. If one or more analysts who cover us downgrade our shares, cease to cover us or fail to publish reports in a regular manner, our share price would likely decline, or we could lose visibility in the financial markets, which could cause a significant and prolonged decline in our stock price due to lack of investor awareness.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Global Market and other applicable securities laws, rules and regulations. Despite recent reforms made possible by the JOBS Act, compliance with these laws, rules and regulations will nonetheless increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to maintain director and officer liability insurance, and we may be

required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

As a result of disclosure of information in filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, brand, reputation and operating results.

Our failure to establish and maintain effective internal control over financial reporting could result in material misstatements in our financial statements, our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

Maintaining effective internal control over financial reporting is necessary for us to produce reliable financial statements. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for fiscal 2016, provide a management report on the internal control over financial reporting. In connection with the preparation of our financial statements for the year ended December 31, 2014, we identified a material weakness in our internal control over financial reporting relating to a lack of effective controls to adequately restrict access and segregate duties. Specifically, certain personnel had the ability to prepare and post journal entries without an independent review performed by someone without this ability. Upon identifying this material weakness, we performed additional procedures to evaluate the impact on the financial statements. Based on these procedures, we believe the material weakness did not result in any material misstatements to our financial statements. However, a material weakness could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected.

Although we have remediated this material weakness as of December 31, 2015, we cannot assure that additional material weaknesses in our internal control over financial reporting will not be identified in the future.

If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We will be evaluating our internal controls systems to allow management to report on our internal control over financial reporting beginning with our annual report for the fiscal 2016. We will be performing the system and process evaluation and testing required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or the NASDAQ. Any failure to maintain new and more precise monitoring controls and improved detection and communication of financial misstatements across all levels of the organization could result in additional material weaknesses, result in material misstatements in our financial statements and cause us to fail to meet our reporting obligations. This could cause us to lose public confidence, and could cause the trading price of our common stock to decline.

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.

We are an “emerging growth company” as defined under the federal securities laws. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the 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 cannot predict if investors will find our common stock less attractive because we will 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 decline.

We could be an emerging growth company until as late as December 31, 2020, although circumstances could cause us to lose that status at the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates is at least $700 million as of the last business day of our most recently completed second fiscal

quarter , (ii) the end of the fiscal year in which we have total annual gross revenues of $1.0 billion or more during such fiscal year, or (iii) the date on which we issue more than $1.0 billion in non-convertible debt in a three-year period.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could discourage a takeover and may prevent attempts by our stockholders to replace or remove current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that might discourage, delay or prevent a merger, acquisition or change of control, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder's notice;
- a supermajority stockholder vote requirement for amending certain provisions of our certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause and only with a supermajority stockholder vote;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our issuance of preferred stock could adversely affect holders of our common stock.

Pursuant to our amended and restated certificate of incorporation, our board is authorized to issue up to 10,000,000 shares of preferred stock without any action on the part of our stockholders. Our board also has the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, including voting rights, except that shares of preferred stock may not have more than one vote per share, dividend rights, preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation or winding up and other terms. In the event that we issue preferred stock in the future that has preference over our common stock with respect to payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock that is convertible into our common stock at greater than a one-to-one ratio, the voting and other rights of the holders of our common stock or the market price of our common stock could be adversely affected.

We have not paid dividends in the past and do not expect to pay dividends in the future on our common stock, and any return on investment may be limited to the value of our common stock.

We have never paid cash dividends and we currently intend to retain any future earnings and do not anticipate paying cash dividends in the foreseeable future. We are not legally or contractually required to pay dividends and both the HCRP loan agreement and the SVB credit facility contain restrictions on our ability to pay cash dividends. The declaration and payment of all future dividends, if any, will be at the sole discretion our board of directors, which retains the right to change our dividend policy at any time, and may be limited by our debt arrangements in place from time to time. The payment of dividends will depend on our earnings, capital requirements, financial condition,

prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our common stock may be less valuable because stockholders must rely on sales of their common stock after price appreciation, which may never occur, to realize any future gains on their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease an aggregate of approximately 38,135 square feet of manufacturing, office and research space in San Francisco, California under a lease expiring in 2024. We currently conduct all of our internal manufacturing at this facility. We believe this facility is sufficient to support our operations and that suitable facilities would be available to us should our operations require it.

In April 2015, we entered into a lease termination agreement with our landlord to terminate the lease for our former facility in San Francisco, California, prior to its scheduled expiration in January 2016. We are no longer obligated to make any lease payments subsequent to the lease termination date of April 30, 2015.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings. We may from time to time become a party to various legal proceedings arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market for Common Equity

Our common stock has traded on the NASDAQ Global Select Market (formerly the NASDAQ National Market) under the symbol "IVTY" since June 15, 2015. The following table sets forth, for the periods indicated, the high and low intraday sales prices for our common stock as reported by the NASDAQ Global Select Market:

| | Common Stock Price | |
|---|---|---|
| | High | Low |
| Year Ended December 31, 2015 | | |
| Quarter ended December 31, 2015 | $15.05 | $8.46 |
| Quarter ended September 30, 2015 | $18.18 | $10.00 |
| Quarter ended June 30, 2015 | $15.59 | $13.30 |

On March 22, 2016, the last reported sale price on the NASDAQ Global Select Market for our common stock was $6.93 per share.

As of March 22, 2016, we had 64 holders of record of our common stock. The number of record holders does not include beneficial holders who hold their shares in "street name," meaning that the shares are held for their accounts by a broker or other nominee. In these instances, the brokers or other nominees are included in the number of registered holders, but the underlying holders of the common stock that have shares held in "street name" are not.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Exchange Act.

The graph below shows the cumulative total stockholder return assuming the investment of $100.00 on the date specified in each of our common stock, The NASDAQ Global Market Index, and the NASDAQ Biotechnology Index for the period commencing on June 15, 2015 (the first day of trading of our common stock) and ending on December 31, 2015. The comparisons in the table are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of future performance of our common stock. All amounts are shown are based on the closing prices of the respective indices and Invuity, Inc. stock.

Performance Graph

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance our operations and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

Sales of Convertible Preferred Stock

In February 2015, the Company sold an aggregate of 1,411,650 shares of its Series F convertible preferred stock to a total of three accredited investors at a purchase price of $14.3449 per share, for aggregate proceeds of approximately $20,250,000.

In March 2015, the Company sold an aggregate of 184,562 shares of its Series F convertible preferred stock to a total of eight accredited investors at a purchase price of $14.3449 per share, for aggregate proceeds of approximately $2,647,572.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Company believes the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with the Company, to information about the Company. The sales of these securities were made without any general solicitation or advertising.

Sales of Common Stock

Prior to filing our registration statement on Form S-8 in June 2015, we granted stock options and stock awards to employees, directors and consultants under our 2005 Stock Plan, covering an aggregate of 521,512 shares of common stock, at a weighted average exercise price of $12.48 per share. In addition, we sold an aggregate of 11,102 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of $22,000 upon the exercise of stock options and stock awards.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (1) and (2) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Initial Public Offering

Use of Proceeds

In June 2015, we completed our IPO and issued 4,600,000 shares of our common stock, including the underwriter's exercise of their over-allotment option, at an initial offering price to the public of $12.00. We received net proceeds from the IPO of approximately $47.2 million, after deducting underwriting discounts and commissions of approximately $3.9 million and offering costs of approximately $4.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. The underwriters were Piper Jaffray, Leerink Partners, Stifel, and William Blair.

Shares of our common stock began trading on the NASDAQ Global Select Market on June 15, 2015. The shares were registered under the Securities Act on registration statement on Form S-1 (Registration No. 333-203505).

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 15, 2015. As of December 31, 2015, we had used approximately $19.5 million of the proceeds from our IPO.

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2015, we did not repurchase any equity securities.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data is qualified in its entirety by, and should be read in conjunction with the financial statements and the notes thereto included in Part II, Item 8 and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II, Item 7 of this Report. The following selected statement of operations data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 have been derived from our audited financial statements included in Part II, item 8, of this report. We derived the selected balance sheet data at December 31, 2013 from our audited financial statements which are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Statements of Operations Data: | | | |
| Revenue | $21,031 | $13,103 | $7,186 |
| Cost of goods sold | 7,733 | 4,630 | 2,294 |
| Gross profit | 13,298 | 8,473 | 4,892 |
| Operating expenses: | | | |
| Research and development | 7,869 | 5,181 | 4,445 |
| Selling, general and administrative | 40,636 | 23,044 | 12,402 |
| Total operating expenses | 48,505 | 28,225 | 16,847 |
| Loss from operations | (35,207) | (19,752) | (11,955) |
| Interest expense | (1,881) | (1,402) | (284) |
| Interest and other income (expense), net | (482) | 492 | 130 |
| Net loss | $(37,570) | $(20,662) | $(12,109) |
| Net loss per common share, basic and diluted | $(4.94) | $(31.63) | $(19.15) |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 7,606,172 | 653,195 | 632,407 |

| | December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Balance Sheet Data: | | | |
| Cash and cash equivalents | $46,296 | $6,048 | $4,953 |
| Working capital | 49,314 | 10,366 | 8,486 |
| Total assets | 66,305 | 25,324 | 12,053 |
| Convertible preferred stock warrant liability | — | 136 | 86 |
| Total long-term debt | 14,480 | 9,347 | 2,477 |
| Convertible preferred stock | — | 73,755 | 52,949 |
| Accumulated deficit | (105,607) | (68,037) | (47,375) |
| Total stockholders' equity (deficit) | $42,343 | $(65,827) | $(45,906) |

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Financial Data" and the financial statements and related notes included elsewhere in this annual report. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in "Risk Factors" and in other parts of this annual report.

### Overview

We are a commercial-stage medical technology company pioneering the use of advanced photonics to provide surgeons with improved direct visualization of surgical cavities during minimally invasive and minimal access surgical procedures. We integrate our Intelligent Photonics technology platform into our single-use and reusable advanced surgical devices to address some of the critical intracavity illumination and visualization challenges facing surgeons today. We utilize our proprietary advanced photonics technology to develop optical waveguides that direct and shape thermally cool, brilliant light into broad, uniform and volumetric illumination of the surgical target. We believe that improving a surgeon's ability to see critical anatomical structures can lead to better clinical and aesthetic outcomes, improved patient safety and reduced surgical time and healthcare costs.

Photonics is the science and technological applications of light. We have applied advanced principles of photonics to develop our Intelligent Photonics technology platform, which enables the transmission, management and manipulation of light in surgical procedures. Our initial application of this technology is integrated into our family of proprietary optical waveguides. Our waveguides are sophisticated devices that rely on the principles of optics to shape and direct light. They are coupled to a modified fiber optic cable and are designed to work with the standard xenon or LED light sources typically found and utilized in the operating room. Our optical waveguides are incorporated into surgical devices, including our customized line of illuminated surgical retractors, handheld illuminated aspiration devices and a drop-in intracavity illuminator. Our handheld illuminated aspiration devices and drop-in intracavity illuminators are single-use products. Our retractor devices are reusable, but utilize a single-use optical waveguide, which we sell separately because a new waveguide must be used for each procedure. Our accessories include sterilization trays and light cables.

We currently sell our devices in the United States, primarily through a direct sales force. We increased the number of our direct sales representatives to 59 as of December 31, 2015, and we expect to continue to expand our direct salesforce and marketing organization to further penetrate and expand the market by demonstrating the benefits of our advanced photonics technology platform to surgeons. Although our sales and marketing efforts are directed at surgeons because they are the primary users of our technology, the hospitals where surgical procedures are performed are our customers, as they typically are responsible for making the decisions to purchase our devices. Our currently marketed devices are commonly treated as general supplies utilized in surgery. As a result, the hospital or surgical center receives a single reimbursement from the third-party payor that is intended to cover the overall cost of treatment, including the cost of devices used during the procedure, as well as the overhead cost associated with the facility where the procedure is performed. There is no separate reimbursement for our devices.

In addition to marketing and selling our existing products, we are engaged in ongoing research and development. Our research and development efforts are focused on developing new devices and modalities to broaden the application and adoption of open minimally invasive and minimal access procedures and enable new advanced surgical techniques. Our manufacturing involves the combined utilization of our internal manufacturing resources and expertise, approved suppliers and contract manufacturers. We outsource the manufacture of components, subassemblies and certain finished devices that are produced to our specifications and shipped to our facilities in San Francisco, California for final assembly or inspection, and certification. Finished products are stored at and distributed from our facility. We believe our facility is sufficient to support our operations and that suitable facilities would be available to us should our operations require it.

Components of Our Results of Operations

Revenue

All of our revenue is currently derived from sales of our devices in the United States. We earn revenue from the sale of our devices primarily through our direct salesforce as complemented by our independent sales agents. Our focus has been on increasing the number of direct sales representatives and sales territories and reducing our reliance on our independent sales agents.

Recent revenue growth has been driven by the growth of our sales and marketing infrastructure and increased surgeon awareness of the benefits of our advanced photonics technology platform over traditional surgical lighting options in the operating room. We are pursuing a number of strategies that we believe will enable us to continue to grow. Our products have broad applicability to open, smaller incision surgeries which we estimate to be approximately 40% of all surgical procedures in the United States. We have

initially targeted our sales and marketing efforts to breast, orthopedics and spine. Although we have made progress towards our goals there are still many areas for growth. To achieve these goals we are focused on the following initiatives:

- Leveraging our unique marketing programs that align with hospital initiatives including safety, patient outcomes and patient satisfaction, for example our Hidden Scar program and recently launched OR Safety Program
- Cross selling within our initial target markets and developing adjacent surgical specialties to broaden the three core categories to Women's health, Spine/ortho and surgical oncology
- To introduce new products to support our entry into adjacent surgical specialities

We have experienced seasonality in the first and fourth quarters of the year. Revenue tends to be the lowest in the first quarter as the result of the resetting of annual patient healthcare insurance plan deductibles and by hospitals and military facilities working off their inventories of products purchased in the fourth quarter. Revenue in the fourth quarter tends to be the highest as demand may be impacted by the desire of patients to spend their remaining balances in their flexible spending accounts or because they have met their annual deductibles under their health insurance plans. In addition, in the fourth quarter, our results can be impacted by the budgeting and buying patterns of hospitals and military facilities.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of material costs, manufacturing overhead, direct labor and third-party services, such as sterilization. Manufacturing overhead represents a significant portion of cost of goods sold and includes the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenue to decrease as our production volume increases and our production process becomes more efficient. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping cost

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs and product yields, adjustments to inventory reserves and the implementation of cost-reduction strategies. Based on our current product portfolio, we expect our gross margin to increase over the long term as our production volume increases and as we spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. However, our gross margin will likely fluctuate from quarter to quarter in the near term.

Selling, General and Administrative Expenses

Our selling, general and administrative, or SG&A, expenses consist primarily of compensation for executive, finance, sales, legal and administrative personnel, including sales commissions and stock-based compensation. Other significant SG&A expenses include independent sales agent commissions, conferences, trade shows, promotional activities, professional fees for legal and accounting services, consulting fees, insurance costs and travel expenses.

We expect SG&A expenses to continue to increase in absolute dollars as we expect to hire additional direct sales representatives and expand our commercial infrastructure to both drive and support our planned revenue growth. We also expect to incur additional SG&A expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Research and Development Expenses

Our research and development, or R&D, expenses consist primarily of product research, engineering, product development, quality assurance and depreciation. These expenses include personnel costs, including stock-based

compensation expense, consulting services, laboratory materials and supplies and an allocation of related facilities costs. We expect our R&D costs to increase in absolute dollars as we hire additional personnel to develop new devices and device enhancements. We expense R&D costs as they are incurred.

Interest Expense

Interest expense consists of cash and non-cash components. The cash component of interest expense is attributable to our borrowings under our loan agreements. The non-cash component consists of interest expense recognized from the amortization of debt discounts derived from the issuance of warrants and debt issuance costs capitalized on our balance sheets.

Interest and Other Income (Expense), Net

Interest and other income (expense), net consists primarily of the fair value re-measurement related to our outstanding convertible preferred stock warrants, which are accounted for as a liability and marked-to-market at each reporting period prior to us becoming a public company and interest income from interest earned on our cash, cash equivalents and marketable securities.

Results of Operations

Revenue, cost of revenue, gross profit and gross margin was as follows for the periods presented

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| | (In thousands) | | |
| Revenue | | | |
| Single use devices | $15,269 | $9,062 | $4,213 |
| Reusable retractors | 3,333 | 1,945 | 859 |
| Sales to 3rd party medical device manufacturers | 1,422 | 1,535 | 1,841 |
| Accessories | 1,007 | 561 | 273 |
| Total revenue | $21,031 | $13,103 | $7,186 |
| Cost of Revenue | 7,733 | 4,630 | 2,294 |
| Gross Profit | $13,298 | $8,473 | $4,892 |
| Gross Margin | 63 % | 65 % | 68 % |

Twelve Months Ended December 31, 2015 as compared to Twelve Months Ended December 31, 2014

Revenue increased $7.9 million, or 61%, to $21.0 million during the year ended December 31, 2015, compared to $13.1 million during the year ended December 31, 2014. The growth in revenue was attributable to an increase in unit sales as a result of selling our products to new customers and also selling more units to existing customers. The increase in units was driven by the expansion of our direct salesforce, which increased the number of customers to whom we sold devices. The number of our direct sales representatives increased from 39 as of December 31, 2014 to 59 as of December 31, 2015 and the number of customers ordering our devices increased from approximately 370 in the fourth quarter of 2014 to approximately 530 in the fourth quarter of 2015.

Cost of goods sold increased $3.1 million, or 67%, to $7.7 million during the year ended December 31, 2015, compared to $4.6 million during the same period in 2014. The increase in cost of goods sold was primarily due to the increase in the number of devices sold as we expanded our sales and marketing efforts and increased our device sales. The increase in cost of goods sold was also attributable to higher overhead costs related to our new leased facility in San Francisco which we occupied at the beginning of the year.

Gross margin for the year ended December 31, 2015 was 63% compared to 65% for the year ended December 31, 2014. The reduction in gross margin is primarily attributable to higher overhead costs associated with our move to our new facilities. This impact was most strongly felt in our second and third quarters of 2015 and began to mitigate as our sales volumes increased and our gross margin improved in our fourth quarter of 2015. The move into our new facility provides us with sufficient production capacity to support sales volumes of our current products into the foreseeable future.

Twelve Months Ended December 31, 2014 as compared to Twelve Months Ended December 31, 2013

Revenue increased $5.9 million, or 82%, to $13.1 million during the year ended December 31, 2014, compared to $7.2 million during the year ended December 31, 2013. The growth in revenue was attributable to an increase in unit sales. The increase in units was driven by the expansion of our direct salesforce, which increased the number of customers to whom we sold devices. The number of our direct sales representatives increased from 18 as of December 31, 2013 to 39 as of December 31, 2014 and the number of customers ordering our devices increased from approximately 170 in the fourth quarter of 2013 to approximately 370 in the fourth quarter of 2014.

Cost of goods sold increased $2.3 million, or 100%, to $4.6 million during the year ended December 31, 2014, compared to $2.3 million during the year ended December 31, 2013. The increase in cost of goods sold was primarily due to the increase in the number of devices sold as we expanded our sales and marketing efforts and increased our device sales. The increase in cost of goods sold was also attributable to charges totaling $0.7 million, which primarily consisted of write-offs of unrecoverable trunk stock inventory provided to direct sales representatives and independent sales agents. We have made improvements in our processes and procedures related to the tracking of our trunk stock inventory to reduce the likelihood of future significant trunk stock write-offs.

Gross margin for the year ended December 31, 2014 decreased to 65%, compared to 68% for the year ended December 31, 2013. The decrease in gross margin was primarily due to the impact of the write-off of inventory and related increase to cost of goods sold.

Operating Expenses

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2015 | | 2014 | | 2013 | |
| | Amount | % of Revenue | Amount | % of Revenue | Amount | % of Revenue |
| | (In thousands) | | | | | |
| Operating Expenses | | | | | | |
| Research and development | $7,869 | 37 % | $5,181 | 40 % | $4,445 | 62 % |
| Selling general and administrative | 40,636 | 193% | 23,044 | 176 % | 12,402 | 173 % |
| Total operating expenses | $48,505 | 231% | $28,225 | 215 % | $16,847 | 234 % |

Twelve Months Ended December 31, 2015 as compared to Twelve Months Ended December 31, 2014

Research and development expenses: expenses increased $2.7 million, or 52%, to $7.9 million during the year ended December 31, 2015, compared to $5.2 million during the year ended December 31, 2014. The increase in expenses was primarily attributable to an increase in personnel related costs of $1.9 million due to our expanding headcount plus an increase of $1.8 million relating to expanding our facility for pilot operations, offset by increased allocations of $1.5 million relating to increased manufacturing production.

Selling, general and administrative expenses: expenses increased $17.6 million, or 176%, to $40.6 million during the year ended December 31, 2015, compared to $23.0 million during the year ended December 31, 2014. The increase in expenses was attributable to a $5.6 million increase in personnel-related expenses, excluding sales commissions, as a result of increased headcount as a result of increasing our direct sales force, marketing and administrative staff, a $2.0 million increase in commissions to direct sales representatives, a $2.0 million increase in marketing, advertising and promotion-related expenses, and a $3.7 million increase in consulting and professional service fees, primarily due to an increase in legal and accounting fees relating to our initial public offering in June 2015, in addition to a $2.4 million increase in facilities, maintenance, and depreciation expense relating to our new building and expanding operations.

Twelve Months Ended December 31, 2014 as compared to Twelve Months Ended December 31, 2013

Research and development expenses: expenses increased $0.7 million, or 17%, to $5.2 million during the year ended December 31, 2014, compared to $4.4 million during the year ended December 31, 2013. The increase in expenses was primarily attributable to a $0.4 million increase in personnel-related expenses as a result of increased headcount and a $0.3 million increase in supplies and testing expenses in development activities.

Selling, general and administrative expenses: expenses increased $10.6 million, or 85%, to $23.0 million during the year ended December 31, 2014, compared to $12.4 million during the year ended December 31, 2013. The increase in expenses was attributable to a $5.7 million increase in personnel-related expenses, excluding sales commissions, as a result of increased headcount, a $2.0 million increase in commissions to direct sales representatives, a $1.1 million increase in independent sales agent commissions, a $0.8 million increase in marketing, advertising and promotion-related expenses and a $0.8 million increase in professional service fees, primarily as a result of an increase in legal, accounting and recruiting services due to the growth in our operations.

Non-operating items, including interest expense, interest, and other income (expense), were as follows for the periods presented:

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2015 | | 2014 | | 2013 | |
| | Amount | % of Revenue | Amount | % of Revenue | Amount | % of Revenue |
| | (In thousands) | | | | | |
| Interest expense | $(1,881) | -9 % | $(1,402) | -11 % | $(284) | -4 % |
| Interest and other income (expense), net | (482) | -2 % | 492 | 4 % | 130 | 2 % |
| Total | $(2,363) | -11 % | $(910) | -7 % | $(154) | -2 % |

Twelve Months Ended December 31, 2015 as compared to Twelve Months Ended December 31, 2014

Interest expense increased $0.5 million to $1.9 million during the year ended December 31, 2015 from $1.4 million during the year ended December 31, 2014. In February 2015, we drew down the remaining $5.0 million from our loan with HealthCare Royalty Partners, or HCRP.

Interest and other income (expense), net changed $1.0 million to an expense of $0.5 million during the year ended December 31, 2015, compared to income of $0.5 million during the year ended December 31, 2014. The change in interest and other income (expense), net was primarily related to the fair value re-measurement of the liability related to our outstanding convertible preferred stock warrants prior to the company going public.

Twelve Months Ended December 31, 2014 as compared to Twelve Months Ended December 31, 2013

Interest expense increased $1.1 million to $1.4 million during the year ended December 31, 2014 from $0.3 million during the year ended December 31, 2013. In February 2014, we drew down $10.0 million from our loan with HCRP and utilized a portion of the proceeds to repay the outstanding balance of our then outstanding loan with Silicon Valley Bank, or SVB. The extinguishment of the SVB loan resulted in the recognition of additional interest expense of $0.2 million comprising an early repayment penalty and the unamortized balances of debt discount and balloon interest payment. In addition, the higher principal amount of our HCRP loan together with the higher interest rate of 12.5% per year contributed to increased interest costs in 2014.

Interest and other income (expense), net increased $0.4 million to $0.5 million during the year ended December 31, 2014, compared to $0.1 million during the year ended December 31, 2013. The increase in interest and other income, net was primarily related to the fair value re-measurement of the liability related to our outstanding convertible preferred stock warrants.

Liquidity and Capital Resources

As of December 31, 2015, our primary sources of liquidity were our cash and cash equivalents totaling $46.3 million, accounts receivable of $3.6 million, net of allowances, and an accounts receivable credit facility with SVB that we entered into in February 2015 that permits the borrowing of the lesser of $7.5 million or an amount representing up to 80% of eligible accounts receivable.

As of December 31, 2015, we had an accumulated deficit of $42.3 million. We have financed our operations primarily through sales of our equity securities, debt financings and the sale of our devices.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

| | Year Ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2015 | 2014 | 2013 |
| Net cash (used in) provided by: | | | |
| Operating activities | $(31,165) | $(19,818) | $(13,897) |
| Investing activities | (3,713) | (7,271) | 15,496 |
| Financing activities | 75,126 | 28,184 | (451) |
| Net increase in cash and cash equivalents | $40,248 | $1,095 | $1,148 |

Twelve Months Ended December 31, 2015

Net cash used in operating activities was $31.2 million, which consisted of a net loss of $37.6 million, adjusted by non-cash charges of $3.8 million and no net change in our net operating assets. The increase in our accounts receivable, inventories and accounts payable balances were driven by the increase in our overall business and were offset by a reduction in our prepaid expenses and accrued liabilities. The reduction in prepaid expenses related to us receiving the tenant allowance associated with qualifying expenditures that were made in connection with taking possession of our new facilities in 2015.

Net cash used in investing activities consisted of the purchase and sale of marketable securities and capital expenditures to purchase property and equipment in connection with the new facility.

Net cash provided by financing activities was from the issuance of common stock upon our initial public offering, convertible preferred stock issued prior to our public offering and net proceeds from drawing down the remaining balance on our loan with HCRP.

Twelve Months Ended December 31, 2014

Net cash used in operating activities was $19.8 million, which consisted of a net loss of $20.7 million, adjusted by non-cash charges of $0.9 million and a net change of $0.1 million in our net operating assets. The increase in our net operating assets and liabilities was primarily due to an increase in accrued liabilities as a result of an increase in our operations and related growth in headcount and an increase in deferred rent related to our new facility lease. This increase was partially offset by an increase in accounts receivable as a result of an increase in revenue and timing of collections, an increase in prepaid expenses and other current assets primarily as a result of the tenant allowance receivable in 2014 and an increase in inventory as a result of an increase in production to support the expected growth in future revenue.

Net cash used in investing activities consisted of the purchase and sale of marketable securities and capital expenditures to purchase property and equipment in connection with the new facility lease entered into in December 2014 including an increase in restricted cash for the security deposit on our new leased facility. The purchase of property and equipment is primarily related to the expansion of our facilities, purchases of office furniture and equipment, leasehold improvements, computer software and manufacturing equipment.

Net cash provided by financing activities was from the issuance of convertible preferred stock and net proceeds from the issuance of long-term debt.

We believe that our existing cash and cash equivalents as of December 31, 2015, and future borrowings available under our accounts receivable credit facility will be sufficient to meet our anticipated cash requirements for at least the next twelve months. Our expected future capital requirements may depend on many factors including customer sales, the expansion of our salesforce, and the timing and extent of spending on the development of our technology to increase our product portfolio. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary to relinquish some rights to our technologies or our devices, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs. Doing so will likely harm our ability to execute on our business plan.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2015:

Payments Due by Period

| (in thousands) | Less Than 1 Year | 1 to 3 Years | 3 to 5 Years | More Than 5 Years | Total |
|---|---|---|---|---|---|
| Long-term debt-related party, including interest | $1,874 | $7,852 | $12,070 | $— | $21,796 |
| Operating leases | 2,053 | 4,292 | 4,553 | 9,511 | 20,409 |
| Total contractual obligations | $3,927 | $12,144 | $16,623 | $9,511 | $42,205 |

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate risks. We had cash and cash equivalents of $46.3 million and $6.0 million as of December 31, 2015 and December 31, 2014, respectively, which consist of bank deposits and money market funds.

Our short-term investments primarily consisted of corporate bonds. The cash and cash equivalents are held for working capital purposes. Our investments are made for capital preservation purposes. We do not enter into investments for trading or speculative purposes. Because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial statements.

As of December 31, 2015 and December 31, 2014, we had drawn down principal debt balances of $15.0 million and $10.0 million, respectively. This debt carries a fixed interest rate equal to 12.5%. A hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material impact on our financial statements. We also have access to an accounts receivable credit facility with Silicon Valley Bank that permits the borrowing of the lesser of $7.5 million or an amount representing up to 80% of eligible accounts receivable. See note 6 to the financial statements for more details. As of December 31, 2015, we have not drawn down on this line of credit.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires our management to make judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these judgments and estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We earn revenue from the sale of our devices to hospitals through direct sales representatives and independent sales agents. Our revenue is recognized when the following criteria are met:

- Persuasive evidence of an arrangement exists. We consider this criterion satisfied when we have a purchase order or contract with the customer in place.
- Delivery has occurred and title passed to the customer, which is typically upon shipment of the device from our location or when received by the customer based on the shipping terms.
- The price is fixed or determinable and collectability is reasonably assured. We determine the satisfaction of these criteria based on our judgment regarding the nature of the fee charged for devices, contractual agreements entered into, and the collectability of those fees under any contract or agreement.

We do not offer rights of return other than our standard warranty, or price protection, and have no post-delivery obligations other than our standard warranty.

Stock-based Compensation

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the period during which the employee is required to provide service in exchange for the award (generally the vesting period).

We estimate the fair value of our stock-based awards using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions. Our assumptions are as follows:

- Expected term. The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is calculated as the average of the time to vesting and the contractual life of the options.

- Expected volatility. The expected volatility is derived from the average historical volatilities of publicly traded companies within our industry that we consider to be comparable to our business over a period approximately equal to the expected term for employee's options and the remaining contractual life for non-employees options.
- Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield with a maturity equal to the expected term of the option in effect at the time of grant.
- Dividend yield. The expected dividend is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Prior to our IPO, the fair value of the shares of the Company's common stock underlying the stock options has historically been determined by the Company's Board of Directors. Because there had been no public market for the Company's common stock, our Board of Directors has determined the fair value of the Company's common stock at the time of grant of the option by considering a number of objective and subjective factors, including the Company's stage of development, sales of the Company's convertible preferred stock, the Company's operating and financial performance, equity market conditions affecting comparable public companies, the lack of liquidity of the Company's capital stock, and the general and industry-specific economic outlooks.

Since our IPO in June 2015, the fair value of our common stock is based on the closing price of our common stock, as quoted on the NASDAQ Global Market, on the date of grant.

In addition to the assumptions used in the Black-Scholes option-pricing model, we also estimate a forfeiture rate to calculate the stock-based compensation for our equity awards. We will continue to use judgment in evaluating the expected volatility, expected term and forfeiture rates utilized for our stock-based compensation calculations on a prospective basis.

Stock-based compensation expense for options granted to non-employees as consideration for services received is measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, using the Black-Scholes option-pricing model, whichever can be more reliably measured. Stock-based compensation expense for options granted to non-employees is periodically remeasured as the underlying options vest.

The following table summarizes the assumptions we used to determine the fair value of stock options granted to employees:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Expected term (in years) | 5.0 – 6.0 | 6.0 | 6.0 |
| Expected volatility | 35 – 50% | 35 – 38% | 43% |
| Risk-free interest rate | 1.31 – 1.89% | 1.80 – 1.93% | 1.08 – 1.82% |
| Dividend yield | 0% | 0% | 0% |

We recorded total stock-based compensation expense of $1.2 million, $0.7 million and $0.3 million, and in the years ended December 31, 2015, 2014 and 2013, respectively. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Convertible Preferred Stock Warrant Liability

Freestanding warrants for shares that were contingently redeemable were classified as liabilities on the balance sheet at their estimated fair value because the shares underlying the warrants may obligate the Company to transfer assets to the holders at a future date under certain circumstances such as a deemed liquidation event. The warrants were subject to re-measurement at each balance sheet date and the change in fair value, if any, was recognized as interest and other income, net in the statements of operations and comprehensive loss. The Company adjusted the liability for changes in

fair value until the completion of its IPO, at which time all convertible preferred stock warrants were converted into warrants to purchase common stock and the liability was reclassified to additional paid-in capital.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern. The new standard provides guidance around 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. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company’s financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which permits companies to measure inventory at the lower of cost and realizable value. ASU 2015-11 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted. The Company is in the process of evaluating whether the adoption of ASU 2015-11 will have a material effect on its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which 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 the related debt liability, consistent with debt discounts. ASU 2015-03 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. The Company does not expect that the adoption of ASU 2015-03 will have a material effect on its financial statements.

In August 2015, the FASB issued ASU No. 2015-15,Interest—Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements—Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting, which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. The Company does not expect that the adoption of ASU 2015-03 will have a material effect on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires 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. In August 2015, FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes to simplify the presentation of deferred income taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The Company has elected to early adopt ASU 2015-17 as of the beginning of our fourth quarter ended December 31, 2015 on a prospective basis. There is no impact to the balance sheet amount as a result of the early adoption.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its financial statements.

In February 2016, the FASB issued ASU 2016-02 – Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or

less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840 Leases. The standard is effective on January 1, 2019, with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

INVUITY, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Invuity, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows present fairly, in all material respects, the financial position of Invuity, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 25, 2016

INVUITY, INC.

Balance Sheets

(In thousands, except share data)

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| | (In thousands, except per share data) | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $46,296 | $6,048 |
| Accounts receivable, net | 3,619 | 2,798 |
| Inventory | 5,182 | 4,271 |
| Prepaid expenses and other current assets | 923 | 2,486 |
| Total current assets | 56,020 | 15,603 |
| Restricted cash | 1,090 | 1,125 |
| Property and equipment, net | 9,195 | 8,541 |
| Other non-current assets | — | 55 |
| Total assets | $66,305 | $25,324 |
| Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit) | | |
| Current liabilities: | | |
| Accounts payable | $2,458 | $1,075 |
| Accrued and other current liabilities | 4,214 | 4,162 |
| Total current liabilities | 6,672 | 5,237 |
| Deferred rent | 2,810 | 2,676 |
| Convertible preferred stock warrant liability | — | 136 |
| Long-term debt—related party | 14,480 | 9,347 |
| Total liabilities | 23,962 | 17,396 |
| Convertible preferred stock, $0.001 par value—0 and 6,207,320 shares authorized at December 31, 2015 and 2014, respectively; 0 and 6,056,403 shares issued and outstanding at December 31, 2015 and 2014, respectively; | — | 73,755 |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.001 par value—10,000,000 and 0 shares authorized at December 31, 2015 and 2014, respectively; 0 shares issued and outstanding at December 31, 2015 and 2014, respectively; | — | — |
| Common stock, $0.001 par value—100,000,000 and 9,189,189 | 13 | 1 |

| | | |
|---|---|---|
| shares authorized at December 31, 2015 and 2014, respectively; | | |
| 13,392,358 and 711,249 shares issued and outstanding at December 31, | | |
| 2015 and 2014, respectively; | | |
| Additional paid-in capital | 147,937 | 2,209 |
| Accumulated deficit | (105,607) | (68,037) |
| Total stockholders' equity (deficit) | 42,343 | (65,827) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $66,305 | $25,324 |

The accompanying notes are an integral part of these financial statements.

INVUITY, INC.

Statements of Operations

(In thousands, except share and per share data)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| | (In thousands, except per share data) | | |
| Revenue | $21,031 | $13,103 | $7,186 |
| Cost of goods sold | 7,733 | 4,630 | 2,294 |
| Gross profit | 13,298 | 8,473 | 4,892 |
| Operating expenses: | | | |
| Research and development | 7,869 | 5,181 | 4,445 |
| Selling, general and administrative | 40,636 | 23,044 | 12,402 |
| Total operating expenses | 48,505 | 28,225 | 16,847 |
| Loss from operations | (35,207) | (19,752) | (11,955) |
| Interest expense (1,777, 1,052 and 0 related party interest, respectively) | (1,881) | (1,402) | (284) |
| Interest and other income (expense), net | (482) | 492 | 130 |
| Net loss | $(37,570) | $(20,662) | $(12,109) |
| Net loss per common share, basic and diluted | $(4.94) | $(31.63) | $(19.15) |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 7,606,172 | 653,195 | 632,407 |

The accompanying notes are an integral part of these financial statements.

INVUITY, INC.

Statements of Comprehensive Loss

(In thousands)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Net loss | $(37,570) | $(20,662) | $(12,109) |
| Other comprehensive loss: | | | |
| Unrealized loss on investments | — | — | (4) |
| Total comprehensive loss | $(37,570) | $(20,662) | $(12,113) |

The accompanying notes are an integral part of these financial statements.

INVUITY, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share and per share data)

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | | Total Stockholders' |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Income (Loss) | Accumulated Deficit | Equity (Deficit) |
| Balances at December 31, 2012 | 4,458,589 | $52,949 | 632,486 | $ 1 | $1,124 | $ 4 | $ (35,266) | $ (34,137) |
| Exercise of common stock options | — | — | 23,698 | — | 65 | — | — | 65 |
| Stock-based compensation expense | — | — | — | — | 279 | — | — | 279 |
| Unrealized loss on investments | — | — | — | — | — | (4) | — | (4) |
| Net loss | — | — | — | — | — | — | (12,109) | (12,109) |
| Balances at December 31, 2013 | 4,458,589 | 52,949 | 656,184 | 1 | 1,468 | — | (47,375) | (45,906) |
| Issuance of Series E convertible preferred stock for cash at $13.3052 per share, net of issuance costs of $454 | 1,597,814 | 20,806 | — | — | — | — | — | — |
| Exercise of common stock options | — | — | 55,065 | — | 78 | — | — | 78 |
| Stock-based compensation expense | — | — | — | — | 663 | — | — | 663 |
| Net loss | — | — | — | — | — | — | (20,662) | (20,662) |
| Balances at December 31, 2014 | 6,056,403 | 73,755 | 711,249 | 1 | 2,209 | — | (68,037) | (65,827) |
| Issuance of Series F convertible preferred stock for cash | 1,596,212 | 22,769 | — | — | — | — | — | — |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| at $14.3449 per share, net of issuance costs of $128 | | | | | | | | |
| Conversion of Convertible Preferred Stock upon IPO | (7,652,615) | (96,524) | 7,979,332 | 8 | 96,516 | | | 96,524 |
| Conversion of preferred stock warrants to common stock warrants | | | | | 608 | | | 608 |
| Proceeds from issuance of common stock, net issuance costs of $7,988 | | | 4,600,000 | 4 | 47,215 | | | 47,219 |
| Exercise of common stock options | — | — | 102,250 | — | 139 | — | — | 139 |
| Repurchase of early exercised options | — | — | (473) | — | (1) | — | — | (1) |
| Vesting of early exercise options | — | — | — | — | 2 | — | — | 2 |
| Stock-based compensation expense | — | — | — | — | 1,249 | — | — | 1,249 |
| Net loss | — | — | — | — | — | — | (37,570) | (37,570) |
| Balances at December 31, 2015 | — | — | $13,392,358 | $ 13 | $147,937 | $ — | $(105,607) | $42,343 |

The accompanying notes are an integral part of these financial statements.

INVUITY, INC.

Statements of Cash Flows

(In thousands)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Cash flows from operating activities | | | |
| Net loss | $(37,570) | $(20,662) | $(12,109) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,710 | 344 | 227 |
| Stock-based compensation | 1,249 | 663 | 279 |
| Changes in fair value of convertible preferred stock warrant liability | 472 | (522) | (168) |
| Provision for (recovery of) doubtful accounts | 216 | 87 | (1) |
| Noncash interest expense | 143 | 90 | 68 |
| Accretion of premium on marketable securities | — | 243 | 191 |
| Changes in operating assets and liabilities | | | |
| Accounts receivable | (1,033) | (1,384) | (677) |
| Inventory | (911) | (786) | (2,384) |
| Prepaid expenses and other current assets | 1,568 | (1,923) | (177) |
| Other non-current assets | — | (55) | — |
| Accounts payable | 1,349 | 143 | 413 |
| Accrued and other current liabilities | 1,537 | 1,034 | 441 |
| Deferred rent | 105 | 2,910 | — |
| Net cash used in operating activities | (31,165) | (19,818) | (13,897) |
| Cash flows from investing activities | | | |
| Purchases of property and equipment | (3,748) | (6,791) | (468) |
| Purchases of marketable securities | — | (17,510) | (2,156) |
| Sales of marketable securities | — | 17,270 | — |
| Maturities of marketable securities | — | 850 | 18,120 |
| Change in restricted cash | 35 | (1,090) | — |
| Net cash (used in) provided by investing activities | (3,713) | (7,271) | 15,496 |
| Cash flows from financing activities | | | |
| Proceeds from issuance of long-term debt, net of issuance costs | — | — | 2,500 |
| Proceeds from issuance of long-term debt -related party, net of issuance costs | 5,000 | 9,800 | — |
| Payments of long-term debt | — | (2,500) | (3,016) |
| Proceeds from issuance of common stock upon exercise of stock options | 139 | 78 | 65 |
| Payments to repurchase early exercised common stock | (1) | — | — |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | 22,769 | 20,806 | — |
| Proceeds from issuance of common stock upon Initial Public Offering, net of issuance costs | 47,219 | — | — |
| Net cash provided by (used in) financing activities | 75,126 | 28,184 | (451) |
| Net increase in cash and cash equivalents | 40,248 | 1,095 | 1,148 |
| Cash and cash equivalents, beginning of year | 6,048 | 4,953 | 3,805 |
| Cash and cash equivalents, end of year | $46,296 | $6,048 | $4,953 |

| | | | |
|---|---|---|---|
| Supplemental disclosures of cash flow information | | | |
| Interest paid | $— | $275 | $165 |
| Interest paid to related party | $1,740 | $1,052 | $— |
| Non-cash investing and financing activities | | | |
| Purchases of property and equipment in accounts payable and accrued liabilities | $78 | $1,462 | $31 |
| Initial public offering costs in accounts payable and accrued liabilities | $— | $30 | $-— |
| Reclassification of preferred stock to warrant liability to additional paid in capital | $608 | $— | $— |
| Conversion of convertible preferred stock into common stock and additional paid in capital | $96,524 | $— | $— |

The accompanying notes are an integral part of these financial statements.

INVUITY, INC.

Notes to Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Invuity, Inc. (the "Company"), was incorporated in the state of California on November 29, 2004 and reincorporated in Delaware in May 2015. The Company is a commercial-stage medical technology company which utilizes its proprietary Intelligent Photonics technology to develop single-use and reusable illuminated surgical devices, which provide surgeons with illumination and direct visualization of surgical cavities during open minimally invasive and minimal access procedures. The Company's facilities are located in San Francisco, California.

Reverse Stock Split

In May 2015, the Company's board of directors and its stockholders approved an amendment to the Company's amended and restated articles of incorporation to effect a reverse split of shares of the Company's common stock on a 1-for-18.5 basis (the "Reverse Stock Split"). All authorized, issued and outstanding shares of common stock, convertible preferred stock, warrants for common stock and preferred stock, options to purchase common stock and the related per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on May 27, 2015.

Initial Public Offering

In June 2015, the Company completed an initial public offering ("IPO") of its common stock. In connection with its IPO, the Company sold 4,600,000 shares of common stock at $12.00 per share for aggregate net proceeds of $47.2 million after underwriting discounts and commissions and offering costs incurred by the Company. These amounts include the exercise in full by the underwriters of their option to purchase up to 600,000 additional shares of common stock at the same price to cover over-allotments. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 7,979,332 shares of common stock.

Upon the effectiveness of the Amended and Restated Certificate of Incorporation of the Company on June 18, 2015, the number of shares of capital stock the Company is authorized to issue was increased to 110,000,000 shares, of which 100,000,000 shares are common stock and 10,000,000 shares are preferred stock. Both the common stock and preferred stock have a par value of $0.001 per share. There are no shares of preferred stock outstanding at December 31, 2015.

Liquidity

The Company has incurred net losses from operations since inception and has an accumulated deficit of $105.6 million as of December 31, 2015. The Company expects to incur additional losses and negative cash flows for the foreseeable future. Management believes that its cash and cash equivalents at December 31, 2015 and additional borrowings available under the its accounts receivable credit facility entered into in February 2015 will provide

sufficient funds to enable the Company to meet its operating plan through at least the next twelve months. However, if the Company's anticipated operating results are not achieved in future periods, additional debt or equity financing may need to be raised, or planned expenditures may need to be reduced.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP).

Reclassifications

Certain prior year amounts in the financial statements and notes thereto have been reclassified where necessary to conform to the current presentation. These reclassifications did not affect the prior period's balance sheet, net loss or net cash used in operating activities.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, fair value of assets and liabilities, inventory, income taxes, common stock, and stock-based compensation. Actual results could differ from those estimates and assumptions.

Out-of-period and Other Adjustments

During the three months ended June 30, 2015, the Company recorded an out-of-period adjustment to reverse revenue that the Company had originally recorded in the fourth quarter of 2014 associated with sales to a distributor for military facilities. The correction of this error resulted in an increase to the Company's net loss of $302,000 for the year ended December 31, 2015 and a corresponding decrease to accounts receivable. The distributor has returned the underlying inventory, and the Company has terminated the relationship with the distributor involved, and started working with a new distributor for military accounts. Management has assessed the impact of the adjustment and does not believe the amount is material to any prior period financial statements, and the impact of correcting the error in the twelve months ended December 31, 2015 is not material to those financial statements. As a result, the Company has not restated any prior period amounts.

During the three months ended March 31, 2015, the Company recorded an out-of-period adjustment to increase the fair value of the convertible preferred stock warrant liability, which was incorrectly valued at December 31, 2014 due to an error in the expected term assumption. The correction of this error resulted in an increase to the Company's net loss of $370,000 for the three months ended March 31, 2015 and a corresponding increase to the convertible preferred stock warrant liability. Management has assessed the impact of the adjustment and does not believe that the amount is material to any prior period financial statements, and the impact of correcting the error in the three months ended March 31, 2015 is not material to those financial statements and is not material to the financial statements for the year ended December 31, 2015. As a result, the Company has not restated any prior period amounts.

During the three months ended March 31, 2015, the Company determined that expenses relating to research and development in 2014 had been incorrectly classified within selling, general and administrative expenses, due to an erroneous allocation of departmental expenses. The Company has revised the statement of operations for the year ended December 31, 2014 to correct the classification, which resulted in an increase to research and development expenses of $564,000, with a corresponding decrease to selling, general and administrative expenses. Management has assessed the impact of the correction and has concluded that it is not material to the previously issued statement of operations for the year ended December 31, 2014.

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consist primarily of amounts invested in money market funds.

Restricted Cash

Restricted cash represents a certificate of deposit held at a financial institution as collateral for the Company credit cards and a letter of credit related to the Company's facility lease.

Short-Term Investments

All short-term investments are classified as "available-for-sale" and carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income (expense), net, respectively, and are derived using the specific identification method for determining the cost of securities sold. Interest on available-for-sale securities is included in interest and other income (expense), net. Unrealized gains and losses and realized gains and losses on sale of short-term investments were not material for the years ended December 31, 2015, 2014 and 2013. The Company did not hold any short-term investments as of either December 31, 2015 and 2014.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company generally does not require collateral or other security in support of accounts receivable. Allowances are provided for individual accounts receivable when the Company becomes aware of a customer's inability to meet its financial obligations, such as in the case of bankruptcy, deterioration in the customer's operating results or change in financial position. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. The Company also considers broad factors in evaluating the sufficiency of its allowance for doubtful accounts, including the length of time receivables are past due, significant one-time events, creditworthiness of customers and historical experience. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote.

The allowance for doubtful accounts balance was $158,000, and $98,000 as of December 31, 2015 and 2014, respectively. The Company has written off $165,000, 0, and 0 as uncollectible accounts receivables to the allowance for doubtful accounts during the twelve months ended December 31, 2015, 2014, and 2013, respectively.

Fair Value of Financial Instruments

Carrying amounts of the Company's financial instruments, including cash equivalents, short-term investments, accounts receivable, and accounts payable approximate fair value due to their relatively short maturities. As of December 31, 2015 and 2014, based on Level 2 inputs and the borrowing rates available to the Company for loans with similar terms and consideration of the Company's credit risk, the carrying value of the Company's long-term debt approximates its fair value.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk at December 31, 2015 and 2014 consist primarily of cash, which is held primarily by one domestic financial institution and exceeds federally insured limits, and cash equivalents. The Company manages its liquidity risk by investing in a variety of money market funds and corporate debt. This diversification of investments is consistent with the Company's policy to maintain liquidity and ensure the ability to collect principal. All investments are made pursuant to corporate investment policy guidelines which restrict investments to issuers evaluated as creditworthy.

Significant customers are those which represent 10% or more of the Company's total revenue or net accounts receivable balance at each respective balance sheet date. For each significant customer, revenue as a percentage of total revenue and accounts receivable as a percentage of net accounts receivable are as follows:

| | Revenue | | Accounts Receivable, net | |
|---|---|---|---|---|
| | Year Ended December 31, | | December 31, | |
| | 2015 | 2014 | 2015 | 2014 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Customers: | | | | | | |
| Customer A | * | 12 | % | * | 12 | % |
| Customer B | * | * | | * | 12 | % |

*Less than 10%

Inventory

Inventories are stated at the lower of cost or market (estimated net realizable value). Cost is determined using the standard cost method, which approximates the first-in, first out basis. The Company periodically assesses the recoverability of all inventories, including raw materials and finished goods, to determine whether adjustments to the carrying value are required. Inventory that is obsolete or in excess of forecasted usage is written down to its estimated net realizable value based on assumptions about future demand and market conditions. Inventory write-downs are charged to cost of goods.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is provided using the straight-line method over the estimated useful lives of the respective assets. The estimated useful lives of the Company's assets are as follows:

| | |
|---|---|
| Laboratory equipment | 3 years |
| Leasehold improvements | Shorter of lease term or estimated life of the assets |
| Furniture and fixtures | 3 years |
| Computer equipment and software | 2 to 3 years |
| Manufacturing equipment | 5 years |

Maintenance and repairs that do not extend the life or improve the asset are expensed when incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (or asset group) may not be recoverable. An impairment loss is recognized when the total of estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. The Company has not recorded impairment charges on long-lived assets for the periods presented in these financial statements.

Convertible Preferred Stock Warrant Liability

Freestanding warrants for shares that were contingently redeemable were classified as liabilities on the balance sheet at their estimated fair value because the shares underlying the warrants may obligate the Company to transfer assets to the holders at a future date under certain circumstances such as a deemed liquidation event. The warrants were subject to re-measurement at each balance sheet date and the change in fair value, if any, was recognized as interest and other income (expense), net in the statements of operations. The Company adjusted the liability for changes in fair value until the completion of its IPO, at which time all convertible preferred stock warrants were converted into warrants to purchase common stock and the liability was reclassified to additional paid-in capital.

Other Comprehensive Income (Loss)

Other comprehensive income (loss) represents all changes in stockholders' equity except those resulting from distributions to stockholders. The Company's unrealized loss on short-term available-for-sale securities represent the components of other comprehensive income (loss) that are excluded from the reported net loss and are presented in the statements of comprehensive loss.

Revenue Recognition

The Company's revenue is generated from the sale of its products to hospitals and medical centers through direct sales representatives and independent sales agents. The Company recognizes revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- the sales price is fixed or determinable;
- collection of the relevant receivable is reasonably assured at the time of sale; and
- delivery has occurred or services have been rendered.

The Company recognizes revenue when title to the goods and risk of loss transfers to the customer, which is upon shipment of the product under the Company's standard terms and conditions. Shipping and handling costs billed to the customer are recorded in revenue.

Warranty Obligations

The Company does not offer rights of return or price protection and has no post-delivery obligations other than its standard warranty which entitles the customer to return defective products for a period of one year after sale. The warranty liability was $35,000 as of December 31, 2015. Prior to 2015, there was no warranty liability. Historical warranty costs have been insignificant.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Medical Device Excise Tax

In March 2010 the Affordable Care Act (the ACA) was signed into law which included a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. Subsequently, this excise tax was suspended effective January 1, 2016.

Research and Development

The Company's research and development costs are expensed as incurred. Research and development costs includes but are not limited to, payroll and personnel-related expenses, including stock-based compensation, laboratory supplies, consulting costs, and allocated facilities and information services costs.

Income Taxes

The Company accounts for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when, in management's estimate, it is more likely than not that the deferred tax asset will not be realized.

The tax effects of the Company's income tax positions are recognized only if they are more likely than not to be sustained based solely on the technical merits as of the reporting date. The Company considers many factors when evaluating and estimating its tax positions and benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes.

Stock-based Compensation

The Company measures its stock-based awards made to employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based compensation expense for options granted to non-employees as consideration for services received is measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, using the Black-Scholes option-pricing model, whichever can be more reliably measured. Compensation expense for options granted to non-employees is periodically remeasured as the underlying options vest.

Segment Reporting

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. All of the Company's assets are maintained in the United States. The Company derives its revenue from sales to customers in the United States, based upon the billing address of the customer.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per common share is the same as basic net loss per common share since the effect of potentially dilutive securities are anti-dilutive. Shares subject to repurchase are excluded from the weighted-average shares.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern. The new standard provides guidance around 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. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company’s financial statements.

INVUITY, INC.

Notes to Financial Statements—(Continued)

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which permits companies to measure inventory at the lower of cost and realizable value. ASU 2015-11 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted. The Company is in the process of evaluating whether the adoption of ASU 2015-11 will have a material effect on its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which 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 the related debt liability, consistent with debt discounts. ASU 2015-03 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. The Company does not expect that the adoption of ASU 2015-03 will have a material effect on its financial statements.

In August 2015, the FASB issued ASU No. 2015-15, Interest—Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements—Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting, which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. The Company does not expect that the adoption of ASU 2015-03 will have a material effect on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires 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. In August 2015, FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes to simplify the presentation of deferred income taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The Company has elected to early adopt ASU 2015-17 as of the beginning of our fourth quarter ended December 31, 2015 on a prospective basis. There was no impact to the Company’s balance sheet as a result of the early adoption.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its financial statements.

In February 2016, the FASB issued ASU 2016-02 - Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840 Leases. The standard is effective on January 1, 2019, with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance.

3. FAIR VALUE MEASUREMENTS

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the

INVUITY, INC.

Notes to Financial Statements—(Continued)

highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The Company's financial instruments consist of Level 1 and 2 assets and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist primarily of highly liquid money market funds that are included in cash, cash equivalents, and restricted cash. At December 31, 2014, the Company's Level 3 liabilities consist of the convertible preferred stock warrant liability. The determination of the fair value of the convertible preferred stock warrant liability is discussed in Note 8. Generally, increases or decreases in the fair value of the underlying convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability.

The following table sets forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

| | December 31, 2015 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets | | | | |
| Money market funds | $44,750 | $ — | $ — | $44,750 |
| | $44,750 | $ — | $ — | $44,750 |

| | December 31, 2014 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets | | | | |
| Money market funds[(a)] | $5,678 | $ — | $— | $5,678 |
| | $5,678 | $ — | $— | $5,678 |
| Liabilities | | | | |
| Convertible preferred stock warrant liability | $— | $ — | $136 | $136 |
| | $— | $ — | $136 | $136 |

The following table sets forth a summary of the changes in the fair value of the convertible preferred stock warrant liability, the Company's Level 3 financial liability, which is measured on a recurring basis (in thousands):

| | 2015 | 2014 |
|---|---|---|
| Beginning balance | $136 | $86 |
| Issuance of convertible preferred stock warrants | — | 572 |
| Change in fair value recorded in interest and other income (expense), net | (136) | (522) |
| Ending balance | $- | $136 |

INVUITY, INC.

Notes to Financial Statements—(Continued)

4. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Raw materials | $1,000 | $894 |
| Work-in-process | 798 | 768 |
| Finished goods | 3,384 | 2,609 |
| Total inventory | $5,182 | $4,271 |

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Prepaid expenses | $907 | $420 |
| Tenant improvement allowance receivable | — | 2,064 |
| Other | 16 | 2 |
| Total prepaid expenses and other current assets | $923 | $2,486 |

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Computer equipment and software | $1,341 | $633 |
| Laboratory and manufacturing equipment | 1,544 | 816 |
| Furniture and fixtures | 1,445 | 1,409 |
| Leasehold improvements | 7,106 | 6,541 |
| Total property and equipment, gross | 11,436 | 9,399 |

| | | |
|---|---|---|
| Less: accumulated depreciation and amortization | (2,241) | (858) |
| Total property and equipment, net | $9,195 | $8,541 |

Depreciation and amortization expense was $1.7 million, $0.3 million, and $0.2 million during the years ended December 31, 2015, 2014, and 2013 respectively.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Accrued payroll-related expenses | $3,052 | $1,599 |
| Accrued independent sales agent commissions | 158 | 227 |
| Accrued professional fees | 373 | 89 |
| Accrued costs for property and equipment | — | 1,453 |
| Accrued sales and marketing expenses | 45 | 95 |
| Deferred rent, current | 261 | 290 |
| Other | 325 | 409 |
| Total accrued and other current liabilities | $4,214 | $4,162 |

5. RELATED PARTY LOAN AGREEMENT

In February 2014, the Company entered into a loan agreement with HealthCare Royalty Partners ("HCRP"), a related party due to its equity ownership interest in the Company, and drew down the first tranche of $10.0 million. The second tranche associated with HCRP, of $5.0 million, was drawn down in March 2015.

Interest is payable quarterly at a fixed rate of 12.5% per annum with interest-only payments to be made from the effective date of the loan until March 31, 2017. Thereafter, the Company will make principal and interest payments until the maturity of the loan on December 31, 2020. The Company is permitted to make a voluntary prepayment in full, but not in part, prior to December 31, 2020, which prepayment must be made together with accrued and unpaid fixed interest on the amount prepaid and any additional amounts due in respect thereof, including an additional percentage of the aggregate loan amount or outstanding principal amount, depending on the date of prepayment. The Company's obligations under the loan agreement are secured by a first priority security interest in all of the Company's assets, other than bank accounts, accounts receivable and inventory. The loan agreement imposes customary affirmative and restrictive covenants, including with respect to fundamental transactions, the incurrence of additional indebtedness or liens and the payment of cash dividends, but does not include any financial covenants. The loan agreement contains a material adverse event clause which provides that an event of default will occur if, among other triggers, there occurs any circumstance that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on the Company's ability to perform its obligations under the loan. The Company recorded interest expense of $1.8 million and $1.1 million on the loan, for the year ending December 31, 2015 and 2014, respectively.

As of December 31, 2015 and 2014, management does not believe that it is probable that the clause will be triggered within the next twelve months, and therefore the debt is classified as long-term. The loan agreement also includes customary representations and warranties, events of defaults and termination provisions. As of December 31, 2015

and 2014, the Company was in compliance with all covenants.

In connection with the loan agreement, the Company issued HCRP a warrant to purchase 84,553 shares of Series E convertible preferred stock at $13.3052 per share. The warrant was recorded on the balance sheet on the date of issuance at its fair value of $572,000 and recorded as a reduction in the carrying value of the debt. Upon completion of the IPO in June 2015, this warrant automatically converted into a warrant to purchase 86,891shares of common stock and the liability was reclassified to additional paid-in capital. The Company also paid $200,000 in debt issuance costs to HCRP, which were recorded as a debt discount. The total debt discount is being amortized as interest expense in the straight-line method over the term of the loan.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Future payments due under the Company's loan agreements as of December 31, 2015 are as follows (in thousands):

| | |
|---|---|
| Year ending December 31 | |
| 2016 | 1,874 |
| 2017 | 3,305 |
| 2018 | 4,547 |
| 2019 | 5,601 |
| Thereafter | 6,469 |
| | 21,796 |
| Less: Amount representing interest | (6,796 ) |
| Less: Amount representing debt discount | (520 ) |
| | $14,480 |

6. DEBT

In December 2010, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB") whereby the Company may borrow funds via a series of term loans. In July 2013, the Company entered into the first amendment to the loan and security agreement with SVB. The Company repaid the outstanding balance of $1.9 million on the original loan, including accrued interest, and drew down a new term loan ("Tranche III") in the amount of $2.5 million. Pursuant to the Tranche III loan agreement, the Company made interest-only payments at a stated rate of 6% per annum for the first eleven months from the funding date. Thereafter, the Company was obligated to pay monthly cash payments of principal and interest for a 30-month period with a balloon payment at maturity which was accreted as interest expense over the term of the loan. The Company was subject to a prepayment penalty equal to 2% of the outstanding principal amount at the prepayment date if the loan was prepaid on or before 18 months after its funding date. The loan balance of $ 2.7 million principal and interest was repaid in February 2014 in connection with the Company entering into a new loan agreement with HCRP (See Note 5 – Related Party Loan Agreement).

In connection with Tranche III, in July 2013, the Company granted SVB a warrant to purchase 11,294 shares of Series D convertible preferred stock at $12.395 per share. The warrant was recorded on the balance sheet on the date of issuance at its fair value of $23,000 and recorded as a reduction in the carrying value of the debt. This debt discount was initially amortized to interest expense over the term of the agreement, resulting in an effective interest rate of approximately 13.3% per annum, until the repayment of Tranche III in February 2014 at which time the remaining unamortized balance of the debt discount of $19,000 was recognized in interest expense, together with a prepayment penalty of $50,000 and the unamortized portion of the balloon interest payment of $143,000. Upon completion of the IPO on June 2016, all convertible preferred warrants automatically converted into warrants to purchase shares of common stock and the liability was reclassified to additional paid-in capital.

In February 2015, the Company entered into an accounts receivable credit facility with Silicon Valley Bank (SVB) that permits the borrowing of the lesser of $7.5 million or an amount representing up to 80% of eligible accounts receivable. The credit facility matures in February 2018 and the Company's obligations under the credit facility are secured by a first priority security interest in the Company's bank accounts, accounts receivable, and inventory. Interest on borrowed amounts is payable monthly at the prime rate plus 0.75%. The credit facility imposes cusomary affirmative and restrictive covenants, including with respect to fundamental transactions, changes to the Company's business, the incurrence of additional indebtedness or liens and the payment of dividends, but does not include any financial covenants. In addition, the credit facility states that if the Company maintains a net cash balance, defined as unrestricted cash held with SVB less any borrowings on the revolving line of credit, of more than $3.0 million, then all collections will be deposited in the Company's operating account. If the net cash balance is below $3.0 million, then all collections will be held in an SVB-controlled account and applied to reduce the loan balance. The credit facility also includes customary representations and warranties, events of defaults and termination provisions. As of December 31, 2015, the Company has not drawn down on the credit facility.

7. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases manufacturing and office space in San Francisco, California, under a non-cancelable operating lease entered into in May 2014. The lease commencement date was November 1, 2014 and the lease expires on October 31, 2024. At the inception of the

INVUITY, INC.

Notes to Financial Statements—(Continued)

lease, the Company provided the landlord with a security deposit of $1.1 million in the form of an irrevocable letter of credit, which was recorded in restricted cash on the balance sheet at both December 31, 2015 and December 31, 2014.

Rent expense is recognized on a straight-line basis over the term of the leases and accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Incentives granted under the Company's facilities leases, including allowances to fund leasehold improvements, are deferred and are recognized as adjustments to rental expense on a straight-line basis over the term of the lease. The Company is entitled to a $2.6 million tenant allowance in connection with the lease entered into in November 2014. The Company has utilized the entire $2.6 million allowance in connection with the qualified costs as of December 31, 2014 and was fully reimbursed by the landlord as of December 31, 2015. The allowance has been recorded in our balance sheet as a leasehold improvement and is being amortized over the term of the lease as a reduction to rent expense.

The following table summarizes the Company's future minimum lease payments as of December 31, 2015 (in thousands):

| Year ending December 31: | |
|---|---|
| 2016 | $2,053 |
| 2017 | 2,114 |
| 2018 | 2,178 |
| 2019 | 2,243 |
| 2020 | 2,310 |
| Thereafter | 9,511 |
| Total | $20,409 |

The Company's rent expense was $2.0 million, $0.6 million and $0.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. Management is currently not aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not

determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Deleware corporate law. The Company currently has directors' and officers' insurance. To date, the Company has not paid any claims, and the Company believes that the estimated fair value of these indemnification obligations is minimal and it has not accrued any amounts for these obligations.

8. WARRANTS

Common Stock Warrants

In March 2010, the Company issued a warrant to purchase 3,532 shares of common stock at an exercise price of $1.30 per share to a third party in exchange for recruiting services. The Company recorded the warrants in equity at their fair value of $3,000 on the date of issuance using the Black-Scholes option-pricing model. The warrant was fully exercisable upon grant and expired upon our initial public offering in June 2015.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Preferred Stock Warrants

In conjunction with various financings between 2008 and 2014, the Company issued warrants to purchase 130,540 shares of convertible preferred stock. The relative fair value of these warrants was determined using the Black-Scholes model and was amortized to interest expense over the term of each loan, unless subsequently modified. All convertible preferred stock warrants were classified as liabilities on the balance sheet at their estimated fair value because the shares underlying the warrants could obligate the Company to transfer assets to the holders at a future date under certain circumstances such as a deemed liquidation event. The warrants were subject to re-measurement at each balance sheet date and the change in fair value, if any, was recognized as interest and other income, net in the statements of operations and comprehensive loss. The Company adjusted the liability for changes in fair value until the completion of its IPO, at which time all convertible preferred stock warrants were converted into137,007 warrants to purchase common stock and the liability was reclassified to additional paid-in capital.

The Company recorded a (loss) / gain of $(472,000), $522,000 and $168,000 during the years ended December 31, 2015, 2014, and 2013, respectively, relating to the change in fair value of the convertible preferred stock warrant liability.

9. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

Convertible Preferred Stock

In February and March 2015, the Company issued an aggregate of 1,596,212 shares of Series F convertible preferred stock. Upon the closing of the Company's IPO in June 2015, all 7,652,615 shares of convertible preferred stock then outstanding converted into 7,979,332 shares of common stock, which includes an aggregate of 326,717 additional shares of common stock related to anti-dilution adjustments upon conversion of the convertible preferred stock.

10. STOCK OPTION PLANS

In April 2015, the Company's board of directors approved the 2015 Equity Incentive plan ("2015 Plan"), effective June 11, 2015, covering incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), restricted stock, restricted stock awards ("RSU"), stock appreciation rights and performance units that may be granted to employees, directors and consultants. In connection with the approval of the 2015 Plan, all remaining shares available for future award under the 2005 Stock Option Plan (the "2005 Plan") were transferred to the 2015 Plan, and the 2005 Plan was terminated. The number of shares initially authorized for issuance under the 2015 Plan was 1,494,272 plus 169,529 shares remaining available for future awards under the Company's 2005 Plan. Any options under the 2005 Plan or 2015 Plan (collectively "the Plans") that expire or otherwise terminate will revert to the 2015 Plan and again become available for issuance.

The number of shares available for issuance under the 2015 Plan will be increased on the first day of each fiscal year in an amount equal to the lessor of (i) 1,494,272 shares; (ii) five percent of the outstanding shares on the last day of the immediately preceding fiscal year or (iii) such number of shares determined by the Company's board of directors. ISOs may be granted to employees or directors holding more than 10% of the voting power of all classes of stock of the Company at an exercise price of no less than 110% of the fair value of the common stock on the grant date and to all other employees or directors at an exercise price of no less than 100% of the fair value of the common stock on the grant date. NSOs may be granted to employees, directors and consultants at an exercise price no less than 100% of the fair value of the common stock on the grant date. Employee stock options under the 2015 plan generally vest 20% upon one year of continued service to the Company, with the remainder in monthly increments over four additional years. Options expire no more than ten years after the date of grant.

The Company's Board of Directors and stockholders previously approved the 2005 Plan. Pursuant to the 2005 plan, options and restricted stock may be granted to employees, directors and consultants of the Company. Options granted under the Company's 2005 plan may be either incentive stock options or nonstatutory stock options. ISOs may be granted to employees with exercise prices of no less than 100% the fair value of the common stock on the grant date and NSOs may be granted to employees, directors or consultants at exercise prices of no less than 85% of the fair value of the common stock on the grant date, as determined by the Board of Directors. All options granted under the 2005 plan may be exercised before they are vested. Employee stock options granted under the 2005 plan generally vest 25% upon one year of continued service to the Company, with the remainder in monthly increments over three additional years. Stock options granted to consultants generally vest over the performance period of the consultancy agreement, ranging from two to four years. Options expire no more than ten years after the date of grant.

As of December 31, 2015, there were 3,445,228 shares authorized for issuance under the Plans of which 1,406,439 were available for grant. In the event of stock splits and stock dividends, the Board of Directors may increase or decrease proportionately the number of

INVUITY, INC.

Notes to Financial Statements—(Continued)

shares and the exercise (purchase) price per share deliverable to the 2015 Plan participants. In the event of a merger in which the Company is not the surviving entity or sale of substantially all the Company's assets, all outstanding options must be either assumed or substituted by the surviving corporation, or may be required to be exercised or settled.

The following table summarizes stock option activity and related information:

| | | Options Outstanding | | |
|---|---|---|---|---|
| | Options Available for Grant | Options Outstanding | Weighted-Average Exercise Price Per Share | Aggregate Intrinsic Value (in thousands) |
| Balances at December 31, 2014 | 315,876 | 1,379,503 | $ 2.57 | $ 9,483 |
| Options authorized | 1,852,097 | — | | |
| Options granted | (865,976 ) | 865,976 | $ 12.57 | |
| Options exercised | — | (102,250 ) | $ 1.39 | |
| Options forfeited | 104,442 | (104,442 ) | $ 6.17 | |
| Balances at December 31, 2015 | 1,406,439 | 2,038,787 | $ 6.69 | $ 7,504 |
| Options exercisable—December 31, 2015 | | 975,314 | $ 3.28 | $ 5,660 |
| Options vested and expected to vest—December 31, 2015 | | 1,929,208 | $ 6.42 | $ 7,409 |

The intrinsic value is the difference between the estimated fair value of the Company's common stock at the date of exercise and the exercise price for in-the-money options. The aggregate intrinsic value of options exercised was $796,000, 310,000, and $24,000 for the years ended December 31, 2015, 2014, and 2013 respectively. The weighted-average grant-date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was $4.82, $5.99, and $4.32 per share, respectively.

As of December 31, 2015 and 2014, the weighted-average remaining contractual life of options outstanding was 7.8 years and for options vested and expected to vest, was 7.7 years, respectively.

The options outstanding, vested and currently exercisable by exercise price under the 2015 Plan at December 31, 2015 are as follows:

| | Options Outstanding | | Options Exercisable | |
|---|---|---|---|---|

| Exercise Price | Number of Options | Weighted-Average Remaining Contractual Life (years) | Weighted-Average Exercise Price Per Share | Number of Options | Weighted-Average Exercise Price Per Share |
|---|---|---|---|---|---|
| $ 1.30 | 300,733 | 4.7 | $ 1.30 | 300,733 | $ 1.30 |
| $1.48-2.78 | 71,748 | 6.0 | $ 2.01 | 68,343 | $ 1.98 |
| $ 3.15 | 831,426 | 7.5 | $ 3.15 | 510,397 | $ 3.15 |
| $4.81-11.09 | 107,818 | 9.5 | $ 10.23 | 19,504 | $ 8.39 |
| $ 11.10 | 336,160 | 9.1 | $ 11.10 | 63,991 | $ 11.10 |
| $11.96-14.25 | 241,218 | 9.8 | $ 13.54 | 770 | $ 12.49 |
| $ 15.91 | 149,686 | 9.4 | $ 15.91 | 11,576 | $ 15.91 |
| | 2,038,789 | 7.8 | $ 6.69 | 975,314 | $ 3.28 |

Early Exercise of Stock Options

The 2005 Plan allowed for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser’s employment or services, at the price paid by the purchaser. The Company’s right to repurchase these shares generally lapses 1/48 of the original grant date amount per month over four years. At December 31, 2015 and 2014, there were 8,648 and 17,566 shares of common stock outstanding, respectively, subject to the Company’s right of repurchase at a weighted-average price of $2.49 and $2.34 per share, respectively.

INVUITY, INC.

Notes to Financial Statements—(Continued)

Employee Stock-Based Compensation

Stock-based compensation expense recognized during the years ended December 31, 2015, 2014, and 2013, includes compensation expense for stock-based awards granted to employees based on the grant date fair value of $1.1 million, $0.6 million, and $0.3 million respectively.

As of December 31, 2015 and 2014, there were total unamortized compensation costs of $4.1 million and 2.0 million, respectively related to unvested stock options which the Company expects to recognize over a period of approximately 3.6 years and 3.0 years, respectively.

On April 30, 2014, the Company modified the terms of 348,871 vested and unvested stock option awards by reducing their exercise price from $4.81 to $3.15 per share. There was no change in any of the other terms of the option awards. The modification resulted in an incremental value of $226,000 being allocated to the options, of which $158,000 was recognized to expense immediately based on options that were vested at the time of the modification. The remaining incremental value of $68,000 attributable to unvested shares is being recognized over their remaining vesting term of which 49,000 is still unvested as of December 31, 2015.

The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. Prior to our IPO, the fair value of the shares of the Company's common stock underlying the stock options has historically been determined by the Company's Board of Directors. Because there had been no public market for the Company's common stock, its Board of Directors has determined the fair value of the Company's common stock at the time of grant of the option by considering a number of objective and subjective factors, including the Company's stage of development, sales of the Company's convertible preferred stock, the Company's operating and financial performance, equity market conditions affecting comparable public companies, the lack of liquidity of the Company's capital stock, and the general and industry-specific economic outlooks.

Since our IPO in June 2015, the fair value of our common stock is based on the closing price of our common stock, as quoted on the NASDAQ Global Market, on the date of grant. In addition to the value determined by our board and closing price on NASDAQ Global Market, the fair value is estimated using the assumptions below. Each of these inputs is subjective and its determination generally requires significant judgment.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Expected term (in years) | 5.0 – 6.0 | 6.0 | 6.0 |
| Expected volatility | 35 – 50% | 35 – 38% | 43% |

| | | | |
|---|---|---|---|
| Risk-free interest rate | 1.31 – 1.89% | 1.80% – 1.93% | 1.08% – 1.82% |
| Dividend yield | 0% | 0% | 0% |

Expected Term. The expected term of stock-based awards represents the weighted-average period that the stock-based awards are expected to remain outstanding. The Company opted to use the “simplified method” for estimating the expected term of the awards, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the awards.

Expected Volatility. The Company determined the share price volatility for stock-based awards based on an analysis of the historical volatilities of a peer group of publicly traded medical device companies. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the stock-based awards.

Dividend Rate. The expected dividend was assumed to be zero as the Company has never paid dividends and has no current plans to do so.

Expected Forfeiture Rate. The Company is required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual

INVUITY, INC.

Notes to Financial Statements—(Continued)

forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.

Non-Employee Stock-Based Compensation

Stock-based compensation expense related to non-employee awards was $103,000, $57,000 and $13,000 during the years ended December 31, 2015, 2014, and 2013, respectively.

Total Stock-Based Compensation

The following table summarizes total stock-based compensation expense for the years ended December 31, 2015, 2014, and 2013, which was included in the statements of operations as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Cost of goods sold | $89 | $23 | $4 |
| Selling, general and administrative | 860 | 547 | 233 |
| Research and development | 300 | 93 | 42 |
| Total stock-based compensation expense | $1,249 | $663 | $279 |

11. INCOME TAXES

The Company has incurred net operating losses for the years ended December 31, 2015, 2014 and 2013, therefore has no provision for income taxes recorded for such years. For the years ended December 31, 2015, 2014 and 2013, the Company generated losses before taxes in the United States of $37.6 million, $20.7 million and $12.1 million, respectively and no foreign income or losses. The Company's deferred tax assets are offset by a full valuation allowance.

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Tax at statutory federal rate | 34.0 % | 34.0 % | 34.0 % |
| State taxes, net of federal benefit | 0.4 | 3.8 | 4.9 |
| Tax credits | 0.9 | 1.3 | 1.0 |
| Change in valuation allowance | (33.9) | (37.8) | (40.1) |
| Other | (1.4 ) | (1.3 ) | 0.2 |

| | | | |
|---|---|---|---|
| Provision for income taxes | 0.0 % | 0.0 % | 0.0 % |

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Deferred tax assets: | | | |
| Net operating loss carryforwards | $35,474 | $23,574 | $17,364 |
| Research and development | 986 | 782 | 626 |
| Accrued liabilities and other | 935 | 590 | 509 |
| Stock-based compensation | 485 | 259 | 194 |
| Fixed assets | 219 | 100 | 95 |
| Tenant improvement allowance | 836 | 970 | — |
| Total deferred tax assets | 38,935 | 26,275 | 18,788 |
| Valuation allowance | (38,935) | (26,275) | (18,788) |
| Net deferred tax assets | $— | $— | $— |

INVUITY, INC.

Notes to Financial Statements—(Continued)

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $12.7million, $7.5 million and $4.9 million for the years ended December 31, 2015, 2014 and 2013, respectively, and there were no releases of the valuation allowance in these years.

As of December 31, 2015, the Company had net operating loss (“NOL”) carryforwards (before tax effects) for federal and state income tax purposes of $95.2 million and $60.9 million, respectively. These federal and state NOL carryforwards will begin to expire in 2026 and 2017, respectively, if not utilized. In addition, the Company has federal and state research and development tax credit carryforwards of $0.7 million and $0.9 million, respectively, to offset future income tax liabilities. The federal research and development tax credits will begin to expire in 2024, if not utilized, while the state research and development tax credit can be carried forward indefinitely.

Federal and California tax laws impose substantial restrictions on the utilization of net operating losses and credit carry-forwards in the event of an “ownership change” for tax purposes, as defined in Section 382 of the Internal Revenue Code. Due to ownership changes since inception, the Company’s net operating losses may be limited as to their usage. In the event the Company has additional changes in ownership, utilization of the carryforwards could be further restricted.

A reconciliation of the Company’s unrecognized tax benefits for the years ended December 31, 2015, 2014, and 2013 is as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Balance at beginning of year | $261 | $209 | $157 |
| Additions for tax positions taken in current year | 86 | 69 | 52 |
| Reductions for tax positions taken in prior years | (18 ) | (17 ) | — |
| Balance at end of year | $329 | $261 | $209 |

The unrecognized tax benefits, if recognized, would not have an impact on the Company’s effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. The Company does not expect a material change to its unrecognized tax benefits over the next 12 months.

The Company’s policy is to include interest and penalties related to unrecognized tax benefits within the provision for income taxes. Management determined that no accrual for interest and penalties was required as of December 31, 2015 and 2014, respectively.

The Company’s tax years 2005-2014 will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any NOL or research and development credits.

12. NET LOSS PER COMMON SHARE

The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2015, 2014, and 2013 (in thousands, except share and per share data):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Numerator: | | | |
| Net loss | $(37,570) | $(20,662) | $(12,109) |
| Denominator: | | | |
| Weighted-average common shares outstanding | 7,619,696 | 673,573 | 633,146 |
| Less: weighted-average unvested common shares subject to repurchase | (13,524) | (20,378) | (739) |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 7,606,172 | 653,195 | 632,407 |
| Net loss per common share, basic and diluted | $(4.94) | $(31.63) | $(19.15) |

INVUITY, INC.

Notes to Financial Statements—(Continued)

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares outstanding:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Convertible preferred stock on an as-converted basis | — | 6,246,196 | 4,648,382 |
| Options to purchase common stock | 2,038,789 | 1,379,503 | 911,403 |
| Warrants to purchase common stock | 137,007 | 3,532 | 3,532 |
| Warrants to purchase convertible preferred stock on an as-converted basis | — | 134,570 | 50,017 |
| Total | 2,175,796 | 7,763,801 | 5,613,334 |

SUPPLEMENTARY FINANCIAL DATA (unaudited)

The following table presents selected unaudited consolidated financial data for each of the eight quarters in the two-year period ended December 31, 2015. The selected quarterly financial data should be read in conjunction with the Company's consolidated financial statements and the related notes and "Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations." This information has been derived from the Company's unaudited consolidated financial statements that, in management's opinion, reflect all recurring adjustments necessary to fairly state this information when read in conjunction with the Company's financial statements and the related notes appearing in the section entitled " Financial Statements," Net loss per share-basic and diluted, for the four quarters of each fiscal year may not sum to the total for the fiscal year because of the different number of shares outstanding during each period. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future period.

| | Three Months Ended | | | |
|---|---|---|---|---|
| | December 31, 2015 | September 30, 2015 | June 30, 2015 | March 31, 2015 |
| Revenue | $6,246 | $5,595 | $4,748 | $4,442 |
| Gross profit | 4,119 | 3,561 | 2,898 | 2,720 |
| Loss from operations | (9,567) | (8,661) | (8,866) | (8,113) |
| Net loss | $(10,055) | $(9,138) | $(9,346) | $(9,031) |
| Net loss per common share, basic and diluted | $(0.76) | $(0.69) | $(3.20) | $(12.84) |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 13,307,031 | 13,292,849 | 2,919,823 | 703,637 |

| | Three Months Ended | | | |
|---|---|---|---|---|
| | December 31, 2014 | September 30, 2014 | June 30, 2014 | March 31, 2014 |
| Revenue | $4,409 | $3,724 | $2,817 | $2,153 |
| Gross profit | 3,010 | 2,430 | 1,588 | 1,445 |
| Loss from operations | (5,348) | (4,920) | (5,112) | (4,371) |
| Net loss | $(5,203) | $(5,290) | $(5,456) | $(4,713) |
| Net loss per common share, basic and diluted | $(7.78) | $(8.11) | $(8.40) | $(7.34) |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 669,202 | 651,959 | 649,511 | 641,810 |

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") refers to controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officers, as appropriate to allow timely decisions regarding required disclosure.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Previously Reported Material Weakness

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. As previously reported, we identified a material weakness in our internal control over financial reporting relating to a lack of effective controls to adequately restrict access and segregate duties. Specifically, certain personnel had the ability to prepare and post journal entries without an independent review performed by someone without this ability. The material weakness did not result in any material misstatements to our financial statements.

Remediation of the Material Weakness in Internal Control Over Financial Reporting

With the oversight of our audit committee, we took corrective steps during 2015 to remediate the underlying causes of the material weakness in our internal control over financial reporting, including the following:

- We amended accounting system access rights so that there are finance personnel without journal entry access who can perform financial statement review activities.
- We have formalized a control requiring financial personnel to review and approve journal entries independent of the person who prepared them.
- We are formalizing our internal control documentation and strengthening supervisory reviews by our management.
- We added additional accounting personnel and improved segregation of duties amongst accounting personnel.
- We have formalized a control requiring monthly management review of the access and permissions of all accounting system users.

As of December 31, 2015, management concluded the material weakness has been remediated.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.
The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

Compliance with Section 16(a) of the Exchange Act

The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.invuity.com. We intend to post on our website all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission or the NASDAQ Global Market concerning any amendment to, or waiver of, our code of business conduct and ethics.

Director Nominees

The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee that is required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee Financial Expert

Our board of directors has determined that William W. Burke is the audit committee’s financial expert within the meaning of the regulation of the SEC and is independent under the SEC and NASDAQ Global Market rules.

ITEM 11. EXECUTIVE COMPENSATION.
The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.
The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item will be set forth in our Proxy Statement for the 2016 Annual Meeting of Shareholders and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.
(a) The following documents are filed as part of this report:

1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

See Item 15(b) below.

(b) We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the Exhibit Index immediately following the Signatures page of this Annual Report on Form 10-K.

(c) See Item 15(a)2 above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Invuity, Inc.

Date: March 25, 2016 By: /s/ Philip Sawyer
Philip Sawyer

President and Chief Executive Officer

(Principal Executive Officer)

Date: March 25, 2016 By: /s/ James Mackaness
James Mackaness

Chief Financial Officer

(Principal Financial Officer and Chief Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Philip Sawyer and James Mackaness and each of them, any of whom may act without the joinder of the others, as his or her true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| Name | Title | Date |
|---|---|---|
| /s/ Philip Sawyer<br>Phillip Sawyer | President, Chief Executive Officer and Director | March 25, 2016 |
| /s/ Eric Roberts<br>Eric Roberts | Director | March 25, 2016 |

| | | |
|---|---|---|
| /s/ Reza Zadno<br>Reza Zadno | Director | March 25, 2016 |
| /s/ Randall Lipps<br>Randall Lipps | Director | March 25, 2016 |
| /s/ Gregory Lucier<br>Gregory Lucier | Director | March 25, 2016 |
| /s/ William Burke<br>William Burke | Director | March 25, 2016 |

EXHIBIT INDEX

| Exhibit Footnote | Exhibit Number | Exhibit Description |
|---|---|---|
| (2) | 3.1 | Amended and Restated Certificate of Incorporation |
| (2) | 3.2 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation |
| (2) | 3.3 | Amended and Restated Bylaws of the Registrant as currently in effect. |
| (1) | 4.1 | Specimen Common Stock certificate of the Registrant. |
| (1) | 4.2 | Fourth Amended and Restated Investor Rights Agreement, dated February 6, 2015, as amended on March 4, 2015, by and among the Registrant and certain of its stockholders. |
| (1) | 4.3 | Warrant to purchase shares of Series B convertible preferred stock issued to Lighthouse Capital Partners VI, L.P., dated September 15, 2008. |
| (1) | 4.4 | Warrant to purchase shares of Series C convertible preferred stock issued to Silicon Valley Bank, dated December 17, 2010. |
| (1) | 4.5 | Warrant to purchase shares of Series D convertible preferred stock issued to Silicon Valley Bank, dated July 25, 2013. |
| (1) | 4.6 | Warrant to purchase shares of Series E convertible preferred stock issued to HealthCare Royalty Partners II, L.P., dated February 28, 2014. |
| (1) | 10.1 | Form of Indemnification Agreement for directors and executive officers. |
| (1) | 10.2† | Invuity, Inc. 2005 Stock Incentive Plan and form of agreement thereunder. |
| (1) | 10.3† | Executive Incentive Compensation Plan of the Registrant. |
| (1) | 10.4† | 2015 Equity Incentive Plan and forms of agreements thereunder. |
| (1) | 10.5 | Lease, dated as of October 29, 2007, by and between the Registrant and Peter P. Tong, as amended on May 6, 2010, September 6, 2011 and November 10, 2012. (Terminated) |
| (1) | 10.6 | Office Lease Agreement, dated May 9, 2014, by and between the Registrant and 444 De Haro VEF VI, LLC, as amended on November 7, 2014. |
| (1) | 10.7 | Loan and Security Agreement, dated as of February 11, 2015, by and between the Registrant and Silicon Valley Bank. |
| (1) | 10.8 | |

| | | |
|---|---|---|
| | | Loan Agreement, dated as of February 28, 2014, by and between the Registrant and HealthCare Royalty Partners II, L.P., as amended on May 19, 2015 and May 28, 2015. |
| (1) | 10.9† | Executive Employment Agreement, dated May 15, 2015, by and between the Registrant and Philip Sawyer. |
| (1) | 10.10† | Executive Employment Agreement, dated May 19, 2015, by and between the Registrant and Doug Heigel. |
| (1) | 10.11† | Executive Employment Agreement, dated May 19, 2015, by and between the Registrant and Paul O. Davison. |
| | 10.12†* | Offer Letter to Susan Martin, dated May 22, 2015. |

| Exhibit Footnote | Exhibit Number | Exhibit Description |
|---|---|---|
| | 10.13†* | Executive Employment Agreement, dated July 28, 2015, by and between the Registrant and James Mackaness. |
| | 23.1* | Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm. |
| | 24.1* | Power of Attorney (included in signature page of this 10-K). |
| | 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| | 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| | 32.1†* | Certification 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. |
| | 101.INS* | XBRL Instance Document |
| | 101.SCH* | XBRL Taxonomy Extension Schema Document |
| | 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| | 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| | 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| | 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

*Filed herewith.

†This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

(1) Filed as an exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-203505)and incorporated herein by reference.

(2) Filed as an exhibit to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2016 and incorporated herein by reference.

82