

Edgar Filing: Invuity, Inc. - Form S-1/A

Invuity, Inc.  
Form S-1/A  
June 11, 2015  
**Table of Contents**

As filed with the Securities and Exchange Commission on June 11, 2015.

Registration No. 333-203505

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Amendment No. 5**  
  
to  
  
**FORM S-1**  
  
**REGISTRATION STATEMENT**  
  
UNDER  
  
**THE SECURITIES ACT OF 1933**

**INVUITY, INC.**

(Exact name of registrant as specified in its charter)

Delaware

3841

04-3803169

Edgar Filing: Invuity, Inc. - Form S-1/A

(State or other jurisdiction of  
incorporation or organization)

(Primary Standard Industrial  
Classification Code Number)

(I.R.S. Employer  
Identification Number)

444 De Haro Street

San Francisco, CA 94107

(415) 655-2100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Philip Sawyer

President and Chief Executive Officer

Invuity, Inc.

444 De Haro Street

San Francisco, CA 94107

(415) 655-2100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

Steven E. Bochner

Brett Robertson

B. Shayne Kennedy

Allison B. Spinner

Vice President of Corporate Development and

Drew Capurro

Wilson Sonsini Goodrich & Rosati, P.C.

General Counsel

Latham & Watkins LLP

650 Page Mill Road

Invuity, Inc.

650 Town Center Drive, 20th Floor

Palo Alto, California 94304

444 De Haro Street

Costa Mesa, California 92626

(650) 493-9300

San Francisco, California 94107

(714) 540-1235

(415) 655-2100

## Edgar Filing: Invuity, Inc. - Form S-1/A

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box: "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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

Large accelerated filer "

Accelerated filer "

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

Smaller reporting company "

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**Table of Contents**

**Table of Contents**

**Table of Contents**

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	13
<u>Special Note Regarding Forward-Looking Statements</u>	43
<u>Market and Industry Data</u>	45
<u>Use of Proceeds</u>	46
<u>Dividend Policy</u>	47
<u>Capitalization</u>	48
<u>Dilution</u>	50
<u>Selected Financial Data</u>	53
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	54
<u>Business</u>	69
<u>Management</u>	95
<u>Executive Compensation</u>	105
<u>Certain Relationships and Related Party Transactions</u>	116
<u>Principal Stockholders</u>	122
<u>Description of Capital Stock</u>	125
<u>Shares Eligible for Future Sale</u>	131
<u>Material U.S. Federal Income Tax Consequences to Non-U.S. Holders</u>	133
<u>Underwriting</u>	137
<u>Legal Matters</u>	146
<u>Experts</u>	146
<u>Additional Information</u>	146
<u>Index to Financial Statements</u>	F-1

Until \_\_\_\_\_, 2015, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus or any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized any other person to provide you with different information. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is only accurate as of the date of this prospectus, regardless of the time or delivery of this prospectus and any sale of our common stock.

**Trademarks**

Invuity, Inc. and our logo, as well as Intelligent Photonics, are our trademarks and are used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames. Additionally, we do not intend for our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

**Investors Outside of the United States**

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about, and to



## Edgar Filing: Invuity, Inc. - Form S-1/A

observe any restrictions relating to, this offering and the distribution of this prospectus outside of the United States.

**Table of Contents**

**PROSPECTUS SUMMARY**

*This prospectus summary highlights information contained elsewhere in this prospectus. This prospectus summary is not complete and does not contain all of the information that you should consider before making a decision to invest in our common stock. You should carefully read this entire prospectus, including the information provided under the headings Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes, before investing in our common stock. Unless otherwise stated in this prospectus, references to Invuity, we, us, our or the Company refer to Invuity, Inc.*

**Invuity**

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 Intelligent 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. We sold our devices to approximately 400 hospitals in the first quarter of 2015, as compared to approximately 200 hospitals in the same quarter of 2014. Based on the number of single-use units we have shipped as of March 31, 2015, we estimate that our devices have been used in over 92,000 surgical procedures. We are also using our Intelligent 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 illuminators are single-use products. Our retractors are reusable, but utilize a single-use optical waveguide, which we sell separately because a new waveguide must be used for 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

## **Table of Contents**

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.

In the last several years, we have transitioned from a focus on research and development to the commercialization of our device portfolio. As of March 31, 2015, we market eight families of illuminated surgical devices, consisting of over 40 devices. We market and sell our devices in the United States primarily through a direct salesforce, which has grown from 16 sales representatives as of December 31, 2012, to 43 as of March 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 and hospitals. Our revenue increased from \$7.2 million in 2013 to \$13.1 million in 2014. We had a net loss of \$12.1 million and \$20.7 million in the years ended December 31, 2013 and 2014, respectively. Our revenue increased from \$2.2 million during the three months ended March 31, 2014 to \$4.4 million during the three months ended March 31, 2015. In 2014 and the three months ended March 31, 2015, approximately 80% and 74% of our revenue, respectively, was generated from the sale of single-use devices. We had a net loss of \$4.7 million and \$9.0 million during the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, we had an accumulated deficit of \$77.1 million.

## **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.

Minimally invasive surgery refers to surgery performed through one or more small incisions as compared to conventional open surgery procedures. 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. Though these 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. Other procedures also use smaller incisions than conventional open surgery but still enable the surgeon 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 believe that open minimally invasive and minimal access procedures provide many of the benefits described above. However, the small incisions used in these procedures

## Edgar Filing: Invuity, Inc. - Form S-1/A

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.

## **Table of Contents**

We estimate that approximately 40% of all surgical procedures in the United States are open minimally invasive and minimal access. 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 oncology, 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 trauma; cardiothoracic; ear, nose and throat; gynecology; urology; general surgery; neurosurgery and craniomaxillofacial 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.

### ***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. We are aware of various publications that identify limitations of these devices. While some of these publications are more than several years old, we believe the limitations they identify continue to exist and these limitations continue to present challenges for surgeons when traditional lighting options are used in procedures where the surgical field is accessed through the small incisions used in open minimally invasive and minimal access procedures.

### ***Overhead Lighting Systems***

The most common illumination method in the operating room setting today is overhead lighting systems. Overhead lighting systems consist of lighting fixtures that are positioned above the surgical field. Overhead lighting systems are frequently inadequate for surgery in deeper cavities due to the creation of significant shadows within the surgical field and the inability of the light to reach the depths of the incision.

### ***Surgical Headlights***

Surgical headlights were developed to address some of the shortcomings of overhead lighting systems. The headlight system consists of a headband worn by the surgeon and, most commonly, coupled with a fiber optic light system that is plugged into a xenon or LED light source. Headlights can be heavy and uncomfortable to use and may be associated with head, neck and shoulder fatigue from the prolonged improper posture required during their use, frequent headaches, neck pain and injury to the cervical spine. Furthermore, because the source of light is still above the surgical cavity, we believe the use of headlights also leads to shadows and glare, caused by hands, instruments and anatomy, which may limit visualization in deep surgical cavities.

### ***On-field Fiber Optic Lighting Systems***

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. However, traditional on-field fiber optic systems have inherent limitations and risks. With traditional fiber optic retractors, light is directed in a straight line in the shape of a cone from the end of the fiber optic. To avoid the light being absorbed by the retractor, the fiber is typically located as close as possible to the distal end. Placing the fiber on the distal end of the retractor puts it in close proximity to the patient's tissue, which can create a very bright, narrow spot of light that can create hot spots on the patient's tissue and create glare in the surgeon's line of vision. In addition, 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.

## **Table of Contents**

### ***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 below the risk of burn.

***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. By improving visualization, our devices may also decrease the 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. Additionally, 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.

***Enhanced operating room efficiency.*** We believe our technology improves operating room workflow by reducing the need for perioperative repositioning of traditional surgical lighting options. 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, we believe surgeons are able to clearly illuminate the surgical target and effectively focus on performing the procedure.

***Economic value proposition to healthcare systems.*** We believe our devices have the potential to substantially reduce procedure costs as well as create incremental revenue

## **Table of Contents**

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 may also create additional capacity in the operating room for surgeons to perform more procedures, which we believe can create incremental revenue for the hospital.

### **Our Strategy**

Our goal is to be the global leader in providing advanced photonics systems to surgeons across a broad array of surgical specialties. The key elements of our strategy include:

***Establish our Intelligent Photonics technology as the standard illumination technology used in open minimally invasive and minimal access procedures.*** We intend to continue to educate and train surgeons on the advantages of our Intelligent Photonics technology compared to traditional operating room lighting options. We believe the benefits of our Intelligent Photonics technology should also enable the broader application and adoption of open minimally invasive and minimal access procedures and help enable new advanced surgical techniques.

***Expand our sales organization to support growth.*** 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 broaden awareness of our Intelligent Photonics technology to new hospitals. As of March 31, 2015, we had 43 direct sales representatives.

***Continue to deliver innovative technologies and broaden our device portfolio.*** We intend to continue to leverage our Intelligent Photonics technology platform to research, design and develop new devices that extend the benefits of open minimally invasive and minimal access techniques to a broader patient population. We believe our ability to introduce new devices to surgeons will allow us to continue to expand our annual total addressable market opportunity over time.

***Focus on key opinion leader surgeons to facilitate adoption.*** We are working in collaboration with key opinion leader surgeons in various surgical specialties to explore new product development and clinical applications for our technology and generate surgeon awareness of the clinical and economic value of our technology.

***Introduce our Intelligent Photonics technology in markets outside the United States.*** While our current commercial plan is to focus our direct sales efforts on continued penetration of the U.S. market, we plan to continue to monitor opportunities to develop a presence internationally.

### **Our Products**

Our Intelligent 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 cavities. Our waveguides also come in narrow or wide configurations to accommodate various retractor blade widths that are designed for various surgical procedures. 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, whereas our handheld illuminated aspiration devices have integrated microlens arrays.

## **Table of Contents**

We currently market eight families of illuminated surgical devices, consisting of over 40 devices. Our Intelligent 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.

### **Risks Related to Our Business**

Our ability to successfully operate our business is subject to numerous risks, including, without limitation, those that are generally associated with operating in the medical device industry. Some of the principal risks relating to our business and our ability to execute our business strategy include:

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

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.

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

We must demonstrate to surgeons and hospitals the merits of our devices compared to those of our competitors.

We have limited experience marketing and selling our devices, and if we fail to develop and retain our direct sales force and independent sales agents, our business could suffer.

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.

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.

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

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

We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.



## Edgar Filing: Invuity, Inc. - Form S-1/A

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.

## **Table of Contents**

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

We are permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus.

We are exempt from the requirement to obtain an attestation report from our independent registered public accounting firm on our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We are permitted to provide less extensive disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements.

We are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including (i) if we become a large accelerated filer as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, (ii) our annual gross revenue equals or exceeds \$1.0 billion or (iii) we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We may choose to take advantage of some or all of these reduced burdens. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from our competitors that are public companies, or other public companies in which you have made an investment.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### **Corporate Information**

We were incorporated in California in 2004 as Spotlight Surgical, Inc. We changed our name to Invuity, Inc. in 2007. We reincorporated in Delaware in May 2015. Our principal executive offices are located at 444 De Haro Street, San Francisco, California, 94107, and our telephone number is (415) 655-2100. Our website is [www.invuity.com](http://www.invuity.com). Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

**Table of Contents**

**THE OFFERING**

Issuer	Invuity, Inc.
Shares of common stock offered by us	4,000,000 shares.
Shares of common stock to be outstanding immediately after this offering	12,701,092 shares (or 13,301,092 shares, if the underwriters exercise in full their option to purchase additional shares) at the assumed initial public offering price of \$12.00 per share.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 600,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	We intend to use the net proceeds received from this offering primarily to expand sales and marketing activities and research and development efforts, and for working capital and general corporate purposes. We may also use a portion of the net proceeds from this offering to acquire or invest in complementary products, technologies or businesses, although we have no present commitments to complete any such transaction. See Use of Proceeds on page 46 of this prospectus for a more complete description of the intended use of proceeds from this offering.
Risk factors	Investing in our common stock involves risks. See the section entitled Risk Factors beginning on page 13 of this prospectus and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	IVTY.
The number of shares of our common stock to be outstanding after this offering is based on 8,701,092 shares of our common stock outstanding as of March 31, 2015, including convertible preferred stock on an as-converted basis assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, and excludes:	

1,359,142 shares of common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2015, with a weighted-average exercise price of \$2.57 per share;

521,512 shares of common stock issuable upon the exercise of options to purchase shares of our common stock which were issued in April and May 2015, with a weighted-average exercise price of \$12.48 per share;

3,532 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$1.30 per share;

**Table of Contents**

137,007 shares of common stock issuable upon conversion of convertible preferred stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$13.35 per share, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share;

2,177,243 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:

682,971 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan as of March 31, 2015, which shares will be added to the shares to be reserved under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering; and

1,494,272 shares of common stock reserved for future grants under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering; and

any shares that become available under our 2015 Equity Incentive Plan, pursuant to provisions thereof that automatically increase the share reserve under such plan each year, as more fully described in Executive Compensation Employee Benefit and Stock Plans.

Except as otherwise indicated, all information in this prospectus assumes:

a 1-for-18.5 reverse stock split of our common stock and convertible preferred stock, which became effective in May 2015;

the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws upon the completion of this offering;

the automatic conversion of all shares of our convertible preferred stock outstanding as of March 31, 2015, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, into an aggregate of 7,979,332 shares of common stock upon the completion of this offering;

the automatic conversion of all outstanding warrants exercisable for shares of our convertible preferred stock as of March 31, 2015 into warrants exercisable for shares of common stock upon the completion of this offering;

no exercise of outstanding options or warrants subsequent to March 31, 2015; and

no exercise of the underwriters' option to purchase additional shares.

**Table of Contents**

The number of shares of our common stock to be issued upon the automatic conversion of all outstanding shares of our convertible preferred stock depends in part on the actual initial public offering price of our common stock in this offering. The terms of our Series D convertible preferred stock, Series E convertible preferred stock and Series F convertible preferred stock provide that the ratio at which each share of such series automatically converts into shares of our common stock in connection with this offering will increase if the initial public offering price is below \$12.395, \$13.3052 and \$14.3449 per share, respectively, which would result in additional shares of our common stock being issued upon conversion of the preferred stock as set forth below immediately prior to the closing of this offering. Based upon the assumed initial public offering price of \$12.00 per share, the outstanding shares of our Series D, Series E and Series F convertible preferred stock will convert into an aggregate of 2,034,709, 1,642,002 and 1,671,168 shares of our common stock, respectively, immediately prior to the closing of this offering. For illustrative purposes only, the table below shows the number of shares of our common stock that would be issuable upon conversion of our Series D, Series E and Series F convertible preferred stock at various initial public offering prices, as well as the resulting total number of outstanding shares of our common stock after this offering, based on our shares outstanding as of March 31, 2015:

Assumed Public Offering Price (\$)	Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		Series F Convertible Preferred Stock		Total Common Stock Outstanding After this Offering (#)
	Shares of		Shares of		Shares of		
	Approximate Conversion Ratio (#)	Common Stock Issuable upon Conversion (#)	Approximate Conversion Ratio (#)	Common Stock Issuable upon Conversion (#)	Approximate Conversion Ratio (#)	Common Stock Issuable upon Conversion (#)	
\$11.00	1.03187	2,081,189	1.04991	1,677,558	1.06836	1,705,321	12,817,281
\$11.50	1.02021	2,057,684	1.03867	1,659,588	1.05755	1,688,072	12,758,557
\$12.00	1.00882	2,034,709	1.02766	1,642,002	1.04696	1,671,168	12,701,092
\$12.50	1.00000	2,016,929	1.01689	1,624,785	1.03658	1,654,602	12,649,529
\$13.00	1.00000	2,016,929	1.00633	1,607,925	1.02641	1,638,358	12,616,425
\$13.50	1.00000	2,016,929	1.00000	1,597,814	1.01643	1,622,429	12,590,385
\$14.00	1.00000	2,016,929	1.00000	1,597,814	1.00664	1,606,808	12,574,764

In addition, the table below shows the number of shares of our common stock that would be issuable upon conversion of all outstanding warrants exercisable for shares of our Series D and Series E convertible preferred stock at various initial public offering prices and the resulting total number of outstanding shares of our common stock for which the warrant will become exercisable as a result:

Assumed Public Offering Price (\$)	Shares of Common Stock Issuable upon Conversion of Warrants to Purchase	
	Series D Convertible Preferred Stock	Shares of Common Stock Issuable upon Conversion of Warrants to Purchase Series E Convertible Preferred Stock
\$11.00	11,653	88,773
\$11.50	11,522	87,822
\$12.00	11,393	86,891
\$12.50	11,294	85,980
\$13.00	11,294	85,088
\$13.50	11,294	84,553
\$14.00	11,294	84,553

**Table of Contents****SUMMARY FINANCIAL DATA**

The following tables set forth a summary of our historical financial data as of and for the periods indicated. We have derived the summary statements of operations data for the years ended December 31, 2013 and 2014 from our audited financial statements included elsewhere in this prospectus. We have derived the summary statements of operations data for the three months ended March 31, 2014 and 2015, and the summary balance sheet data as of March 31, 2015, from our unaudited interim financial statements included elsewhere in this prospectus. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of our future results and our interim results are not necessarily indicative of results to be expected for the full year ending December 31, 2015, or any other period. The following summary financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31, 2013	Year Ended December 31, 2014	Three Months Ended March 31, 2014	Three Months Ended March 31, 2015
	(In thousands, except share and per share data)			
<b>Statements of Operations Data:</b>				
Revenue	\$ 7,186	\$ 13,103	\$ 2,154	\$ 4,442
Cost of goods sold	2,294	4,871	747	1,731
Gross profit	4,892	8,232	1,407	2,711
Operating expenses:				
Selling, general and administrative	12,402	22,803	4,574	8,923
Research and development	4,445	5,181	1,203	1,900
Total operating expenses	16,847	27,984	5,777	10,823
Loss from operations	(11,955)	(19,752)	(4,370)	(8,112)
Interest expense	(284)	(1,402)	(370)	(369)
Interest and other income (expense), net	130	492	28	(551)
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
Net loss per common share, basic and diluted <sup>(1)</sup>	\$ (19.15)	\$ (31.63)	\$ (7.34)	\$ (12.84)
Weighted-average shares used to compute net loss per common share, basic and diluted <sup>(1)</sup>	632,407	653,195	641,810	703,637
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		\$ (3.15)		\$ (1.07)
Weighted-average shares used to compute pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		6,727,430		7,940,112

<sup>(1)</sup> See Notes 2, 12 and 13 to our financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, pro forma basic and diluted net loss per common share, and the weighted-average number of shares used in the computation of the per share amounts.



**Table of Contents**

		March 31, 2015	
	Actual	Pro Forma <sup>(1)</sup> (In thousands)	Pro Forma As Adjusted <sup>(2)(3)</sup>
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 25,251	\$ 25,251	\$ 66,391
Working capital	28,230	28,230	69,370
Total assets	46,151	46,151	87,291
Convertible preferred stock warrant liability	640		
Long-term debt related party	14,382	14,382	14,382
Convertible preferred stock	96,524		
Accumulated deficit	(77,069)	(77,069)	(77,069)
Total stockholders' (deficit) equity	(74,668)	22,496	63,636

- (1) Reflects (i) the automatic conversion of the outstanding shares of our convertible preferred stock as of March 31, 2015 into 7,979,332 shares of our common stock upon the completion of this offering and (ii) the automatic conversion of warrants to purchase shares of convertible preferred stock into warrants to purchase shares of common stock upon the completion of this offering and the related reclassification of our convertible preferred stock warrant liability to additional paid-in capital.
- (2) Reflects the pro forma adjustments described in footnote (1) and the sale and issuance of 4,000,000 shares of our common stock by us in this offering, at the assumed initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$3.7 million, assuming that the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the amount of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$11.2 million, assuming an initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.



---

**Table of Contents**

**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 prospectus, 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 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 \$12.1 million and \$20.7 million for the years ended December 31, 2013 and 2014, respectively, and \$4.7 million and \$9.0 million for the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, our accumulated deficit was \$77.1 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 private placements of our 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, 2013 and December 31, 2014 and the three months ended March 31, 2015, our revenue was \$7.2 million, \$13.1 million and \$4.4 million, respectively, and was 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. Intelligent 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 to develop and commercialize improvements to existing product lines 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 where these surgeons treat patients will typically require us to receive approval from the facility's value analysis committee, or

## **Table of Contents**

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 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 the surgeons in that 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 in these costly and time-consuming processes and still may not obtain VAC approval or a purchase contract from such hospitals or GPOs.

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

Surgeons play a significant role in determining the devices used in the operating room and in 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 Intelligent 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.

*We have limited experience marketing and selling our devices, and if we fail to develop and retain our direct salesforce and independent sales agents, our business could suffer.*

We began selling our first FDA-cleared 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 or agencies, whom we refer to as independent sales agents, who assist us in educating targeted surgeons. We increased the number of our direct sales representatives from 16 as of December 31, 2012 to 43 as of March 31, 2015. Our operating results are dependent upon the sales and marketing efforts of our direct sales representatives. If our direct salesforce 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 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 surgeons expect from sales representatives with respect to understanding

---

**Table of Contents**

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 have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we may be subject to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers.

*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, salesforce experience and relationships. We face significant competition 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.

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.



## **Table of Contents**

*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;

buying patterns of the distributors that serve our military customers;

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.*

## Edgar Filing: Invuity, Inc. - Form S-1/A

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 2013 and 2014, and

**Table of Contents**

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 three months ended March 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.

## Edgar Filing: Invuity, Inc. - Form S-1/A

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.



---

**Table of Contents**

*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. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory becomes 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. For example, our gross margin decreased from 68% for the year ended December 31, 2013 to 63% for the year ended December 31, 2014, primarily due to the impact of inventory write-offs for unrecoverable trunk stock inventory provided to direct sales representatives and independent sales agents and related increase to cost of goods sold.

*We have no 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 require 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;

**Table of Contents**

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.

## Edgar Filing: Invuity, Inc. - Form S-1/A

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 Chief Financial Officer, Michael Gandy, has informed us of his intention to resign from his position to pursue other interests. We are actively engaged in a process to identify and hire a new Chief

## **Table of Contents**

Financial Officer. While Mr. Gandy has indicated that he will continue in his current role until we have hired his replacement, we cannot assure you that we will be able to identify and hire an appropriate candidate in a timely manner or on terms reasonable to us or at all. Any delay in hiring a new Chief Financial Officer could significantly disrupt our business and operations. In addition, many members of our management team have only joined us in the last year as part of our investment in the expansion of our business, including our Vice President of Research and Development and Vice President of Operations. 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. Further, our employees' ability to exercise those options and sell their stock in a public market after the closing of this offering may result in a higher than normal turnover rate.

### ***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 49 at December 31, 2012 to 116 at March 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

---

**Table of Contents**

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.*

We have recently 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 that are sold 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 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. customers purchase because they choose to reuse our devices rather than purchasing additional single-use devices from us.

**Table of Contents**

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

## **Table of Contents**

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 or 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



## **Table of Contents**

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, that 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 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 other proprietary rights of others. Significant litigation regarding patent rights occurs in the medical 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, 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.

## **Table of Contents**

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 any patent litigation. 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, and 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 three months ended March 31, 2015, our net cash used in operating activities was \$6.9 million, and was \$13.9 million and \$19.8 million for the years ended December 31, 2013 and 2014, respectively.

---

**Table of Contents**

As of March 31, 2015, we had working capital of \$28.2 million, which included \$25.3 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 salesforce 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 March 31, 2015, we owed an aggregate principal amount of \$15.0 million, and accrued interest of \$21,000, to HealthCare Royalty Partners, 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 March 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 0.75%. 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.

---

**Table of Contents**

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 don't attain profitability in an amount necessary to offset such losses.*

As of December 31, 2014, we had net operating loss, or NOL, carryforwards for federal and state income tax purposes of approximately \$60.9 million and \$53.8 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 connection with or after this offering, 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.

---

**Table of Contents**

**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 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 over 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.



## **Table of Contents**

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 timely, 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. Six MDRs for our devices have been filed, which includes a discontinued reusable aspiration device that we voluntarily recalled in 2012, four reports in 2012 of device breakage and one report in 2014 relating to tissue irritation.

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 publicly 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 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;

---

**Table of Contents**

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.



## **Table of Contents**

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 its 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, 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,

---

**Table of Contents**

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 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 federal 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 federal 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;

---

**Table of Contents**

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 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 90<sup>th</sup> 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 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

---

**Table of Contents**

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 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. The PPACA includes, among other things, 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. This excise tax has resulted in an increase in the tax burden on our industry, and if any efforts we undertake to offset the excise tax are unsuccessful, the increased tax burden could have an adverse effect on our results of operations and cash flows. Other elements of the PPACA, including comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and may result in fundamental changes to federal healthcare reimbursement programs, any of which may adversely affect numerous aspects of our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. 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

---

**Table of Contents**

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 this Offering and Ownership of our Common Stock**

*Our common stock has never been publicly traded, and we expect that the price of our common stock will fluctuate substantially.*

Before this offering, there has been no public market for our common stock, and we cannot be certain that an active trading market for our common stock will develop or be sustained following this offering. 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. Upon closing of this offering, we anticipate that our common stock will be listed on the NASDAQ Global Market. If we fail to satisfy the continued listing standards of the NASDAQ Global Market, however, we could be de-listed, which would negatively impact the price of our common stock.

The trading price of our common stock is likely to be volatile and could fluctuate widely regardless of our operating performance. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price, if at all. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary substantially from the market price of our common stock following this offering. In addition, 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 prospectus 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;

## Edgar Filing: Invuity, Inc. - Form S-1/A

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;

---

**Table of Contents**

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. Based upon the number of shares outstanding as of March 31, 2015, immediately upon completion of this offering, we will have 12,701,092 shares of common stock outstanding, assuming an initial public offering price of \$12.00 per share and no exercise of our outstanding options and warrants. This includes the 4,000,000 shares we are selling in this offering, which may be resold in the public market immediately, except for any shares held or purchased in this offering by our affiliates, as defined in Rule 144 under the Securities Act. The remaining 8,701,092 shares of common stock outstanding after this offering will be restricted as a result of applicable securities laws, lock-up or market standoff agreements, or other contractual restrictions that restrict transfers for at least 180 days after the date of this prospectus. However, Piper Jaffray & Co. and Leerink Partners LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements with the underwriters prior to expiration of the lock-up period. As restrictions on resale expire, the market price could drop significantly if the holders of these restricted shares sell them or are perceived by the market as intending to sell them. For a more detailed description, see the sections of this prospectus entitled "Shares Eligible for Future Sale" and "Underwriting."

After this offering, the holders of 7,979,332 shares of common stock and holders of warrants to purchase 137,007 shares of common stock, based on shares outstanding as of March 31, 2015, assuming an initial public offering price of \$12.00 per share, 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.

We also intend to file 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

## **Table of Contents**

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. Once we register these shares, they 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 will continue to have significant voting power after this offering and may take actions that may not be in the best interests of our other stockholders.*

Upon completion of this offering, our directors and executive officers and stockholders holding more than 5% of our capital stock and their affiliates will beneficially own, in the aggregate, approximately 51.1% of our outstanding common stock (assuming an initial public offering price of \$12.00 per share and no exercise of the underwriters' option to purchase additional shares). To the extent our existing stockholders purchase additional shares in this offering or otherwise, 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. For information regarding the ownership of our outstanding stock by our executive officers and directors and their affiliates, see the section of this prospectus entitled "Principal Stockholders."

*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. We do not currently have and may never obtain research coverage by these analysts. Investors have numerous investment opportunities and may limit their investments to publicly traded companies that receive thorough research coverage. If no analysts commence coverage of us or 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. There is no guarantee that the equity research organizations affiliated with the underwriters of this offering will elect to initiate or sustain research coverage of us, nor whether such research, if initiated, will be positive towards our stock price or our business prospects.

*New investors purchasing our common stock will experience substantial and immediate dilution as a result of this offering.*

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$6.99 in pro forma as adjusted net tangible book value per share of common stock, based on an assumed initial public offering price of \$12.00 per share. In addition, we have issued options and warrants to acquire common stock at prices significantly below the initial public offering price. The number of shares available for issuance under our 2015 Equity Incentive Plan will increase annually without further stockholder approval. To the extent such options and warrants are ultimately exercised, investors will incur additional dilution. For more information, see the section of this prospectus entitled "Dilution."



## **Table of Contents**

*We have broad discretion in the use of proceeds from this offering and may not use the proceeds effectively.*

We intend to use the net proceeds received from this offering primarily to fund sales and marketing activities, research and development efforts, working capital and general corporate purposes. We also may use a portion of the net proceeds from this offering to acquire or invest in complementary products, technologies or businesses, although we have no present commitments to complete any such transaction. Within those categories, our management will have broad discretion over the use and investment of the net proceeds of this offering and may spend these proceeds in ways in which you may not agree. Accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds with only limited information concerning management's specific intentions. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

*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 will be 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 obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur

## **Table of Contents**

substantially higher costs to obtain 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 this prospectus and 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.

*We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.*

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following this offering, which will be our year ending December 31, 2016, provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the audit of our financial statements as of and for the year ended December 31, 2014, we identified a material weakness in our internal control over financial reporting. The material weakness related 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 our financial statements. Based on these procedures, we believe the material weakness did not result in any material misstatements to the financial statements. However, this 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. We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

We amended accounting system access rights so that there are finance personnel without journal entry access who can perform review activities.

We are formalizing our internal control documentation and strengthening supervisory reviews by our management.

We are in the process of adding accounting personnel and segregating duties amongst accounting personnel.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

---

**Table of Contents**

In addition to the remediation efforts related to the material weakness described above, we are in the process of designing and implementing the internal control over financial reporting required to comply with Section 404 of the Sarbanes Oxley Act. This process will be time consuming, costly and complicated. If during the evaluation and testing process, we identify one or more other material weaknesses in our internal control over financial reporting, our management will be unable to assert that our internal control over financial reporting is effective. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

*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 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, the fiscal year-end following the fifth anniversary of the completion of this offering, 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 \$700.0 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.*

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. 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.

**Table of Contents**

*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 will 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 will be 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. For more information, see the section of this prospectus entitled "Description of Capital Stock."

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

Pursuant to our amended and restated certificate of incorporation, our board will be authorized to issue up to 10,000,000 shares of preferred stock without any action on the part of our stockholders. Our board will also have 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



**Table of Contents**

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 of 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.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, including the sections entitled Prospectus Summary, Risk Factors, Use of Proceeds, Management's Discussion and Analysis of Financial Condition and Results of Operations, and Business contains forward-looking statements. The words believe, may, will, potentially estimate, continue, anticipate, intend, could, would, project, plan, expect and similar expressions that convey uncertainty of future outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

our expectations regarding the potential market size and widespread adoption of our devices, including applications in additional surgical specialties;

our ability to demonstrate to surgeons and hospitals the merits of our devices and timely obtain approval by hospitals to sell our devices;

developments and projections relating to our competitors or our industry;

the expected growth in our business and our organization, including outside of the United States;

our financial performance, our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;

our ability to retain and recruit key personnel, including the continued development and expansion of a sales and marketing infrastructure;

our ability to obtain an adequate supply of components for our devices from our third-party suppliers;

our ability to identify and develop new and planned devices;

our ability to obtain and maintain intellectual property protection for our devices or avoid claims of infringement;

our compliance with extensive government regulation;

our expected uses of the net proceeds from this offering;

the volatility of our share price; and

our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act under the federal securities laws.

## Edgar Filing: Invuity, Inc. - Form S-1/A

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in **Risk Factors** and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person



**Table of Contents**

assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission, or the SEC, as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

**Table of Contents**

**MARKET AND INDUSTRY DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various sources, on assumptions we have made based on such data and other similar sources, and on our knowledge of the markets for our solutions and services. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in **Risk Factors** and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds from our sale of 4,000,000 shares of common stock in this initial public offering at an assumed initial public offering price of \$12.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$41.1 million, or \$47.8 million if the underwriters exercise in full their option to purchase additional shares.

A \$1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) the net proceeds to us from this offering by \$3.7 million, assuming the number of shares offered by us, as reflected on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by approximately \$11.2 million, at the assumed initial public offering price of \$12.00 per share, and after deducting estimated underwriting discount and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our stock, thereby enabling access to the public equity markets by our stockholders and employees, and increase our visibility in the marketplace. We intend to use approximately \$28.0 million of the net proceeds received from this offering to expand sales and marketing activities, approximately \$8.0 million to expand research and development efforts, and the remainder of the net proceeds from this offering for working capital and general corporate purposes. At this time, we cannot quantify the amounts we intend to expend on any of these activities.

We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies or businesses, although we have no present commitments to complete any such transaction. The amounts and timing of our expenditures will depend upon numerous factors, including the rate of adoption of our devices, the expenses we incur in selling and marketing our devices, the scope of research and development efforts, the timing and success of clinical trials we may commence in the future, and the timing of regulatory submissions.

Accordingly, our management will have broad discretion over the use of the net proceeds from this offering. Pending the use of the proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities, certificates of deposit or government securities.

**Table of Contents**

**DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future, if at all. Both our loan agreement with HealthCare Royalty Partners, or HCRP, and our credit facility with Silicon Valley Bank, or SVB, restrict our ability to pay cash dividends on our capital stock. In addition to the restrictions imposed by the HCRP loan agreement and the SVB credit facility, as well as any limitations set forth by the terms of any future debt or preferred securities or future credit facility, any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2015 on:

an actual basis;

a pro forma basis, giving effect to (i) the automatic conversion of the outstanding shares of our convertible preferred stock as of March 31, 2015 into 7,979,332 shares of our common stock upon completion of this offering assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share; (ii) the automatic conversion of warrants to purchase shares of our convertible preferred stock into warrants to purchase shares of common stock upon the completion of this offering and the related reclassification of our convertible preferred stock warrant liability to additional paid-in capital; and (iii) the effectiveness of our amended and restated certificate of incorporation; and

a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 4,000,000 shares of our common stock by us in this offering, based upon the assumed initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares issuable upon conversion of our preferred stock, as referenced in the second bullet above, depends in part on the actual initial public offering price of our common stock in this offering. For a description of the impact of changes in the offering price on the shares issuable upon conversion of the preferred stock, see Prospectus Summary The Offering.

You should read this information together with the section of this prospectus entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	Actual	March 31, 2015 Pro Forma	Pro Forma as Adjusted <sup>(1)</sup>
	(In thousands, except share and per share data)		
Cash and cash equivalents	\$ 25,251	\$ 25,251	\$ 66,391
Convertible preferred stock warrant liability	\$ 640	\$	\$
Long-term debt related party	14,382	14,382	14,382
Convertible preferred stock, \$0.001 par value 7,861,914 shares authorized; 7,652,615 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	96,524		
Stockholders' (deficit) equity:			
Preferred stock, \$0.001 par value no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.001 par value 11,384,324 shares authorized; 721,760 shares issued and outstanding, actual; 100,000,000 shares authorized, 8,701,092 shares issued and outstanding, pro forma; and 12,701,092 shares issued and outstanding, pro forma as adjusted	1	9	13

*continues on following page*

**Table of Contents**

	March 31, 2015		
	Actual (In thousands, except share and per share data)	Pro Forma	Pro Forma as Adjusted <sup>(1)</sup>
Additional paid-in capital	\$ 2,400	\$ 99,556	\$ 140,692
Accumulated deficit	(77,069)	(77,069)	(77,069)
Total stockholders (deficit) equity	(74,668)	22,496	63,636
Total capitalization	\$ 36,878	\$ 36,878	\$ 78,018

<sup>(1)</sup> Each \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$3.7 million, assuming that the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the amount of our pro-forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$11.2 million, assuming an initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock reflected in the discussion and table above is based on 8,701,092 shares of our common stock outstanding as of March 31, 2015, including convertible preferred stock on an as-converted basis, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, and excludes the following:

1,359,142 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2015, with a weighted-average exercise price of \$2.57 per share;

521,512 shares of common stock issuable upon the exercise of options to purchase shares of our common stock which were issued in April and May 2015, with a weighted-average exercise price of \$12.48 per share;

3,532 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$1.30 per share;

137,007 shares of common stock issuable upon conversion of convertible preferred stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$13.35 per share, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share;

2,177,243 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:

682,971 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan as of March 31, 2015, which shares will be added to the shares to be reserved under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering,

1,494,272 shares of common stock reserved for future grants under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering, and

## Edgar Filing: Invuity, Inc. - Form S-1/A

any shares that become available under our 2015 Equity Incentive Plan pursuant to provisions thereof that automatically increase the share reserve under such plan each year, as more fully described in Executive Compensation Employee Benefit and Stock Plans.

**Table of Contents****DILUTION**

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of March 31, 2015, our historical net tangible book value (deficit) was approximately \$(76.0) million, or \$(105.33) per share of common stock. Historical net tangible book value (deficit) per share represents our total tangible assets, less deferred initial public offering costs, less total liabilities, less convertible preferred stock, divided by the number of our outstanding shares of common stock.

As of March 31, 2015, our pro forma net tangible book value was approximately \$21.1 million, or \$2.43 per share of common stock. Our pro forma net tangible book value per share represents our total tangible assets, less deferred initial public offering costs, less total liabilities, divided by the number of our outstanding shares of common stock as of March 31, 2015, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 7,979,332 shares of our common stock, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, which conversion will occur upon the completion of the offering, the automatic conversion of warrants to purchase shares of our convertible preferred stock into warrants to purchase shares of common stock upon the completion of this offering and the related reclassification of our convertible preferred stock warrant liability to additional paid-in capital. The number of shares issuable upon conversion of our preferred stock referenced above depends in part on the actual initial public offering price of our common stock in this offering. For a description of the impact of changes in the offering price on the shares issuable upon conversion of the preferred stock, see Prospectus Summary The Offering.

After giving further effect to the sale of 4,000,000 shares of our common stock in this offering, at the assumed initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2015 would have been approximately \$63.6 million, or \$5.01 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$2.58 per share to our existing stockholders and an immediate dilution of \$6.99 per share to investors purchasing common stock in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Assumed initial public offering price per share		\$ 12.00
Historical net tangible book value (deficit) per share as of March 31, 2015		\$(105.33)
Pro forma increase in net tangible book value (deficit) per share		107.76
Pro forma net tangible book value per share as of March 31, 2015		2.43
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in this offering		2.58
Pro forma as adjusted net tangible book value per share, after giving effect to this offering		5.01
Dilution in pro forma as adjusted net tangible book value per share to investors purchasing shares in this offering		\$ 6.99

A \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately \$0.29 per share



**Table of Contents**

and the dilution per share to new investors in this offering by \$0.71 per share, assuming the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us.

Similarly, a 1,000,000 increase in the number of shares of our common stock offered by us would increase our pro forma as adjusted net tangible book value by approximately \$0.45 per share and decrease the dilution per share to new investors in this offering by \$0.45 per share, and a 1,000,000 decrease in the number of shares of our common stock offered by us would decrease our pro forma as adjusted net tangible book value by \$0.53 per share and increase the dilution per share to new investors in this offering by \$0.53 per share assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions payable by us.

If the underwriters exercise their option to purchase additional shares in this offering in full, the pro forma as adjusted net tangible book value per share of our common stock would be \$5.29 per share, and the dilution in pro forma net tangible book value per share to investors purchasing shares in this offering would be \$6.71 per share.

The following table summarizes, on the pro forma basis described above, the difference between existing stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us, and the average price per share paid, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration Amount		Average Price Per Share
	Number	Percent	(in thousands)	Percent	
Existing stockholders	8,701,092	68.5%	\$ 184,625	79.4%	\$ 21.22
Investors purchasing shares in this offering	4,000,000	31.5	48,000	20.6	12.00
<b>Total</b>	<b>12,701,092</b>	<b>100.0%</b>	<b>\$ 232,625</b>	<b>100.0%</b>	<b>18.32</b>

A \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) total consideration paid by new investors and total consideration paid by all stockholders by approximately \$3.7 million, assuming that the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions payable by us.

Similarly, a 1,000,000 increase (decrease) in the number of shares of our common stock offered by us would increase (decrease) the shares purchased by new investors and total shares purchased by all stockholders by 1,000,000, would increase (decrease) the percentage of shares purchased by new investors by 5.0%, and would increase (decrease) the total consideration paid by new investors and total consideration paid by all stockholders by approximately \$12.0 million, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions payable by us.

If the underwriters exercise their option to purchase additional shares in this offering in full, our existing stockholders would own approximately 65.4% and our new investors would own approximately 34.6% of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock reflected in the discussion and tables above is based on 8,701,092 shares of our common stock outstanding as of March 31, 2015, including convertible preferred stock on an as-converted basis assuming a conversion rate based on the assumed initial public

**Table of Contents**

offering price of \$12.00 per share, and excludes the following:

1,359,142 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2015, with a weighted-average exercise price of \$2.57 per share;

521,512 shares of common stock issuable upon the exercise of options to purchase shares of our common stock which were issued in April and May 2015, with a weighted-average exercise price of \$12.48 per share;

3,532 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$1.30 per share;

137,007 shares of common stock issuable upon conversion of convertible preferred stock issuable upon the exercise of warrants outstanding as of March 31, 2015 with a weighted-average exercise price of \$13.35 per share, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share;

2,177,243 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:

682,971 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan as of March 31, 2015, which shares will be added to the shares to be reserved under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering,

1,494,272 shares of common stock reserved for future grants under our 2015 Equity Incentive Plan, which will become effective upon completion of this offering, and

any shares that become available under our 2015 Equity Incentive Plan pursuant to provisions thereof that automatically increase the share reserve under such plan each year, as more fully described in Executive Compensation Employee Benefit and Stock Plans.

To the extent that any outstanding options to purchase shares of our common stock or warrants to purchase shares of our common stock or convertible preferred stock are exercised or new awards are granted under our equity compensation plans, there will be further dilution to investors participating in this offering.

**Table of Contents****SELECTED FINANCIAL DATA**

The following selected statement of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the three months ended March 31, 2014 and 2015, and the balance sheet data as of March 31, 2015, are derived from our unaudited interim financial statements included elsewhere in this prospectus. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of our future results and our interim results are not necessarily indicative of results to be expected for the full year ending December 31, 2015, or any other period. You should read the following selected financial and other data below in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
	(In thousands, except share and per share data)			
<b>Statements of Operations Data:</b>				
Revenue	\$ 7,186	\$ 13,103	\$ 2,154	\$ 4,442
Cost of goods sold	2,294	4,871	747	1,731
Gross profit	4,892	8,232	1,407	2,711
<b>Operating expenses:</b>				
Selling, general and administrative	12,402	22,803	4,574	8,923
Research and development	4,445	5,181	1,203	1,900
Total operating expenses	16,847	27,984	5,777	10,823
Loss from operations	(11,955)	(19,752)	(4,370)	(8,112)
Interest expense	(284)	(1,402)	(370)	(369)
Interest and other income (expense), net	130	492	28	(551)
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
Net loss per common share, basic and diluted <sup>(1)</sup>	\$ (19.15)	\$ (31.63)	\$ (7.34)	\$ (12.84)
Weighted-average shares used to compute net loss per common share, basic and diluted <sup>(1)</sup>	632,407	653,195	641,810	703,637
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		\$ (3.15)		\$ (1.07)
Weighted-average shares used to compute pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		6,727,430		7,940,112

<sup>(1)</sup> See Notes 2, 12 and 13 to our financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, pro forma basic and diluted net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

Edgar Filing: Invuity, Inc. - Form S-1/A

	December 31,		March 31,
	2013	2014	2015
	(In thousands)		
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 4,953	\$ 6,048	\$ 25,251
Working capital	8,486	10,366	28,230
Total assets	12,053	25,324	46,151
Convertible preferred stock warrant liability	86	136	640
Total long-term debt	2,477	9,347	14,382
Convertible preferred stock	52,949	73,755	96,524
Accumulated deficit	(47,375)	(68,037)	(77,069)
Total stockholders' deficit	(45,906)	(65,827)	(74,668)

---

**Table of Contents**

**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 prospectus. 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 prospectus.*

**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 Intelligent 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. We sold our devices to approximately 400 hospitals in the first quarter of 2015, as compared to approximately 200 hospitals in the same quarter of 2014. Based on the number of single-use units we have shipped as of March 31, 2015, we estimate that our devices have been used in over 92,000 surgical procedures. We are also using our Intelligent 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 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.

We currently sell our devices in the United States, primarily through a direct sales force. We increased the number of our direct sales representatives from 16 as of December 31, 2012 to 39 as of December 31, 2014 and to 43 as of March 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 Intelligent Photonics technology platform to surgeons. Our direct salesforce works with independent sales agents or agencies, whom we refer to as independent sales agents, who assist us in educating targeted 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. We have a diverse customer base of hospitals in the United States. One customer accounted for 12% of our total revenue in each of 2013 and 2014, and another customer accounted for 13% of our total revenue in 2013. There were no sales to any customer in excess of 10% of our total revenue for the three months ended March 31, 2015. Our currently marketed devices are commonly treated as general supplies utilized

---

## **Table of Contents**

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 expect our existing facility to meet expected demand for the foreseeable future.

Our revenue increased from \$7.2 million in 2013 to \$13.1 million in 2014. We incurred a net loss of \$12.1 million and \$20.7 million for the years ended December 31, 2013 and 2014, respectively. For the three months ended March 31, 2015, our revenue was \$4.4 million and we incurred a net loss of \$9.0 million compared to revenue of \$2.2 million and a net loss of \$4.7 million for the three months ended March 31, 2014. We expect to continue to incur losses for the next several years as we expand our organization to support planned sales growth, while also continuing to invest in development of new devices and modalities. As of March 31, 2015, we had an accumulated deficit of \$77.1 million. We have increased our number of employees from 49 on December 31, 2012 to 116 employees as of March 31, 2015. Our primary sources of capital to date have been from sales of our devices, private placements of our convertible preferred securities and amounts borrowed under certain debt financing arrangements.

## **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. Recent revenue growth has been driven by, and we expect our revenue to continue to increase in the future as a result of, the growth of our sales and marketing infrastructure and increased surgeon awareness of the benefits of our Intelligent Photonics technology platform over traditional surgical lighting options in the operating room. We expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including:

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;

the timing, expense and results of research and development activities and obtaining future regulatory clearances and approvals;

buying patterns of the distributors that serve our military customers;

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 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

## Edgar Filing: Invuity, Inc. - Form S-1/A

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

## **Table of Contents**

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, as well as a 2.3% excise tax on the sale of medical devices in the United States. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows.

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, and the implementation of cost-reduction strategies. 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.



**Table of Contents****Interest and Other Income (Expense), Net**

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

**Results of Operations**

	Three Months Ended March 31,		\$	%
	2014	2015	Change	Change
	(In thousands)			
Revenue	\$ 2,154	\$ 4,442	\$ 2,288	106
Cost of goods sold	747	1,731	984	132
Gross profit	1,407	2,711	1,304	93
Gross margin	65%	61%		
Operating expenses:				
Selling, general and administrative	4,574	8,923	4,349	95
Research and development	1,203	1,900	697	58
Total operating expenses	5,777	10,823	5,046	87
Loss from operations	(4,370)	(8,112)	(3,742)	86
Interest expense	(370)	(369)	1	*
Interest and other income (expense), net	28	(551)	(579)	*
Net loss	\$ (4,712)	\$ (9,032)	\$ (4,320)	92

\* Not meaningful

**Comparison of the Three Months Ended March 31, 2014 and 2015****Revenue**

Revenue increased \$2.3 million, or 106%, to \$4.4 million during the three months ended March 31, 2015, compared to \$2.2 million during the three months ended March 31, 2014. The growth in revenue was attributable to an increase in unit sales. The increase in units was driven by the increased number of customers to whom we sold devices. The number of our direct sales representatives increased from 35 as of March 31, 2014 to 43 as of March 31, 2015 and the number of customers purchasing our devices increased from approximately 200 in the first quarter of 2014 to approximately 400 in the first quarter of 2015.

Revenue attributable to our reusable metal retractors increased 294%, from \$0.2 million during the three months ended March 31, 2014 to \$0.9 million during the three months ended March 31, 2015, and represent 10% and 20% of our total revenue for the respective quarters. Of this increase in revenue, 98% is the result of an increase in unit volume and changes to the product mix, and 2% is the result of price changes. Revenue from our single-use optical waveguides used with our metal retractors increased 72%, from \$1.0 million during the three months ended March 31, 2014 to \$1.6 million during the three months ended March 31, 2015, also primarily as a result of unit volume increases. Revenue from our single-use illumination devices not used in conjunction with a retractor increased 136% during the three months ended March 31, 2015, growing from \$0.6 million during the three months ended March 31, 2014 to \$1.4 million during the three months ended March 31, 2015, with unit volume increases accounting for all of the revenue growth. Revenue from our single use optical waveguides for use in



## **Table of Contents**

retractors sold by original equipment manufacturers decreased 12% from \$0.34 million during the three months ended March 31, 2014 to \$0.30 million during the three months ended March 31, 2015 primarily as the result of continued focus on direct sales to our customers.

### *Cost of Goods Sold and Gross Margin*

Cost of goods sold increased \$1.0 million, or 132%, to \$1.7 million during the three months ended March 31, 2015, compared to \$0.7 million during the three months ended March 31, 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 as well as idle capacity costs of \$0.2 million related to the move of our production team and operations to the new leased facility in mid-March 2015.

Gross margin for the three months ended March 31, 2015 decreased to 61%, compared to 65% for the three months ended March 31, 2014. The decrease in gross margin was primarily due to the impact of idle capacity costs.

### *Selling, General and Administrative Expenses*

SG&A expenses increased \$4.3 million, or 95%, to \$8.9 million during the three months ended March 31, 2015, compared to \$4.6 million during the three months ended March 31, 2014. The increase in SG&A expenses was attributable to a \$1.4 million increase in personnel-related expenses, excluding sales commissions, as a result of increased headcount, a \$0.7 million increase in marketing, advertising and promotion related expenses, a \$0.6 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, a \$0.5 million increase in commissions to direct sales representatives, and a \$0.3 million increase in independent sales agent commissions. The increase in SG&A expenses was also attributable to an increase in facility related costs of \$0.8 million primarily related to rent expense and depreciation for our new leased facility.

### *Research and Development Expenses*

R&D expenses increased \$0.7 million, or 58%, to \$1.9 million during the three months ended March 31, 2015, compared to \$1.2 million during the three months ended March 31, 2014. The increase in R&D expenses was primarily attributable to a \$0.7 million increase in personnel-related expenses as a result of increased headcount.

### *Interest and Other Income (Expense), Net*

Interest and other income (expense), net changed \$0.6 million to \$(0.6) million expense during the three months ended March 31, 2015, compared to income of \$28,000 during the three months ended March 31, 2014. The change was primarily due to the fair value re-measurement and related increase of the liability related to our outstanding convertible preferred stock warrants. We 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 expense of \$370,000 for the three months ended March 31, 2015 and a corresponding increase to the convertible preferred stock warrant liability.

**Table of Contents**

	Year Ended December 31,		\$ Change	% Change
	2013	2014 (In thousands)		
Revenue	\$ 7,186	\$ 13,103	\$ 5,917	82
Cost of goods sold	2,294	4,871	2,577	112
<b>Gross profit</b>	<b>4,892</b>	<b>8,232</b>	<b>3,340</b>	<b>68</b>
<i>Gross margin</i>	68%	63%		
<b>Operating expenses:</b>				
Selling, general and administrative <sup>(a)</sup>	12,402	22,803	10,401	84
Research and development <sup>(a)</sup>	4,445	5,181	736	17
<b>Total operating expenses</b>	<b>16,847</b>	<b>27,984</b>	<b>11,137</b>	<b>66</b>
<b>Loss from operations</b>	<b>(11,955)</b>	<b>(19,752)</b>	<b>(7,797)</b>	<b>65</b>
Interest expense	(284)	(1,402)	(1,118)	*
Interest and other income, net	130	492	362	*
<b>Net loss</b>	<b>\$ (12,109)</b>	<b>\$ (20,662)</b>	<b>\$ (8,553)</b>	<b>71</b>

\* Not meaningful

<sup>(a)</sup> We have revised the statement of operations for the year ended December 31, 2014 to correct the classification between research and development expenses and selling, general and administrative expenses due to an erroneous allocation of departmental expenses, which resulted in an increase to research and development expenses of \$564,000, with a corresponding decrease to selling, general and administrative expenses.

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

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 150 in the fourth quarter of 2013 to approximately 350 in the fourth quarter of 2014.

Revenue attributable to our reusable metal retractors increased 126%, from \$0.9 million during the year ended December 31, 2013 to \$2.0 million during the year ended December 31, 2014 and represent 12% and 15% of our total revenue for the respective periods. Of this increase in revenue, 96% is the result of an increase in unit volume and changes to the product mix, and 4% is the result of price changes. Revenue from our single-use optical waveguides used with our metal retractors increased 84%, from \$2.7 million during the year ended December 31, 2013 to \$5.0 million during the year ended December 31, 2014, also primarily as a result of unit volume increases. Revenue from our single-use illumination devices not used in conjunction with a retractor increased 170%, from \$1.5 million during the year ended December 31, 2013 to \$3.9 million during the year ended December 31, 2014, with unit volume increases representing nearly all of the growth. Revenue from our single use optical waveguides for use in retractors sold by original equipment manufacturers decreased 17% from \$1.8 million during the year ended December 31, 2013 to \$1.5 million during the year ended December 31, 2014 primarily as the result of continued focus on direct sales to our customers.

*Cost of Goods Sold and Gross Margin*

Cost of goods sold increased \$2.6 million, or 112%, to \$4.9 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



---

## **Table of Contents**

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 63%, 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.

### *Selling, General and Administrative Expenses*

SG&A expenses increased \$10.4 million, or 84%, to \$22.8 million during the year ended December 31, 2014, compared to \$12.4 million during the year ended December 31, 2013. The increase in SG&A 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.

### *Research and Development Expenses*

R&D 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 R&D expenses was primarily attributable to a \$0.3 million increase in personnel-related expenses as a result of increased headcount, a \$0.3 million increase in supplies and testing expenses in development activities and a \$0.1 million increase in recruiting fees.

### *Interest Expense*

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 HealthCare Royalty Partners, or 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, Net*

Interest and other income, 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 remeasurement of the liability related to our outstanding convertible preferred stock warrants.

## **Liquidity and Capital Resources**

### *Overview*

As of March 31, 2015, we had cash and cash equivalents of \$25.3 million and an accumulated deficit of \$77.1 million, compared to cash, cash equivalents and short-term investments of \$6.0 million and an accumulated deficit of \$68.0 million as of December 31, 2014. We have financed our operations

**Table of Contents**

primarily through sales of our convertible preferred securities, debt financings and the sale of our devices. As of March 31, 2015, we have raised \$96.5 million from private placements of our convertible preferred securities, including proceeds from convertible notes, and had \$14.4 million of borrowings outstanding under our loan agreements. We have additional availability under our accounts receivable credit facility 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.

We believe that our existing cash and cash equivalents as of March 31, 2015, and borrowings available under our accounts receivable credit facility with SVB that we entered into in the first quarter of 2015, will be sufficient to meet our anticipated cash requirements through at least December 31, 2015 and, after giving effect to the net proceeds of this offering, through at least December 31, 2016. Our expected future capital requirements may depend on many factors including customer expansion, 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 need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. 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.

**Cash Flows**

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

(in thousands)	Year Ended December 31,		Three Months Ended March 31	
	2013	2014	2014	2015
Net cash (used in) provided by:				
Operating activities	\$ (13,897)	\$ (19,818)	\$ (4,608)	\$ (6,941)
Investing activities	15,496	(7,271)	(15,128)	(1,467)
Financing activities	(451)	28,184	28,132	27,611
Net increase in cash and cash equivalents	\$ 1,148	\$ 1,095	\$ 8,396	\$19,203

**Net Cash Used in Operating Activities**

During the three months ended March 31, 2015, net cash used in operating activities was \$6.9 million, which consisted of a net loss of \$9.0 million, adjusted by non-cash charges of \$1.2 million and a net increase of \$0.9 million in our net operating assets. The non-cash charges primarily consist of stock-based compensation of \$0.2 million, depreciation and amortization of \$0.4 million and a \$0.5 million loss from the revaluation of the convertible preferred stock warrant liability. The change in our net

---

**Table of Contents**

operating assets and liabilities was primarily due to a \$0.7 million increase in accounts payable and accrued liabilities as a result of an increase in our operations and related growth in headcount and a decrease of \$1.1 million of prepaid expenses and other assets primarily due to the receipt of tenant improvement allowance from our landlord in the first quarter of 2015. This change was partially offset by an increase of \$0.9 million in accounts receivable due to the increase in revenue and the timing of collections.

During the three months ended March 31, 2014, net cash used in operating activities was \$4.6 million, which consisted of a net loss of \$4.7 million, adjusted by non-cash charges of \$0.2 million and a net increase of \$0.1 million in our net operating assets. The non-cash charges primarily consist of depreciation and amortization of \$0.1 million and stock-based compensation of \$0.1 million. The change in our net operating assets and liabilities was primarily the result of a \$0.2 million increase in accounts payable due to the growth in our operations.

During the year 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 non-cash charges primarily consist of stock-based compensation of \$0.7 million, depreciation and amortization of \$0.3 million, amortization of the premium on marketable securities of \$0.2 million, an increase in the provision for doubtful accounts of \$0.1 million and non-cash interest expense of \$0.1 million, offset by a \$0.5 million gain from the revaluation of the convertible preferred stock warrant liability. The increase in our net operating assets and liabilities was primarily due to a \$1.0 million increase in accrued liabilities as a result of an increase in our operations and related growth in headcount and an increase of \$2.9 million in deferred rent related to our new facility lease. This increase was partially offset by a \$1.4 million 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 of \$1.9 million primarily as a result of the tenant allowance receivable in 2014 and a \$0.8 million increase in inventory as a result of an increase in production to support the expected growth in future revenue.

During the year ended December 31, 2013, net cash used in operating activities was \$13.9 million, which consisted of a net loss of \$12.1 million, adjusted by non-cash charges of \$0.6 million and a net increase of \$2.4 million in our net operating assets. The non-cash charges primarily consist of depreciation and amortization of \$0.2 million, stock-based compensation of \$0.3 million, amortization of the premium on marketable securities of \$0.2 million, and non-cash interest expense of \$0.1 million, partially offset by the gain from the revaluation of the convertible preferred stock warrant liability of \$0.2 million. The net decrease in our net operating assets and liabilities was primarily the result of a \$2.4 million increase in inventory as a result of the expected growth in revenue, a \$0.7 million increase in accounts receivable as a result of an increase in revenue and a \$0.2 million increase in other assets as a result of capitalized issuance costs for the Series E convertible preferred stock that was issued in February 2014. These changes were offset by a \$0.9 million increase in accounts payable and accrued liabilities as a result of an increase in operations and company growth.

*Net Cash Provided by (Used in) Investing Activities*

During the three months ended March 31, 2015, net cash used in investing activities was \$1.5 million, which consisted of capital expenditures to purchase property and equipment in connection with the new facility lease entered into in December 2014.

During the three months ended March 31, 2014, net cash used in investing activities was \$15.1 million, which consisted of \$15.9 million for the purchase of marketable securities and \$0.1 million of capital expenditures to purchase property and equipment, offset by \$0.9 million in proceeds from the maturities of marketable securities.



---

**Table of Contents**

During the year ended December 31, 2014, net cash used in investing activities was \$7.3 million, which consisted of cash outflows of \$17.5 million for purchases of marketable securities, \$6.8 million of capital expenditures to purchase property and equipment in connection with the new facility lease entered into in December 2014 and a \$1.1 million increase in restricted cash for the security deposit on our new leased facility, offset by sales and maturities of marketable securities of \$18.1 million. 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.

During the year ended December 31, 2013, net cash provided by investing activities was \$15.5 million, which consisted of \$18.1 million from the sale and maturities of marketable securities, offset by purchases of marketable securities of \$2.2 million and \$0.5 million of capital expenditures to purchase property and equipment.

*Net Cash Provided by (Used in) Financing Activities*

During the three months ended March 31, 2015, net cash provided by financing activities was \$27.6 million, consisting of net proceeds of \$22.8 million from the issuance of our convertible preferred stock and net proceeds of \$5.0 million from borrowings under our long-term debt facility partially offset by \$0.2 million of payments of deferred initial public offering costs.

During the three months ended March 31, 2014, net cash provided by financing activities was \$28.1 million, consisting of net proceeds of \$20.8 million from the issuance of our convertible preferred stock and net proceeds of \$9.8 million from the issuance of long-term debt, partially offset by \$2.5 million in payments on long-term debt.

During the year ended December 31, 2014, net cash provided by financing activities was \$28.2 million consisting of net proceeds of \$20.8 million from the issuance of convertible preferred stock, net proceeds of \$9.8 million from the issuance of long-term debt and proceeds of \$0.1 million from the issuance of common stock upon exercise of stock options, partially offset by \$2.5 million in payments on long-term debt.

During the year ended December 31, 2013, net cash used in financing activities was \$0.5 million consisting of \$3.0 million in payments on long-term debt, offset by proceeds of \$2.5 million from the issuance of long-term debt.

***Indebtedness***

In February 2014, we entered into a loan agreement with HCRP, a related party due to its equity ownership interest in us, for an aggregate principal amount of up to \$15.0 million in two separate tranches. We drew down the first tranche of \$10.0 million upon execution of the HCRP loan agreement and drew down the second tranche of \$5.0 million 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, we will make principal and interest payments until the maturity of the loan on December 31, 2020. We are 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. Our obligations under the HCRP loan agreement are secured by a first priority security interest in all of our assets, other than bank accounts, accounts receivable and inventory. The HCRP 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 HCRP loan agreement 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 our business, operations or condition, or on our

**Table of Contents**

ability to perform our obligations under the loan. The HCRP loan agreement also includes customary representations and warranties, other events of default and termination provisions. As of March 31, 2015, we were in compliance with all covenants.

Also in February 2015, we entered into an accounts receivable credit facility with SVB that permits the borrowing of the lesser of \$7.5 million or an amount representing up to 80% of eligible accounts receivable. The SVB credit facility matures in February 2018 and our obligations under the SVB credit facility are secured by a first priority security interest in our bank accounts, accounts receivable, and inventory. Interest on borrowed amounts is payable monthly at the prime rate plus 0.75%. The SVB credit facility imposes customary affirmative and restrictive covenants, including with respect to fundamental transactions, changes to our business, the incurrence of additional indebtedness or liens and the payment of dividends, but does not include any financial covenants. In addition, the SVB 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. The SVB credit facility also includes customary representations and warranties, events of defaults and termination provisions. As of March 31, 2015, we have not drawn down on the SVB credit facility.

**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, 2014:

(in thousands)	Payments Due by Period				Total
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	
Long-term debt-related party, including interest	\$ 1,250	\$ 3,453	\$ 6,768	\$ 4,313	\$ 15,784
Operating leases	2,053	4,167	4,421	11,821	22,462
<b>Total contractual obligations</b>	<b>\$ 3,303</b>	<b>\$ 7,620</b>	<b>\$ 11,189</b>	<b>\$ 16,134</b>	<b>\$ 38,246</b>

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

(in thousands)	Payments Due by Period				Total
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	
Long-term debt-related party, including interest	\$ 1,405	\$ 5,180	\$ 10,149	\$ 6,469	\$ 23,203
Operating leases	1,722	4,167	4,421	11,821	22,131
<b>Total contractual obligations</b>	<b>\$ 3,127</b>	<b>\$ 9,347</b>	<b>\$ 14,570</b>	<b>\$ 18,290</b>	<b>\$ 45,334</b>

**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 \$5.0 million, \$6.0 million and \$25.3 million as of December 31, 2013, December 31, 2014 and March 31, 2015, respectively, which consist of bank deposits and money market funds.

## **Table of Contents**

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.

We had total outstanding debt of \$2.5 million as of December 31, 2013, which was subsequently repaid in February 2014. As of December 31, 2014 and March 31, 2015, we had total outstanding debt of \$9.3 million and \$14.4 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.

## **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 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).

**Table of Contents**

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.* As our common stock has never been publicly traded, 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 employees 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.

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,		Three Months Ended	
	2013	2014	2014	2015 <sup>(1)</sup>
Expected term (in years)	6.0	6.0	6.0	
Expected volatility	43%	35%	38%	38%
Risk-free interest rate	1.08%	1.82%	1.80%	1.93%
Dividend yield	0%	0%	0%	0%

<sup>(1)</sup> No stock options were granted during the three months ended March 31, 2015.

We recorded total stock-based compensation expense of \$0.3 million and \$0.7 million in the years ended December 31, 2013 and 2014, respectively, and \$0.1 million and \$0.2 million in the three months ended March 31, 2014 and 2015, 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.

Historically, for all periods prior to this offering, the fair values of the shares of common stock underlying our stock-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute



## **Table of Contents**

of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; our operating results and financial condition, including our levels of available capital resources; equity market conditions affecting comparable public companies; general U.S. market conditions and the lack of marketability of our common stock.

For stock awards after the completion of this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

The intrinsic value of all outstanding options as of March 31, 2015 was \$12.8 million based on an assumed initial public offering price of \$12.00 per share.

### ***Convertible Preferred Stock Warrant Liability***

We have issued freestanding warrants to purchase shares of convertible preferred stock in connection with the issuance of various debt facilities and debt instruments. We account for these warrants as a liability in our financial statements because the underlying instrument into which the warrants are exercisable contains deemed liquidation provisions that are outside our control.

The warrants outstanding at December 31, 2013 were recorded at fair value using the Black-Scholes option pricing model. The fair value of the warrants at December 31, 2014 and March 31, 2015 was determined using a hybrid method of the option-pricing model and a probability of various liquidity events required to trigger the conversion of the convertible preferred stock warrants. The scenarios included merger and acquisition events ranging in time to event of one to three years, an initial public offering occurring within six months to two years, and dissolution. The warrants are re-measured at each financial reporting period with any changes in fair value being recognized as a component of interest and other income (expense), net in the statements of operations. We will continue to adjust the liability for changes in fair value until the earlier of (i) exercise or expiration of the warrants, or (ii) the completion of an initial public offering, at which time all convertible preferred stock warrants will be converted into warrants to purchase common stock and the liability will be reclassified to additional paid-in capital.

### ***Internal Control Over Financial Reporting***

In connection with the audit of our financial statements as of and for the year ended December 31, 2014, we identified a material weakness in our internal control over financial reporting. The material weakness related 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, this 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. We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

We amended accounting system access rights so that there are finance personnel without journal entry access who can perform review activities.

We are formalizing our internal control documentation and strengthening supervisory reviews by our management.

## **Table of Contents**

We are in the process of adding additional accounting personnel and segregating duties amongst accounting personnel. We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

### **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 May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers, or ASU 2014-09. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard update under the full retrospective method or the modified retrospective method. Early adoption is not permitted. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, or ASU 2014-15. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective in the first quarter of 2016 with early adoption permitted. We are currently evaluating the impact of adopting ASU 2014-15 on our financial statements and related disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest-Imputation of Interest*, or ASU 2015-03. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance of debt issuance costs is not affected by the amendments in this update. The standard will be effective beginning in the first quarter of 2016 and requires us to apply the new guidance on a retrospective basis on adoption. We do not expect the adoption of this guidance to have a material impact on our financial statements.

---

**Table of Contents**

**BUSINESS**

**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 Intelligent 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. We sold our devices to approximately 400 hospitals in the first quarter of 2015, as compared to approximately 200 hospitals in the same quarter of 2014. Based on the number of single-use units we have shipped as of March 31, 2015, we estimate that our devices have been used in over 92,000 surgical procedures. We are also using our Intelligent 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



---

## **Table of Contents**

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, oncology, 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 trauma; cardiothoracic; ear, nose and throat; gynecology; general surgery; neurosurgery and craniomaxillofacial 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 March 31, 2015, we market eight families of illuminated surgical devices, consisting of over 40 devices. We market and sell our devices in the United States primarily through a direct salesforce, which has grown from 16 sales representatives as of December 31, 2012, to 39 as of December 31, 2014 to 43 as of March 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 and hospitals. Our revenue increased from \$7.2 million in 2013 to \$13.1 million in 2014 and from \$2.2 million to \$4.4 million for the three months ended March 31, 2014 and 2015, respectively. In each of the year ended December 31, 2014 and the three months ended March 31, 2015, approximately 80% and 74% of our revenue, respectively, was generated by the sale of single-use devices. We had a net loss of \$12.1 million and \$20.7 million in the years ended December 31, 2013 and 2014, respectively, and \$4.7 million and \$9.0 million for the three months ended March 31, 2014 and 2015, respectively. As of December 31, 2014 and March 31, 2015, we had an accumulated deficit of \$68.0 million and \$77.1 million, respectively.

### **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

## Edgar Filing: Invuity, Inc. - Form S-1/A

improved aesthetic outcomes.

Minimally invasive surgery refers to surgery performed through one or more small incisions as compared to conventional open surgery procedures. Some minimally invasive procedures, such as endoscopic, laparoscopic and arthroscopic procedures, use small tubes, tiny cameras and surgical instruments to access,

---

## **Table of Contents**

visualize and perform the surgery. Though these 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. Other procedures also use smaller incisions than conventional open surgery but still enable the surgeon 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 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.

We estimate that approximately 40% of all surgical procedures in the United States are open minimally invasive and minimal access. Based on the benefits of these procedures over conventional open surgery, we believe this percentage will continue to grow. We have developed illuminated surgical devices that enable and facilitate the use of open minimally invasive and minimal access techniques. We have initially targeted our sales and marketing efforts to surgeons in the following specialties: orthopedics, spine, breast oncology, plastics and thyroid. However, our current illuminated surgical devices have a broad 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 trauma; cardiothoracic; ear, nose and throat; gynecology; urology; general surgery; neurosurgery and craniomaxillofacial 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.

### **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. We are aware of various publications that identify limitations of these devices. While some of these publications are more than several years old, we believe the limitations they identify continue to exist and these limitations continue to present challenges for surgeons when traditional lighting options are used in procedures where the surgical field is accessed through the small incisions used in open minimally invasive and minimal access procedures.

#### ***Overhead Lighting Systems***

The most common illumination method in the operating room setting today is overhead lighting systems. Overhead lighting systems consist of lighting fixtures that are positioned above the surgical field. When used in open minimally invasive and minimal access procedures, overhead lighting systems can present numerous challenges. In order to effectively illuminate the surgical field, the surgical field must be in a direct line of sight from the overhead lighting system. This can be difficult to maintain as changes in patient or surgeon positioning may interfere with the path of illumination at various points throughout the procedure. For example, the position of the surgeon's head can interfere with the overhead illumination and obstruct light from reaching the surgical cavity. When this occurs, adjustments by the surgeon to the overhead lighting systems may be required to maintain the light's direct exposure to the different parts of the surgical field. We believe these adjustments pose an inconvenience for the surgeon, disrupt surgical flow and increase operating room procedure time. We believe the adjustments can also result in contamination of the surgical field as the overhead lighting systems are not sterile and the constant repositioning can contaminate the gloves and gown of the surgeon and operating room staff. Moreover, overhead lighting systems may be inadequate for surgery in deeper cavities due to the creation of significant shadows within the surgical field and the inability of the light to reach the depths of the incision.

## **Table of Contents**

### *Surgical Headlights*

Surgical headlights were developed to address some of the shortcomings of overhead lighting systems. The headlight system consists of a headband worn by the surgeon and, most commonly, coupled with a fiber optic light system that is plugged into a xenon or LED light source. Headlights have the effect of bringing the light source closer to the surgical cavity thereby improving its direct exposure. Additionally, due to the position of the headlight, the surgeon's head no longer interferes with the light, and the light is typically directed to the area that the surgeon wants to view without having to manipulate an overhead light. Despite these benefits, we believe headlights still present limitations. For example, headlights can be heavy and uncomfortable to use and may be associated with head, neck and shoulder fatigue from the prolonged improper posture required during their use, frequent headaches, neck pain and injury to the cervical spine. These devices require the surgeon to maintain a steady head and neck position to provide constant and steady illumination of the surgical field, which can limit the surgeon's mobility and visibility of the surgical field by other members of the operating team. When two or more surgeons are wearing these headlights opposite each other during the procedure, the headlights can collide, which we believe can dislodge particles and contaminate the sterile field. 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 accidentally mishandles the device. For these reasons, we believe surgical headlights do not provide an optimal intracavity illumination system and are not used by all surgeons.

### *On-field Fiber Optic Lighting Systems*

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. One end of the fiber optic cable must be connected to a light source. Typically, a 300-watt xenon light source is utilized in operating rooms, due to its high amount of total emitted white light which can exceed 2,000 lumen output. The other end of the fiber optic cable is coupled to a fiber optic surgical retractor. This coupling is accomplished by placing the end face of the cable against the end face of the fiber optics on the 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. There are two locations where significant amounts of heat are generated in these light systems. The first area is at the fiber-to-fiber coupling of the fiber optic cable to the fiber optic surgical retractor. It is virtually impossible to perfectly align each fiber in the fiber optic cable with each fiber in the fiber optic retractor. This inefficient optical coupling yields significant light loss. The location of light loss then generates substantial heat and is a known source of thermal injury to patients and operating room staff. The second area where a significant amount of heat is generated is at the point where light exits the fiber optic bundles. With traditional on-field fiber optic lighting systems, light is directed in a narrow beam, with intensity at a maximum at the center of the spot of light, and dropping off exponentially toward the edges. Since light exits these bundles from a small active area and due to this tight intensity profile, there is a significant amount of heat concentrated at the illumination spot at the exit surface of the fiber optic bundles, with temperatures significant enough to melt surgical drapes, coagulate blood, and burn patients.

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 resembles a cone and is circular, with a common center around the mechanical axis of the fiber bundle. Because of these

---

## **Table of Contents**

properties, when the fiber is placed adjacent to the retractor, a portion of light is obstructed, reducing the light available to the surgical field and causing heat buildup on the retractor. To address this problem, the majority of current commercial fiber optic retractors locate the fiber as close as possible to the distal end of the retractor blade in order to minimize this absorption effect. However, placing the fiber on the distal end of the retractor puts it in close proximity to the patient's tissue, which can result in a significant amount of energy and heat being transposed onto the surgical target. Additionally, it can create a very bright, narrow spot of light. Since this bright, narrow spot 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.

***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. By improving visualization, our devices may also decrease risk of unintended retained foreign objects by improving the surgeon's

## **Table of Contents**

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 headlamps, thereby helping to reduce some of the associated head, neck and shoulder fatigue, frequent headaches, neck pain and injury to the cervical spine.

***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 headlamps 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.

## **Table of Contents**

### *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.

## **Table of Contents**

### *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 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.

### *Bench Testing*

A bench test is a quality and function test carried out to evaluate the mechanical and technical properties of a device and to confirm that it operates according to its design specifications. We performed bench testing on certain traditional surgical instruments incorporating fiber optic lighting and on surgical instruments enabled by our waveguide technology and used the results to compare the performance aspects of the various devices. In particular, we compared light distribution and uniformity and surgical target thermal profile between a traditional 130mm Tebbetts fiber optic retractor and our 130mm Eikon retractor system. In addition, we also compared Electrosurgical Instrument s Yankauer fiber optic aspiration device and our Saber Yankauer aspiration device. We caution the reader that our bench testing is limited in scope and



**Table of Contents**

nature, with a focus on only four devices, and was conducted by us without any third-party involvement or review. As a result, we cannot assure you that a third-party evaluation of a broader number of competitive devices would yield similar results. The following table summarizes the results from this bench testing. Light distribution was calculated based on using the same minimum illuminance, or light per area, values:

	Light Distribution		Thermal Profile
	Illuminance	Uniformity	
Traditional fiber optic retractor	6.3 cm <sup>2</sup>	3.868	50.3°C
Eikon retractor system	30.8 cm <sup>2</sup>	0.398	33.2°C
Traditional fiber optic aspiration device	25.4 cm <sup>2</sup>	0.731	61.5°C
Saber Yankauer aspiration device	28.6 cm <sup>2</sup>	0.572	35.0°C

**Light Distribution.** Optical ray tracing software technology is widely used to conduct various performance analyses of illumination and imaging systems. We use this software to model and understand how light propagates through various devices and how light is projected onto desired surgical targets. Using this software, we are able to build three dimensional geometrical models of a particular optical waveguide and its associated microstructures or microlenses to analyze how light transmits through the solid core of the waveguide and how light is extracted. We input and design the specific proprietary geometries of the microstructures or microlenses, and the software models device performance. We used optical ray tracing modeling to evaluate the light distribution of a traditional 130mm Tebbetts fiber optic retractor compared to our waveguide-enabled Eikon retractor system. We also modeled a traditional fiber optic aspiration device compared to our Saber Yankauer aspiration device.

**Illumination.** In order to analyze the size and distribution of a light pattern, we identified a target plane location and size. For this analysis, the target plane was defined to be located at the distal tip of the retractor, as that would be the working plane of the surgeon. We also defined the size of the plane, which had to be large enough to assure that we captured all the light rays hitting that plane. The light pattern was then analyzed with each light ray striking the surface of the target at certain brightness. The total light pattern was then produced by each of the light ray intensities and was used to calculate the illumination area. We chose consistent minimum illuminance for each device to determine the size and intensity of the illumination pattern.

**Uniformity.** To evaluate the uniformity of the illuminance pattern of each device, we used optical ray tracing modeling to measure the light spot pattern for each device. We then divided the light spot pattern into a 128x128 pixel array and exported the illuminance values for each pixel to a software program used for engineering calculations and analyses. Using this data, we calculated the mean illuminance value for the light spot pattern. Next, we compared the illuminance value for every data point in the array to the mean illuminance value. Finally, using the difference in each illuminance value from the mean we determined the standard deviation for each device. A standard deviation close to zero indicates that the illuminance values fall close to the mean, meaning that the device produces uniform illumination.

With the traditional fiber optic retractor, the conical light output is directed downward and due to its output geometry, a portion of light is obstructed and absorbed by the retractor. This has the effect of reducing the illuminated area and the uniformity of light within the spot pattern. For the traditional fiber optic retractor, the illuminated area was measured at approximately 6.3cm<sup>2</sup> area and the uniformity of light within the spot pattern had a standard deviation of 3.868. In comparison, for the same target plane, the light from our waveguide-enabled Eikon retractor system was directed away from the retractor blade, creating a much larger usable illumination area with a more uniform pattern of illuminance. The usable illumination area from the Eikon retractor system was measured at approximately 30.8cm<sup>2</sup>, or approximately 5 times larger than that of the traditional fiber optic retractor. Correspondingly, the

**Table of Contents**

uniformity of light within the spot pattern for the Eikon retractor systems had a standard deviation of 0.398, or approximately 9.7 times more uniform than the traditional fiber optic retractor.

Similar methods were applied in modeling the two aspiration devices. The traditional fiber optic aspiration device provided a usable illumination area that measured approximately 25.4cm<sup>2</sup>, with the uniformity of light within the spot pattern demonstrating a standard deviation of 0.731. In comparison, our Saber Yankauer provided a usable illumination area that measured approximately 28.6cm<sup>2</sup>, with the uniformity of light within the spot pattern demonstrating a standard deviation of 0.572. We believe the increased amount of illumination, combined with greater uniformity, provides a better quality of light.

*Light projection output of traditional fiber optic retractor device vs. our optical waveguide retractor device*

**Thermal Profile.** To evaluate the thermal profile of each of these same devices, we measured temperature at the target plane with a FLIR thermal imager after stabilizing the xenon light source for 10 minutes. A thermal imager is used to detect radiation in the infrared range, between 7 to 14 microns, of the electromagnetic spectrum and produce visual images of that radiation. The amount of radiation emitted by an object increases with temperature, thus allowing the thermal imager to see and measure variations in temperature.

With traditional fiber optic retractors, light is directed in a narrow beam, with intensity at a maximum at the center of the spot, and dropping off exponentially toward the edges. As a result, 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. The peak temperature on the target plane, for the tested Tebbetts fiber

## **Table of Contents**

optic retractor was measured at 50.3°C. In comparison, at the same target plane, our waveguide-enabled Eikon retractor system dispersed light away from the retractor in a broader pattern, resulting in heat at the hottest spot on the target plane that measure 33.2°C, which is below the risk of thermal burn, which occurs at or above a temperature of 44°C. Similar thermal imaging testing was performed on the traditional fiber optic aspiration device and our Saber Yankauer aspiration device. The concentrated beam of the traditional fiber optic aspiration device produced heat at the hottest point on the target plane that measured almost 61.5°C, well above the temperature of thermal burn risk. In comparison, the better uniformity of light from our Saber Yankauer aspiration device resulted in heat at the hottest spot on the target plane that measured 35.0°C, which is significantly less than that of the traditional fiber optic aspiration device and is below the temperature of thermal burn risk.

*Thermal profile of traditional fiber optic retractor vs. our optical waveguide retractor*

## **Our Strategy**

Our goal is to be the global leader in providing advanced photonics systems to surgeons across a broad array of surgical specialties, while improving patient safety. The key elements of our strategy include:

***Establish our Intelligent Photonics technology as the standard illumination technology used in open minimally invasive and minimal access procedures.*** We intend to continue to educate and train surgeons on the advantages of our Intelligent Photonics technology compared to traditional operating room lighting options. We believe the benefits of our Intelligent Photonics technology should also enable the broader application and adoption of open minimally invasive and minimal access procedures and help enable new advanced surgical techniques.

***Expand our sales organization to support growth.*** We plan to continue to expand our direct sales organization in the United States to help facilitate further adoption among

## **Table of Contents**

existing hospital accounts as well as broaden awareness of our Intelligent Photonics technology to new hospitals. In 2012, we began to scale our sales organization through a combination of direct sales representatives, who are complemented by independent sales agents or agencies, whom we refer to as independent sales agents. As of March 31, 2015 we had 43 direct sales representatives.

***Continue to deliver innovative technologies and broaden our device portfolio.*** We intend to continue to leverage our Intelligent Photonics technology platform to research, design and develop new devices that extend the benefits of open minimally invasive and minimal access techniques to a broader patient population. We are developing new applications of our proprietary Intelligent Photonics technology to expand utility, including in general surgery and in a number of additional surgical specialties outside our existing markets. We also plan to introduce next-generation illumination, visualization and advanced photonics technologies that further enable minimally invasive and minimal access procedures. We believe our ability to introduce new devices to surgeons will allow us to continue to expand our annual total addressable market opportunity over time.

***Focus on key opinion leader surgeons to facilitate adoption.*** We place significant emphasis on collaborating with key opinion leaders. We believe adoption of our technology by these thought leaders will accelerate broader application and adoption throughout a given specialty area. We are working in collaboration with key opinion leader surgeons in various surgical fields to explore new product development and clinical applications for our technology and generate surgeon awareness of the clinical and economic value of our technology.

***Introduce our Intelligent Photonics technology in markets outside the United States.*** While our current commercial plan is to focus our direct sales efforts on continued penetration of the U.S. market, we plan to continue to monitor opportunities to develop a presence internationally.

## **Our Products**

Our Intelligent 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 broad 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.

**Table of Contents**

We currently market eight families of illuminated surgical devices, consisting of over 40 devices. Our Intelligent 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.

<b>Product Family</b>	<b>Image</b>	<b>Description</b>	<b>Surgical Specialties</b>
<b><i>Eikon Illuminated Retractor System</i></b>		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
<b><i>Saber Yankauer</i></b>		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
<b><i>Saber Frazier</i></b>		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

**Table of Contents**

<b>Product Family</b>	<b>Image</b>	<b>Description</b>	<b>Surgical Specialties</b>
<i>Eika Illuminated Retractor System</i>		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
<i>Breiten Illuminated Retractor System</i>		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
<i>Eipex Illuminated Retractor System</i>		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
<i>Eivector Illuminated Retractor System</i>		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
<i>Waveguide XT System</i>		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

## **Table of Contents**

### **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 Intelligent 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: Anterior Hip Arthroplasty***

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, techniques involve operating from the side or the back of the hip, which can involve 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.

---

**Table of Contents**

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 sell primarily directly to hospitals, surgeons typically drive the purchasing decision. We sold our devices to approximately 400 hospitals in the first quarter of 2015. As of March 31, 2015, we had a sales and marketing team of 64 employees. Our sales team consisted of a Vice President of Sales, a Senior Director of U.S. Sales, seven regional sales directors, a Director of National Strategic Accounts, a sales analyst, 43 direct sales representatives and 43 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 five marketing and four customer service employees. We have significantly expanded our direct sales representatives from 16 at December 31, 2012 to 39 at December 31, 2014 to 43 at March 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 broaden awareness of our Intelligent Photonics technology to new hospitals. Using our expanded direct salesforce, we intend to continue to educate and train surgeons on the advantages of our Intelligent Photonics technology compared to traditional operating room lighting options. We believe the benefits of our Intelligent Photonics 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 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 through original equipment manufacturers of surgical systems. The majority of these sales have been through Biomet, Inc. as part of its spinal implant surgical systems. Sales to Biomet, Inc. or its predecessor in interest, Lanx, Inc., accounted for approximately 12% of our total revenue in each of 2013 and 2014. In addition, sales to Medtronic, Inc. accounted for approximately 13% of our





**Table of Contents**

total revenue in 2013. There were no sales to any customer in excess of 10% of our total revenue for the three months ended March 31, 2015. We do not expect sales to these customers to increase significantly in the future.

**Surgeon Survey**

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 require 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. Information relating to the benefits of our devices is limited to management's beliefs and our direct observation of and feedback from surgeons using our devices during surgery, surgeon feedback resulting from surgeon surveys and the bench testing performed by us. We summarize the surgeon survey below and caution readers that it is limited in scope and nature, focuses on the use of our device in only one type of surgery, NSM, and involves a small number of surgeons.

We engaged an independent third party to perform a survey of breast surgeon thought leaders. The average breast surgeon in the survey had approximately 12 months experience using our Eikon retractors and performed over 150 breast cancer procedures annually. The 12 surgeons surveyed are all amongst the leadership of the American Society of Breast Surgeons, or ASBS, including three former presidents, as well as the chairperson and principal investigator of the NSM registry for ASBS. Each surgeon in the survey was asked to respond to the list of questions below, with a yes or no, or with a ranking of importance using a descending scale of most important, very important, important, not very important, and not important. The results of the survey are listed in the table below.

	<b>Number of Surgeons Responding Positively</b>
<b>Customer Survey</b>	
<b>Surgical Efficiency</b>	
Improving surgical efficiency is important / very important / most important	12/12
Reducing operating room time is important / very important / most important	12/12
Eikon improved surgical efficiency for NSM	12/12
Eikon reduced procedure time for NSM	11/12
<b>Safety and Visualization</b>	
Reducing thermal hazards with lighted retractors is very important / most important	12/12
Eikon reduced heat and associated thermal hazards in the operating room	11/12
Eikon improved patient safety	11/12
Eikon improved staff safety	10/12
Eikon improved operating room safety	10/12
Prefer not to use headlight in operating room when performing NSM	11/12
Eikon eliminated or minimized dependence on a headlight	12/12
Prior to Eikon, the surgeon used traditional fiber optic retractors	11/12
Poor lighting or excessive heat is a concern or limitation of traditional fiber optic retractors	8/11
Eikon improved visualization of tissue planes and anatomical landmarks without generating heat and without associated thermal hazards	12/12
<b>Coverage and Reimbursement</b>	

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

---

## **Table of Contents**

do not directly bill any third-party payors and 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 would 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 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. Most recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provided for a 0.5% update from 2013 payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenues and results of operations.

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 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



## **Table of Contents**

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.

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, salesforce 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 May 26, 2015, we held 27 issued U.S. patents and had 44 U.S. utility patent applications and 9 Patent Cooperation Treaty (PCT) applications pending. As of May 26, 2015, we also had one issued patent from the Japan Patent Office, three issued patents from the Chinese patent office, and four patents from the European Patent Office which have effect in one or more of Germany, France, Great Britain and Italy. As of May 26, 2015, we had 26 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 2034. 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.

## **Table of Contents**

As of May 27, 2015, we held one United States trademark registration, one United States trademark application, sixteen foreign trademark registrations, three foreign trademark applications and one international trademark registration, which is designated in eight countries/regions.

### **Manufacturing 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, or 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.

## **Table of Contents**

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.

### **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, or 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 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 Class 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 and trays 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 for which the FDA has not yet called for the submission of PMAs. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it 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

## Edgar Filing: Invuity, Inc. - Form S-1/A

and for the Eigr Surgical Illumination System in February of 2012. All of our other commercial products to date have been commercialized as either Class I, Class II exempt or Class II devices.



---

**Table of Contents**

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 evaluates 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

**Table of Contents**

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;

finances 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 federal 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.

## Edgar Filing: Invuity, Inc. - Form S-1/A

The penalties for violating the federal 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

---

**Table of Contents**

PPACA, amends the intent requirement of the federal anti-kickback 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 federal 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

## **Table of Contents**

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.

## **Table of Contents**

### **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 March 31, 2015, we had 10 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, biomedics 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 \$4.4 million and \$5.2 million in the years ended December 31, 2013 and 2014, respectively. For the three months ended March 31, 2014 and 2015, our research and development expenses totaled \$1.2 million and \$1.9 million, 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.

### **Employees**

As of March 31, 2015, we had 116 full-time employees, which included 64 employees engaged in sales and marketing, 10 employees engaged in research and development, 30 employees engaged in manufacturing and quality assurance and 12 general and administrative employees. None of our employees are represented by collective bargaining agreement and we have never experienced any work stoppage. We believe we have good relations with our employees.

### **Facilities**

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.

### **Legal Proceedings**

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table sets forth information, as of May 29, 2015, regarding our executive officers and directors.

<b>Name</b>	<b>Age</b>	<b>Title</b>
<b>Executive Officers</b>		
Philip Sawyer	50	President, Chief Executive Officer and Director
Robert Gerberich	48	Vice President of Sales
Paul O. Davison	46	Vice President of Research and Development
Doug Heigel	54	Vice President of Operations
Alex Vayser	47	Chief Technology Officer and Co-Founder
Brett Robertson	55	Vice President of Corporate Development, General Counsel and Secretary
Michael Gandy <sup>(4)</sup>	55	Chief Financial Officer
Susan H. Martin	49	Vice President of Marketing
<b>Non-Employee Directors</b>		
Gregory B. Brown, M.D. <sup>(1)(2)(3)</sup>	61	Director and Chairman of the Board
William W. Burke <sup>(1)(3)</sup>	56	Director
Randall A. Lipps <sup>(2)</sup>	58	Director
Gregory T. Lucier <sup>(2)(3)</sup>	51	Director
Eric W. Roberts <sup>(1)(2)</sup>	51	Director
Reza Zadno, Ph.D. <sup>(1)(3)</sup>	60	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

(3) Member of our nominating and corporate governance committee.

(4) Mr. Gandy intends to resign as our Chief Financial Officer.

**Executive Officers**

*Philip Sawyer* has served as our Chief Executive Officer and a member of our board of directors since March 2010 and as our President since June 2012. In 2008, Mr. Sawyer co-founded Helix Ventures, a healthcare venture capital fund. In 1993, Mr. Sawyer co-founded Fusion Medical Technologies, a surgical sealant company, where he held the positions of President and Chief Executive Officer for nine years, guiding the company through two private financings, an initial public offering and an acquisition by Baxter International. Mr. Sawyer worked in marketing and business development at Stryker Corporation from 1991 to 1993. Mr. Sawyer received a B.A. in political science from Haverford College and an M.B.A. from Harvard Business School. We believe Mr. Sawyer is qualified to serve as a member of our board of directors because of the perspective he brings as our Chief Executive Officer and his management, operational and investment experience in the healthcare industry.

*Robert Gerberich* has served as our Vice President of Sales since May 2015 and Vice President of Sales and Marketing from October 2012 to May 2015. From April 2012 to October 2012, Mr. Gerberich served as Senior Vice President of Global Sales and Field Development at Primcogent Solutions, a non-invasive low-level laser therapy company. From January 2006 to April 2012, Mr. Gerberich served as President of UltraShape North America. Prior to UltraShape, Mr. Gerberich served as the Vice President of Marketing and Sales and Vice President of Sales at Thermage Inc., a medical device company (now Solta Medical). Mr. Gerberich received a B.S. in marketing from Illinois State University.

*Paul O. Davison* has served as our Vice President of Research and Development since November 2014. From October 2011 to November 2014, Mr. Davison served as Vice President and General Manager at

**Table of Contents**

ConMed, a surgical and patient monitoring products company. From July 2006 to September 2011, Mr. Davison served as Vice President of Research and Development at PEAK Surgical, a surgical tools company acquired by Medtronic, Inc. in 2011. Mr. Davison received a B.S. in manufacturing engineering from California Polytechnic University at Pomona and an M.S. in engineering management with a stem in mechanical engineering from Santa Clara University.

*Doug Heigel* has served as our Vice President of Operations since September 2014. From July 2003 to January 2014, Mr. Heigel served as Vice President of Operations for Solta Medical, a medical aesthetics company which was sold to Valeant Pharmaceuticals in January 2014. In May 2002, Mr. Heigel joined Solta Medical's predecessor company, Thermage, as Senior Director of Operations. From October 1995 to February 2002, Mr. Heigel worked for Argonaut Technologies, a life sciences company, first as Director of Manufacturing and then as Vice President of Manufacturing. Prior to Argonaut, Mr. Heigel served in various operational and technical leadership roles in the semiconductor and measurement instrumentation markets. Mr. Heigel received a B.S. in mechanical engineering from Oregon State University.

*Alex Vayser* co-founded Invuity and has served as our Chief Technology Officer since November 2004. Prior to joining Invuity, Mr. Vayser co-founded and served as President of Medvision, a manufacturer of custom surgical endoscopes and imaging devices. While at Medvision, Mr. Vayser co-founded Parallax Devices, a company focused on single channel stereoscopic and 3-D optical systems for medical and industrial applications. Mr. Vayser received a B.S. in optical engineering from the University of Rochester's Institute of Optics.

*Brett Robertson* has served as our Vice President of Corporate Development, General Counsel and Secretary since September 2010. From 2008 to September 2010, Ms. Robertson served as an advisor to executives and board members on capital markets and growth strategies for a portfolio of private companies. From 2006 to 2007, Ms. Robertson was Senior Vice President and General Counsel at StubHub, an online ticket sales marketplace. From 2003 to 2006, Ms. Robertson was Executive Vice President and General Counsel at Ask Jeeves, a search engine company. Ms. Robertson received a B.A. from the University of California, Berkeley and a J.D. from the University of Virginia.

*Michael Gandy* has served as our Chief Financial Officer since January 2013. From July 2010 to January 2013, Mr. Gandy was the Chief Financial Officer of Novasys Medical, a company focused on women's health. From August 2009 to June 2010, Mr. Gandy was the Chief Financial Officer of Baxano Surgical, an orthopedic company. Mr. Gandy has informed us that he plans to resign as our Chief Financial Officer to pursue other interests but has agreed to remain as our Chief Financial Officer until an appropriate replacement is hired. Mr. Gandy received a B.S. in finance from the California State University, Long Beach and an M.B.A. from California State University, Fullerton.

*Susan H. Martin* has served as our Vice President of Marketing since May 2015. From February 2011 to August 2014, Ms. Martin served as Vice President of Global Marketing at Zimmer Holdings, Inc., a medical device company. From 2009 to 2011, Ms. Martin served as Executive Director of Global Marketing at Ethicon, Inc., a subsidiary of Johnson & Johnson focused on surgical products. Prior to her role as Executive Director of Global Marketing at Ethicon, Inc., Ms. Martin served in various roles at Ethicon, Inc. from 2001-2009, including Executive Director, General Manager and Integration Lead and Executive Director of Procedure Marketing. Ms. Martin received a B.S. in Business Administration from Bowling Green State University.

***Non-Employee Directors***

*Gregory B. Brown, M.D.* has served as a member of our board of directors since February 2014 and as the Chairman of our board of directors since March 2015. Since October 2007, Dr. Brown has served as



---

**Table of Contents**

a Founding Managing Director of HealthCare Royalty Partners, a healthcare investment firm. Prior to co-founding HealthCare Royalty Partners, Dr. Brown was a partner at Paul Capital Partners, an investment firm, from 2002 to 2007. From 1997 to 2002, Dr. Brown was Co-Head of Investment Banking and Head of Healthcare at Adams, Harkness & Hill (now Canaccord Genuity) and a biotechnology research analyst and investment banker at Vector Securities International from 1992 to 1997. Prior to that, Dr. Brown practiced as a thoracic and vascular surgeon. Dr. Brown received an A.B. from Yale University, an M.D. from SUNY Upstate Medical Center and an M.B.A. from Harvard Business School. We believe Dr. Brown is qualified to serve as a member of our board of directors because of his medical background and investment experience in the healthcare industry.

*William W. Burke* has served as a member of our board of directors since May 2015. From 2009 to 2013, Mr. Burke served as Executive Vice President & Chief Financial Officer of IDEV Technologies, a developer of medical devices used by interventional radiologists, vascular surgeons and cardiologists that was acquired by Abbott Laboratories in 2013. From 2004 to 2007, Mr. Burke served as Executive Vice President & Chief Financial Officer of ReAble Therapeutics, a diversified orthopedic device company that was sold to the Blackstone Group in a going private transaction in 2006 and subsequently merged with DJ Orthopedics in 2007. From 2001 to 2004, Mr. Burke served as Chief Financial Officer of Cholestech Corporation, a medical diagnostic products company. Mr. Burke currently serves on the board of directors of LDR Holding Corporation, a publicly traded company focused on designing and commercializing novel and proprietary surgical technologies for the treatment of spine disorders. From 2004 to 2014, Mr. Burke served on the board of directors of Medical Action Industries, a publicly traded manufacturer of disposable medical products that was acquired by Owens & Minor in 2014. Mr. Burke received his B.B.A. in Finance from the University of Texas at Austin and an M.B.A. from The Wharton School of the University of Pennsylvania. We believe Mr. Burke is qualified to serve as a member of our board of directors because of his knowledge of accounting matters, his business experience with other medical technology companies and his experience as chief financial officer of other companies, including other publicly traded companies.

*Randall A. Lipps* has served as a member of our board of directors since June 2013. In September 1992, Mr. Randall founded Omnicell, a publicly traded automated healthcare solutions company, and has served as its Chairman of the Board since that time and as its President and Chief Executive Officer since October 2002. From 1989 to 1992, Mr. Lipps served as the Senior Vice President of ST Holdings, a travel and marketing company. From 1987 to 1989, he served as Assistant Vice President of Sales and Operations for a subsidiary of AMR, the parent company of American Airlines. Mr. Lipps received both a B.S. in economics and a B.B.A. from Southern Methodist University. We believe Mr. Lipps is qualified to serve on our board of directors because of his management and operational experience in the healthcare industry.

*Gregory T. Lucier* has served as a member of our board of directors since October 2014. Since May 2015, Mr. Lucier has served as the Chief Executive Officer of NuVasive, a publicly traded medical device company. From November 2008 to February 2014, Mr. Lucier was Chairman of the board of directors and Chief Executive Officer of Life Technologies, a global life sciences company acquired by Thermo Fisher Scientific in 2014. In May 2003, Mr. Lucier joined Life Technologies' predecessor company, Invitrogen Corporation, as Chief Executive Officer. Prior to Life Technologies, Mr. Lucier was a corporate officer at General Electric Company from 1994 to 2003 where he served in a variety of leadership roles. Mr. Lucier serves on the board of directors of NuVasive and CareFusion. Mr. Lucier received a B.S. with honors in industrial engineering from Pennsylvania State University and an M.B.A. from Harvard Business School. We believe Mr. Lucier is qualified to serve as a member of our board of directors because of his management and operational experience in the healthcare industry.

*Eric W. Roberts* has served as a member of our board of directors since June 2012. Since January 2012, Mr. Roberts has been a founding Managing Director of Valence Life Sciences. Since June 2006, Mr. Roberts has been a founding Managing Director of Caxton Advantage Venture Partners. From 1986

---

## **Table of Contents**

to 2004, Mr. Roberts served in a variety of roles as an investment banker, including as Managing Director and Partner at Dillon, Read & Co. and Managing Director and Co-Head of the Healthcare Investment Banking Group at Lehman Brothers. Mr. Roberts received a B.S. in economics from the Wharton School of the University of Pennsylvania. We believe Mr. Roberts is qualified to serve as a member of our board of directors because of his experience as an investment banker and venture capitalist in the healthcare industry.

*Reza Zadno, Ph.D.* has served as a member of our board of directors since January 2013. Since January 2015, Dr. Zadno has served as an Innovation Advisor to Novartis Venture Fund and has served as an Executive in Residence at InterWest Partners, a venture capital firm, where he served as a Venture Partner from January 2012 to December 2014. From January 2011 to January 2012, Dr. Zadno served as a Venture Partner at New Leaf Venture Partners, a venture capital firm. From March 2001 to September 2009, Dr. Zadno was founder, President, and Chief Executive Officer of Visiogen, a medical device company, which was acquired by Abbott-Medical Optics, a medical supply company, in 2009, at which time Dr. Zadno served as its General Manager until January 2011. From August 2000 to March 2001, Dr. Zadno worked as Entrepreneur in Residence at Three Arch Partners, a healthcare investment firm. Dr. Zadno currently serves on the board of directors of Carbylan Therapeutics, Oraya Therapeutics and Gobiquity. Dr. Zadno received a Ph.D. (Docteur-Ingenieur) in Mechanical Properties of Materials from Ecole des Mines de Paris. We believe Dr. Zadno is qualified to serve on our board because of his medical background, venture capital experience and his leadership and management experience.

### **Executive Officers**

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

### **Board of Directors**

Our business is managed under the direction of our board of directors, which consists of six directors. Our directors hold office until the earlier of their death, resignation, removal, or disqualification, or until their successors have been elected and qualified. We are actively searching for qualified candidates to add to our board of directors. Our board of directors does not have a formal policy on whether the roles of chief executive officer and chairman of our board of directors should be separate. Prior to this offering, the members of our board of directors were elected in compliance with the provisions of our amended and restated articles of incorporation and a voting agreement among us and certain of our stockholders. The voting agreement will terminate upon the completion of this offering and, following the completion of this offering, none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

Immediately prior to the completion of this offering, our bylaws will be amended and restated to provide that the authorized number of directors may be changed only by resolution of the board of directors. Upon the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Our directors will be divided among the three classes as follows:

The Class I directors will be Dr. Brown and Mr. Sawyer, and their terms will expire at our annual meeting of stockholders to be held in 2016;

The Class II directors will be Mr. Roberts and Dr. Zadno, and their terms will expire at our annual meeting of stockholders to be held in 2017; and

The Class III directors will be Messrs. Burke, Lipps and Lucier, and their terms will expire at our annual meeting of stockholders to be held in 2018.

## **Table of Contents**

This classification of the board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management. See "Description of Capital Stock - Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws" in this prospectus for a discussion of other anti-takeover provisions that will be included in our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering.

### **Director Independence**

In connection with this offering, we intend to list our common stock on the NASDAQ Global Market. Under the rules of the NASDAQ Global Market, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of this offering. In addition, the rules of the NASDAQ Global Market require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Our board of directors has reviewed the independence of each director and determined that Drs. Brown and Zadno and Messrs. Burke, Lipps, Lucier and Roberts are independent. Our board of directors will review the independence of each director at least annually. During these reviews, the board of directors will consider transactions and relationships between each director (and his or her immediate family and affiliates) and our company and its management to determine whether any such transactions or relationships are inconsistent with a determination that the director is independent. This review will be based primarily on responses of the directors to questions in a directors' and officers' questionnaire regarding employment, business, familial, compensation and other relationships with our company including its management.

We believe that the composition of our board of directors meets the requirements for independence under the current requirements of the NASDAQ Global Market. As required by the NASDAQ Global Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

### **Corporate Governance**

We believe that good corporate governance is important to ensure that, as a public company, we will be managed for the long-term benefit of our stockholders. In preparation for the offering being made by this prospectus, we and our board of directors have been reviewing the corporate governance policies and practices of other public companies, as well as those suggested by various authorities in corporate governance. We have also considered the provisions of the Sarbanes-Oxley Act and the rules of the SEC and the NASDAQ Global Market.

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, we have established charters for the audit committee, compensation committee and nominating and corporate governance committee, as well as a code of business conduct and ethics applicable to all of our directors, officers and employees.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. Our board of directors has assessed the independence of the members of each of these standing committees as defined under the rules of the NASDAQ Global Market and, in the case of the audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Under Rule 10A-3 under the Exchange Act and the applicable rules of the NASDAQ Global Market, we are permitted to phase in compliance with the independent committee requirements as follows: one

**Table of Contents**

independent member on each of the audit committee, compensation committee and nominating and corporate governance committee upon the listing date of our common stock, a majority of independent members on each of these committees within 90 days of the listing date and fully independent committees within one year of the listing date.

**Audit Committee.** Drs. Brown and Zadno and Messrs. Burke and Roberts serve on our audit committee. Mr. Burke serves as chair of the audit committee and will be the audit committee's financial expert within the meaning of the regulations of the SEC. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of the NASDAQ Global Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Drs. Brown and Zadno and Messrs. Burke and Roberts met these requirements and are independent under SEC and the NASDAQ Global Market rules. The audit committee's primary responsibilities include:

appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is PricewaterhouseCoopers LLP;

overseeing the work of our independent registered public accounting firm, including the receipt and assessment of reports from the independent registered public accounting firm;

reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;

preparing the audit committee report required by SEC rules to be included in our annual proxy statements;

monitoring our internal control over financial reporting, disclosure controls and procedures;

reviewing our risk management status;

establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;

meeting independently with our independent registered public accounting firm and management; and

monitoring compliance with the code of ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our board of directors has adopted a written charter for the audit committee to be effective prior to the completion of this offering, which will be available on our website at [www.invuity.com](http://www.invuity.com) upon the completion of this offering.

**Compensation Committee.** Dr. Brown and Messrs. Lipps, Lucier and Roberts serve on our compensation committee. Mr. Lucier serves as the chair of the compensation committee. Our board of directors has assessed whether all members of our compensation committee meet the composition requirements of the NASDAQ Global Market. Our board of directors found that Dr. Brown and Messrs. Lipps, Lucier and Roberts met these requirements and are independent under SEC and the NASDAQ Global Market rules. The compensation committee's responsibilities include:

## Edgar Filing: Invuity, Inc. - Form S-1/A

annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;

determining the compensation of our chief executive officer and our other executive officers;

reviewing and making recommendations to our board of directors with respect to director compensation;

## **Table of Contents**

overseeing an evaluation of our senior executives; and

overseeing and administering our cash and equity incentive plans.

From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, in January 2015, we engaged Compensia to advise us on compensation philosophy as we transition towards becoming a publicly traded company, selection of a group of peer companies to use for compensation benchmarking purposes and cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our board of directors has adopted a written charter for the compensation committee to be effective prior to the completion of this offering, which will be available on our website at [www.invuity.com](http://www.invuity.com) upon the completion of this offering.

***Nominating and Corporate Governance Committee.*** Drs. Brown and Zadno and Messrs. Burke and Lucier serve on our nominating and corporate governance committee. Dr. Brown serves as the chair of the nominating and corporate governance committee. Our board of directors has assessed whether all members of our nominating and corporate governance committee meet the composition requirements of the NASDAQ Global Market. Our board of directors found that Drs. Brown and Zadno and Messrs. Burke and Lucier met these requirements and are independent under SEC and the NASDAQ Global Market rules. The nominating and corporate governance committee's responsibilities include:

identifying individuals qualified to become members of our board of directors;

recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;

reviewing and making recommendations to our board of directors with respect to management succession planning;

developing, updating and recommending to our board of directors corporate governance principles and policies;

overseeing the evaluation of our board; and

reviewing and making recommendations to our board of directors with respect to director compensation.

Our board of directors has adopted a written charter for the nominating and corporate governance committee, to be effective prior to the completion of this offering, which will be available on our website at [www.invuity.com](http://www.invuity.com) upon the completion of this offering.

## **Code of Business Conduct and Ethics**

Our board of directors has adopted a code of business conduct and ethics, to be effective prior to the completion of the offering, that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the closing of this offering, our code of business conduct and ethics will be available on our website at [www.invuity.com](http://www.invuity.com). We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

## **Limitation on Liability and Indemnification Matters**

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, contains provisions that limit the liability of our directors for monetary



---

**Table of Contents**

damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; and

any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the completion of this offering, provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board of directors has ever been one of our employees.

**Director Compensation**

Prior to this offering, non-employee members of our board of directors did not receive any cash compensation for service on our board of directors, including attending board meetings. However, we did reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in attending board and committee meetings. In addition, from time to time we have granted stock options to some of our directors.

***Outside Director Compensation Policy***

*Cash Compensation.* After the completion of this offering, each non-employee director will be eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards. All non-employee directors will be entitled to receive the following cash compensation for their services following the completion of this offering:



**Table of Contents**

\$45,000 per year for service as a board member;

\$25,000 per year additionally for service as chairman of the audit committee;

\$12,500 per year additionally for service as an audit committee member;

\$12,500 per year additionally for service as chairman of the nominating and corporate governance committee;

\$6,500 per year additionally for service as a nominating and corporate governance committee member;

\$20,000 per year additionally for service as chairman of the compensation committee; and

\$10,000 per year additionally for service as a compensation committee member.

All cash payments to non-employee directors will be paid quarterly in arrears on a prorated basis.

*Equity Compensation.* Following the closing of this offering, nondiscretionary, automatic grants of nonstatutory stock options will be made to our non-employee directors. On the date occurring once each calendar year on the date of each annual meeting of our stockholders, beginning with the first annual meeting following the closing of this offering, each non-employee director will be granted an option to purchase shares having a grant date fair value equal to \$125,000, or the Annual Option. However, an individual who first becomes a non-employee director after December 31 in a fiscal year and who receives an Initial Option will not receive an Annual Option in the same fiscal year in which the individual first becomes an outside director.

The exercise price per share of each stock option granted under our outside director compensation policy, including Initial Options and Annual Options, will be the fair market value of a share of our common stock, as determined in accordance with our 2015 Equity Incentive Plan, or the 2015 Plan, on the date of the option grant. The grant date fair value is computed in accordance with the Black-Scholes option valuation methodology or such other methodology our board of directors or compensation committee may determine.

Subject to the terms of our 2015 Plan, each stock option granted under our outside director compensation policy will be scheduled to vest as to 100% of the shares subject to such option on the first annual anniversary of the date of grant of such option, provided that the optionee remains a director through such anniversary.

Any stock option granted under our outside director compensation policy will fully vest and become exercisable in the event of a change in control, as defined in our 2015 Plan, provided that the optionee remains a director through such change in control. Further, our 2015 Plan, as described below under the section titled *Employee Benefit and Stock Plans*, provides that in the event of a change in control, as defined in our 2015 Plan, each outstanding equity award granted under our 2015 Plan that is held by a non-employee director will fully vest, all restrictions on the shares subject to such award will lapse, and with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels, and all of the shares subject to such award will become fully exercisable, if applicable, provided such optionee remains a director through such change in control.

**Table of Contents**

The following table sets forth a summary of the compensation received by our non-employee directors who received compensation during our fiscal year ended December 31, 2014:

**Director Compensation**

Name	Option Awards (\$) <sup>(1)</sup>
Philip Sawyer <sup>(2)</sup>	
Gregory B. Brown, M.D.	
William W. Burke <sup>(3)</sup>	
Randall A. Lipps	7,110
Gregory T. Lucier	131,647
Eric W. Roberts	
Reza Zadno, Ph.D.	

(1) The amounts reported in this column represent the aggregate grant date fair value of the awards as computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 (FASB ASC Topic 718). The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. As of December 31, 2014, Messrs. Sawyer, Lipps and Lucier held options to purchase 466,862; 2,054; and 24,648 shares of our common stock, respectively, and Messrs. Burke and Roberts and Drs. Brown and Zadno held no options to purchase our common stock.

(2) For options and stock awards held by Mr. Sawyer as of December 31, 2014, including awards received by him in his capacity as President and Chief Executive Officer, see the disclosure under Executive Compensation Outstanding Equity Awards at 2014 Year-End.

(3) Mr. Burke joined our board of directors in May 2015.

In April 2015, our board of directors approved option grants to purchase 10,810 shares of our common

stock to Mr. Roberts and 4,054 shares of our common stock to Mr. Lucier. These options have an exercise price of \$11.10 per share, the fair market value of our common stock as determined by our board of directors on the grant date. The option granted to Mr. Roberts vests as to 50% of the underlying shares on April 16, 2015, the date of grant, and the remaining 50% vests as to 1/24<sup>th</sup> per month over the following 24 months, subject to continued service through such date. The option granted to Mr. Lucier vests as to 100% of the underlying shares on April 16, 2015, the date of grant.

In May 2015, our board of directors approved an option grant to purchase 44,306 shares of our common stock to Mr. Burke. This option has an exercise price of \$15.91 per share, the fair market value of our common stock as determined by our board of directors on the grant date. The option granted to Mr. Burke vests as to 1/36<sup>th</sup> per month over the following 36 months from the date of grant, subject to continued service through such date.

**Table of Contents****EXECUTIVE COMPENSATION****Summary Compensation Table**

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an emerging growth company as defined in the JOBS Act under federal securities laws, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by each individual who served as our principal executive officer at any time in 2014, and our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2014. These individuals were our named executive officers for 2014.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Philip Sawyer <i>President and Chief Executive Officer</i>	2014	375,000	232,448 <sup>(2)</sup>	151,088	5,939	764,475
Doug Heigel <i>Vice President of Operations</i>	2014	70,923 <sup>(3)</sup>	447,313	17,486	412	536,134
Paul O. Davison <i>Vice President of Research and Development</i>	2014	24,615 <sup>(4)</sup>	489,322		0	513,937

(1) The amounts reported in this column represent the aggregate grant date fair value of the awards as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus.

(2) Includes the incremental fair value computed in accordance with FASB ASC Topic 718 in connection with an option exercise price adjustment effective as of April 2014, as described below under the section titled "Stock Option Repricing."

(3) Mr. Heigel's salary reflects the prorated portion of his annual base salary of \$240,000 paid in fiscal 2014.

(4) Mr. Davison's salary reflects the prorated portion of his annual base salary of \$240,000 paid in fiscal 2014.

**Executive Officer Employment Agreements*****Philip Sawyer***

We expect to enter into an employment agreement with Mr. Sawyer that will take effect as of the effectiveness of the registration statement of which this prospectus forms a part. Pursuant to the agreement, Mr. Sawyer will continue to serve as our President and Chief Executive Officer on an at will basis. Mr. Sawyer's employment agreement provides for a base salary of \$425,000, eligibility to receive an annual performance bonus with the target amount determined as 80% of Mr. Sawyer's annual base salary, and eligibility to participate in employee benefit or group insurance plans maintained from time to time by us.

Pursuant to the employment agreement of Mr. Sawyer, if we terminate the employment of Mr. Sawyer other than for death, disability, or cause or Mr. Sawyer resigns for good reason (as such terms are defined in Mr. Sawyer's employment agreement), and, within 60 days following his termination, Mr. Sawyer executes a waiver and release of claims in our favor and resigns from all positions he may hold as an officer or director, Mr. Sawyer is entitled to receive (i) continuing payments of his highest base salary rate in effect during the employment period for a period of 12 months, payable pursuant to our regular payroll procedures, (ii) an amount equal to Mr. Sawyer's target annual bonus for the year of termination, payable in accordance with our regular payroll procedures, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for him and his respective dependents



---

**Table of Contents**

for up to 12 months and (iv) vesting acceleration of 50% with respect to any outstanding equity awards held by him on the date of his termination (with performance-based awards vesting based on achievement of target levels of performance).

Pursuant to the employment agreement of Mr. Sawyer, if, within the 3 month period prior to or the 12 month period following a change of control (as defined in Mr. Sawyer's employment agreement), the employment of Mr. Sawyer is terminated under the circumstances described in the above paragraph and, within 60 days following his termination, Mr. Sawyer executes a waiver and release of claims in our favor, Mr. Sawyer is entitled to receive (i) a lump sum payment equal to 24 months of his highest base salary rate in effect during the employment period, payable pursuant to our regular payroll procedures, (ii) a lump sum payment equal to 200% of the greater of his target annual bonus for the year of termination or for the year of the change in control, payable pursuant to our regular payroll procedures, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for him and his respective dependents for up to 24 months, and (iv) vesting acceleration of 100% with respect to any outstanding equity awards held by him on the date of his termination (with performance-based awards vesting based on achievement of target levels of performance).

In the event any payment to Mr. Sawyer pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, or the Code (as a result of a payment being classified as a parachute payment under Section 280G of the Code), Mr. Sawyer will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

***Doug Heigel***

We expect to enter into an employment agreement with Mr. Heigel that will take effect as of the effectiveness of the registration statement of which this prospectus forms a part. Pursuant to the agreement, Mr. Heigel will continue to serve as our Vice President of Operations on an at will basis. Mr. Heigel's employment agreement provides for a base salary of \$250,000, eligibility to receive an annual performance bonus with the target amount determined as 40% of Mr. Heigel's annual base salary, and eligibility to participate in employee benefit or group insurance plans maintained from time to time by us.

Pursuant to the employment agreement of Mr. Heigel, if we terminate the employment of Mr. Heigel other than for death, disability, or cause or Mr. Heigel resigns for good reason (as such terms are defined in Mr. Heigel's employment agreement), and, within 60 days following his termination, Mr. Heigel executes a waiver and release of claims in our favor and resigns from all positions he may hold as an officer or director, Mr. Heigel is entitled to receive (i) continuing payments of his highest base salary rate in effect during the employment period for a period of 9 months, payable pursuant to our regular payroll procedures, and (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for him and his respective dependents for up to 9 months.

Pursuant to the employment agreement of Mr. Heigel, if, within the 3 month period prior to or the 12 month period following a change of control (as defined in Mr. Heigel's employment agreement), the employment of Mr. Heigel is terminated under the circumstances described in the above paragraph and, within 60 days following his termination, Mr. Heigel executes a waiver and release of claims in our favor, Mr. Heigel is entitled to receive (i) a lump sum payment equal to 18 months of his highest base salary rate in effect during the employment period, payable pursuant to our regular payroll procedures, (ii) a lump sum payment equal to 150% of the greater of his target annual bonus for the year of termination or for the year of the change in control, payable pursuant to our regular payroll procedures, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to

---

**Table of Contents**

COBRA for him and his respective dependents for up to 18 months, and (iv) vesting acceleration of 100% with respect to any outstanding equity awards held by him on the date of his termination (with performance-based awards vesting based on achievement of target levels of performance).

In the event any payment to Mr. Heigel pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, or the Code (as a result of a payment being classified as a parachute payment under Section 280G of the Code), Mr. Heigel will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

***Paul O. Davison***

We expect to enter into an employment agreement with Mr. Davison that will take effect as of the effectiveness of the registration statement of which this prospectus forms a part. Pursuant to the agreement, Mr. Davison will continue to serve as our Vice President of Research and Development on an at will basis. Mr. Davison's employment agreement provides for a base salary of \$250,000, eligibility to receive an annual performance bonus with the target amount determined as 40% of Mr. Davison's annual base salary, and eligibility to participate in employee benefit or group insurance plans maintained from time to time by us.

Pursuant to the employment agreement of Mr. Davison, if we terminate the employment of Mr. Davison other than for death, disability, or cause or Mr. Davison resigns for good reason (as such terms are defined in Mr. Davison's employment agreement), and, within 60 days following his termination, Mr. Davison executes a waiver and release of claims in our favor and resigns from all positions he may hold as an officer or director, Mr. Davison is entitled to receive (i) continuing payments of his highest base salary rate in effect during the employment period for a period of 9 months, payable pursuant to our regular payroll procedures, and (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for him and his respective dependents for up to 9 months.

Pursuant to the employment agreement of Mr. Davison, if, within the 3 month period prior to or the 12 month period following a change of control (as defined in Mr. Davison's employment agreement), the employment of Mr. Davison is terminated under the circumstances described in the above paragraph and, within 60 days following his termination, Mr. Davison executes a waiver and release of claims in our favor, Mr. Davison is entitled to receive (i) a lump sum payment equal to 18 months of his highest base salary rate in effect during the employment period, payable pursuant to our regular payroll procedures, (ii) a lump sum payment equal to 150% of the greater of his target annual bonus for the year of termination or for the year of the change in control, payable pursuant to our regular payroll procedures, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for him and his respective dependents for up to 18 months, and (iv) vesting acceleration of 100% with respect to any outstanding equity awards held by him on the date of his termination (with performance-based awards vesting based on achievement of target levels of performance).

In the event any payment to Mr. Davison pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, or the Code (as a result of a payment being classified as a parachute payment under Section 280G of the Code), Mr. Davison will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

**Table of Contents****Non-Equity Incentive Plan Compensation**

We provided our named executive officers an opportunity to receive formula-based incentive payments under our 2014 Executive Bonus Plan. The payments were based on a target incentive amount for each named executive officer.

The 2014 Executive Bonus Plan provided for non-equity incentive compensation based upon our achievement of performance goals for 2014. The actual incentive payments had two components: financial goals and product goals, with financial goals being weighted more heavily.

The financial goals had two components: quarterly revenue and EBIDTA goals, with quarterly revenue goals being weighted more heavily. The quarterly revenue component included a minimum threshold level of achievement. If we exceeded the quarterly revenue target, our named executive officers would be eligible to receive a payment of up to 130% of the portion of the incentive payment allocated to the revenue component. If we achieved quarterly EBITDA that was equal to or greater than our quarterly EBITDA target, then our named executive officers would receive 100% of that component.

The product development component required achievement of all product goals for the quarter in order to receive the target incentive payment allocated to that component. If we failed to meet all product goals for a quarter, the named executive officers would receive no portion of that target incentive payment allocated to that component. If we achieved all of our product goals for a quarter, then our named executive officers would receive 100% of that component.

**Pension Benefits and Nonqualified Deferred Compensation**

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2014.

**Outstanding Equity Awards at 2014 Year-End**

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2014:

Name	Grant Date <sup>(1)</sup>	Option Awards		
		Number of Securities Underlying Unexercised Options (#) Exercisable	Option Exercise Price (\$) <sup>(2)</sup>	Option Expiration Date
Philip Sawyer	3/17/10 <sup>(3)</sup>	94,444	1.30	3/17/20
	11/17/10 <sup>(3)</sup>	114,360	1.30	11/17/20
	1/18/12 <sup>(3)</sup>	9,944	1.67	1/18/22
	9/19/12 <sup>(4)</sup>	17,347	3.15	9/19/22
	9/19/12 <sup>(4)</sup>	112,853	3.15	9/19/22
	3/5/14 <sup>(5)</sup>	23,597	3.15	3/5/24
Doug Heigel	3/5/14 <sup>(6)</sup>	94,317	3.15	3/5/24
	11/5/14 <sup>(7)</sup>	79,120	3.15	11/5/24
Paul O. Davison	12/2/14 <sup>(8)</sup>	79,120	3.15	12/2/24

<sup>(1)</sup> Each of the outstanding equity awards was granted pursuant to our 2005 Stock Incentive Plan.

<sup>(2)</sup> This column represents the fair value of a share of our common stock on the date of grant, as determined by our board of directors.

<sup>(3)</sup> The stock option is fully vested and immediately exercisable.

<sup>(4)</sup> The stock option is fully vested and immediately exercisable. The stock option was originally granted on September 19, 2012 and was amended on April 30, 2014 as part of our option repricing.





---

## **Table of Contents**

- (5) The shares subject to the option are early exercisable and vest in 48 equal monthly installments with a vesting commencement date of June 11, 2012, subject to Mr. Sawyer's continuous status as a service provider on each such vesting date.
- (6) The shares subject to the option are early exercisable and vest in 48 equal monthly installments with a vesting commencement date of February 28, 2014, subject to Mr. Sawyer's continuous status as a service provider on each such vesting date.
- (7) The shares subject to the option are early exercisable. 25% of the shares subject to the option will vest on September 15, 2015 and the remaining shares subject to the option will vest in 36 equal monthly installments thereafter, subject to Mr. Heigel's continuous status as a service provider on each such vesting date.
- (8) The shares subject to the option are early exercisable. 25% of the shares subject to the option will vest on November 24, 2015 and the remaining shares subject to the option will vest in 36 equal monthly installments thereafter, subject to Mr. Davison's continuous status as a service provider on each such vesting date.
- In April 2015, our board of directors approved option grants to purchase 125,440 shares of our common stock to Mr. Sawyer, 17,802 shares of our common stock to Mr. Heigel and 17,802 shares of our common stock to Mr. Davison. These options have an exercise price of \$11.10 per share, the fair market value of our common stock as determined by our board of directors on the grant date. Each of these options vests as to 1/60th over 60 months, subject to continued service through such date.

### **Stock Option Repricing**

In April 2014, we amended certain of our outstanding stock options to reset their respective exercise prices to \$3.15 per share, the fair market value of our common stock as of April 30, 2014, as determined by our board of directors. Options repriced included all then current employee options with an exercise price higher than \$3.15 per share that remained outstanding and unexercised on April 30, 2014. Pursuant to this repricing, options to purchase 348,871 shares of common stock held by our then current employees were repriced, including options to purchase 130,200 shares held by our named executive officers.

### **Employee Benefit and Stock Plans**

#### ***2015 Equity Incentive Plan***

In April 2015, our board of directors adopted, and in May 2015 our stockholders approved, a 2015 Equity Incentive Plan, or the 2015 Plan. Our 2015 Plan will permit the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

*Authorized shares.* A total of 1,494,272 shares of our common stock will be reserved for issuance pursuant to the 2015 Plan. In addition, the shares reserved for issuance under our 2015 Plan will also include shares reserved but not issued under the 2005 Stock Incentive Plan, as amended, or the 2005 Plan, and shares subject to stock options or similar awards granted under the 2005 Plan that expire or terminate without having been exercised in full and shares issued pursuant to awards granted under the 2005 Plan that are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2015 Plan pursuant to this sentence is 2,056,665 shares). In addition, shares may become available under the 2015 Plan as described below.

The number of shares available for issuance under the 2015 Plan will also include an annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the least of:

1,494,272 shares;

5% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; or

such other amount as our board of directors may determine.

---

**Table of Contents**

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under our 2015 Plan. With respect to stock appreciation rights, the net shares issued will cease to be available under the 2015 Plan and all remaining shares will remain available for future grant or sale under the 2015 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under our 2015 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under our 2015 Plan.

*Plan administration.* Our board of directors or one or more committees appointed by our board of directors will administer our 2015 Plan. In the case of awards intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Code, the committee will consist of two or more outside directors within the meaning of Section 162(m). In addition, if we determine it is desirable to qualify transactions under the 2015 Plan as exempt under Rule 16b-3 of the Securities Exchange Act of 1934, as amended, or Rule 16b-3, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2015 Plan, the administrator has the power to administer the plan, including but not limited to, the power to interpret the terms of our 2015 Plan and awards granted under it, to create, amend and revoke rules relating to our 2015 Plan, including creating sub-plans, and to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. The administrator also has the authority to amend existing awards to reduce or increase their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type and/or cash.

*Stock options.* Stock options may be granted under our 2015 Plan. The exercise price of options granted under our 2015 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2015 Plan, the administrator determines the other terms of options.

*Stock appreciation rights.* Stock appreciation rights may be granted under our 2015 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2015 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased

**Table of Contents**

appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Restricted stock.* Restricted stock may be granted under our 2015 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2015 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions for lapse of the restriction on the shares it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to the restriction, unless the administrator provides otherwise. Shares of restricted stock as to which the restrictions have not lapsed are subject to our right of repurchase or forfeiture.

*Restricted stock units.* Restricted stock units may be granted under our 2015 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2015 Plan, the administrator will determine the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restricted stock units will vest.

*Performance units and performance shares.* Performance units and performance shares may be granted under our 2015 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance criteria or other vesting provisions for such performance units or performance shares. Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares or in some combination

*Outside directors.* Our 2015 Plan provides that all non-employee directors are eligible to receive all types of awards (except for incentive stock options) under the 2015 Plan. Our 2015 Plan provides that in any given fiscal year, a non-employee director may not receive under the 2015 Plan awards having a grant date fair value greater than \$500,000 increased to \$750,000 in connection with her or her initial service, as grant fair value is determined under generally accepted accounting principles.

*Non-transferability of awards.* Unless the administrator provides otherwise, our 2015 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

*Certain adjustments.* In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2015 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2015 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in

**Table of Contents**

our 2015 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or change in control.* Our 2015 Plan provides that in the event of a merger or change in control, as defined under the 2015 Plan, each outstanding award will be treated as the administrator determines, except that if a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on the shares subject to such award will lapse, all performance goals or other vesting criteria applicable to the shares subject to such award will be deemed achieved at 100% of target levels and all of the shares subject to such award will become fully exercisable, if applicable, for a specified period prior to the transaction. The award will then terminate upon the expiration of the specified period of time.

*Amendment, termination.* The administrator will have the authority to amend, suspend or terminate the 2015 Plan provided such action will not impair the existing rights of any participant. Our 2015 Plan will automatically terminate in 2025, unless we terminate it sooner.

***2005 Stock Incentive Plan, as Amended***

Our board of directors adopted, and our stockholders approved, our 2005 Stock Incentive Plan, or the 2005 Plan, in May 2005. Our 2005 Plan was most recently amended in May 2015. Our 2005 Plan allows for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options and restricted stock to our employees, directors and consultants and our parent and subsidiary corporations' employees, directors and consultants.

*Authorized Shares.* Our 2005 Plan will be terminated in connection with this offering, and accordingly, no shares will be available for issuance under the 2005 Plan following the completion of this offering. Our 2005 Plan will continue to govern outstanding awards granted thereunder. As of March 31, 2015, options to purchase 1,359,142 shares of our common stock remained outstanding under our 2005 Plan. In the event that an outstanding option or other right for any reason expires or is canceled, the shares allocable to the unexercised portion of such option or other right shall be added to the number of shares then available for issuance under the 2005 Plan.

*Plan Administration.* Our board of directors or a committee of our board (the administrator) administers our 2005 Plan. Subject to the provisions of the 2005 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2005 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2005 Plan.

*Options.* Stock options may be granted under our 2005 Plan. The exercise price per share of incentive stock options and nonstatutory stock options must equal at least 100% and 85%, respectively, of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The term of a stock option may not exceed 10 years. With respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price per share of such incentive stock option must equal at least 110% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The 2005 Plan administrator determines the terms and conditions of options.

After termination of an optionee's service as an employee, director or consultant, the optionee may exercise the vested shares subject to his or her option as of the date of such termination for the period of

**Table of Contents**

time as specified in the option agreement, subject to the terms of the 2005 Plan. If termination is due to death or disability, the option will remain exercisable for at least 6 months, or such longer period of time as specified in the option agreement. If termination is due to cause, the option agreement may provide that the option will terminate immediately on the effective date of the optionee's termination. In all other cases, the option will remain exercisable for at least thirty days, or such longer period of time as specified in the option agreement. However, an option generally may not be exercised later than the expiration of its term.

*Restricted Shares.* Restricted shares may be granted under our 2005 Plan as a purchasable award. Restricted shares are shares of our common stock that vest in accordance with the terms and conditions established by the administrator, provided that with respect to recipients of restricted shares who are not officers, directors, or consultants, restricted shares will vest at a rate no slower than 20% per year over five years starting on the date of grant of the award or sale of the underlying shares. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2015 Plan, will determine the terms and conditions of such awards. The purchase price per share of restricted shares must equal at least 85% of the fair market value per share of our common stock on the date of grant, as determined by the administrator, provided that restricted shares granted to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date must have a purchase price per share equal to at least 100% of the fair market value per share of our common stock on the date of grant. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to the restriction, unless the administrator provides otherwise. Shares of restricted stock as to which the restrictions have not lapsed are subject to our right of repurchase or forfeiture. Rights to purchase restricted shares must be exercised within 30 days after we communicate the grant of such rights to the award recipient.

*Transferability of Awards.* Our 2005 Plan generally does not allow for the transfer or assignment of options, except by will or by the laws of descent and distribution. However, to the extent permitted by our board of directors in its sole discretion, a nonstatutory stock option may be transferred by an optionee to family members or a trust established for the benefit of the optionee or the optionee's family members to the extent permitted by applicable securities laws. Restricted shares and shares issued upon exercise of an option will be subject to such special forfeiture conditions, rights of repurchase, rights of first refusal, and other transfer restrictions as the administrator may determine.

*Certain Adjustments.* In the event of a subdivision of our outstanding stock, a declaration of a dividend payable in shares, a declaration of an extraordinary dividend payable in a form other than shares in an amount that has a material effect on the fair market value of our shares, a combination or consolidation of our outstanding stock into a lesser number of shares, a recapitalization, a spin-off, a reclassification, or a similar occurrence, our board of directors will make appropriate adjustments to the number of shares under the 2005 Plan available for future awards, the number of shares covered by each outstanding option, the exercise price under each outstanding option, or the price of shares subject to our right of repurchase.

*Merger or Change in Control.* Our 2005 Plan provides that, in the event of a merger or consolidation, or in the event of a transaction providing for the sale of all or substantially all of our stock or assets, all outstanding options will be subject to the agreement of merger or consolidation. Such agreement may provide for one or more of the following:

the continuation of the options by us (if we are the surviving corporation);

the assumption of the options by the surviving corporation or its parent;

the substitution by the surviving corporation or its parent of new options with substantially similar terms;

---

**Table of Contents**

immediate exercisability of the options, followed by cancellation of the options; or

the cancellation of the options and payments to optionees equal to the full value of the options.

In the event of a change in control, as defined under the 2005 Plan, our repurchase rights with respect to restricted shares held by our non-employee directors will lapse, and all other restricted shares will be treated as set forth in the applicable restricted share award agreement.

*Amendment; Termination.* Our board of directors may amend, suspend or terminate our 2005 Plan at any time, provided that such action does not adversely affect a participant's rights under outstanding awards granted under the 2005 Plan without such participant's written consent. As noted above, upon completion of this offering, our 2005 Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

***Executive Incentive Compensation Plan***

We expect our board of directors to adopt an Executive Incentive Compensation Plan, or the Bonus Plan. The Bonus Plan will become effective immediately prior to this offering and be administered by our compensation committee following the completion of this offering. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation, (i) attainment of research and development milestones, (ii) sales bookings, (iii) business divestitures and acquisitions, (iv) cash flow, (v) cash position, (vi) earnings (which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest and taxes, depreciation and amortization and net earnings), (vii) earnings per share, (viii) net income, (ix) net profit, (x) net sales, (xi) operating cash flow, (xii) operating expenses, (xiii) operating income, (xiv) operating margin, (xv) overhead or other expense reduction, (xvi) product defect measures, (xvii) product release timelines, (xviii) productivity, (xix) profit, (xx) return on assets, (xxi) return on capital, (xxii) return on equity, (xxiii) return on investment, (xxiv) return on sales, (xxv) revenue, (xxvi) revenue growth, (xxvii) sales results, (xxviii) sales growth, (xxix) stock price, (xxx) time to market, (xxxi) total stockholder return, (xxxii) working capital, (xxxiii) individual objectives such as peer reviews or other subjective or objective criteria, and (xxxiv) consummation of financial transactions. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the compensation committee's discretion. Our compensation committee may determine the amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

**Table of Contents**

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid. Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

***401(k) Plan***

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. We may make a discretionary matching and profit sharing contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. To date, we have not made any matching or profits sharing contributions into the 401(k) plan. All participants' interests in our matching and profit sharing contributions, if any, vest pursuant to a four-year graded vesting schedule from the time of contribution. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

**Table of Contents****CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

We describe below transactions and series of similar transactions, since January 1, 2012, to which we were a party or will be a party, in which:

the amounts involved exceeded or will exceed \$120,000; and

any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under Executive Compensation.

**Loan Agreement**

In February 2014, we entered into a loan agreement with HealthCare Royalty Partners, or HCRP, a holder of more than 5% of our capital stock, for an aggregate principal amount of up to \$15.0 million in two separate tranches. We drew down the first tranche of \$10.0 million upon execution of the loan agreement and the second tranche of \$5.0 million 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, we will make principal and interest payments until the maturity of the loan on December 31, 2020. We are 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 prepayment amounts are as follows:

<b>Prepayment Date</b>	<b>Prepayment Amount</b>
After December 31, 2014 and on or prior to December 31, 2015	140% of the aggregate loan amount, less any previously made payments of accrued fixed interest
After December 31, 2015 and on or prior to December 31, 2016	150% of the aggregate loan amount, less any previously made payments of accrued fixed interest
After December 31, 2016 and on or prior to December 31, 2017	112% of the outstanding principal amount
After December 31, 2017 and on or prior to December 31, 2018	108% of the outstanding principal amount
After December 31, 2018 and on or prior to December 31, 2019	104% of the outstanding principal amount
After December 31, 2019 and on or prior to December 31, 2020	100% of the outstanding principal amount

In connection with the loan agreement, we issued HCRP a warrant to purchase 84,553 shares of Series E convertible preferred stock at \$13.3052 per share. The \$572,000 estimated fair value of the warrant was recorded as a reduction in the carrying value of the debt. We also paid \$200,000 in debt issuance costs to HCRP in 2014, which were recorded as a debt discount. In 2014, we made interest payments to HCRP pursuant to the loan agreement in the amount of \$1.1 million and no payments of principal were made.



**Table of Contents**

The outstanding principal balance of the loan was \$10.0 million and \$15.0 million as of December 31, 2014 and March 31, 2015, respectively.

Gregory B. Brown, M.D., a member of our board of directors, is a Founding Managing Director of HealthCare Royalty Management, LLC, the investment manager of HCRP.

**Series F Preferred Stock Financing**

In February and March 2015, we issued an aggregate of 1,596,212 shares of our Series F convertible preferred stock at a price per share of \$14.3449. The shares of Series F convertible preferred stock will convert into shares of common stock on a 1-to-1.0469621828 basis upon the completion of this offering, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share. The table below sets forth the number of shares of Series F convertible preferred stock sold to our directors, executive officers or holders of more than 5% of any class of our capital stock:

Name	Number of Shares of Series F Convertible Preferred Stock	Aggregate Purchase Price
Entities affiliated with Wellington <sup>(1)</sup>	1,394,223	\$ 19,999,999.99
Robertson Revocable Trust <sup>(2)</sup>	47,868	\$ 686,668.66
RiverRoad Capital Partners, LLC <sup>(3)</sup>	17,427	\$ 249,999.82

<sup>(1)</sup> Affiliates of Wellington holding our securities, whose shares are aggregated for purposes of reporting the above share ownership information, are Hadley Harbor Master Investors (Cayman) L.P. (Nominee Italianflare & Co.) and the Hartford Capital Appreciation Fund (Nominee: Cudd & Co.). As a result of the Series F preferred stock financing, the entities affiliated with Wellington became holders of more than 5% of the Company's outstanding capital stock.

<sup>(2)</sup> Brett Robertson, an executive officer, is related to Sanford Robertson, trustee of the Robertson Revocable Trust.

<sup>(3)</sup> Gregory T. Lucier, a member of our board of directors, is a managing member of RiverRoad Capital Partners, LLC.

**Series E Preferred Stock Financing**

In February 2014, we issued an aggregate of 1,597,814 shares of our Series E convertible preferred stock at a price per share of \$13.3052. The shares of Series E convertible preferred stock will convert into shares of common stock on a 1-to-1.0276626722 basis upon the completion of this offering, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share. The table below sets forth the number of shares of Series E convertible preferred stock sold to our directors, executive officers or holders of more than 5% of any class of our capital stock:

Name	Number of Shares of Series E Convertible Preferred Stock	Aggregate Purchase Price
HealthCare Royalty Partners II, L.P. <sup>(1)</sup>	1,127,378	\$ 14,999,999.84
InterWest Partners X, LP <sup>(2)</sup>	56,368	\$ 749,999.74
CDK Associates, L.L.C. <sup>(3)</sup>	40,585	\$ 539,999.82
Helix Founders Fund, L.P. <sup>(4)</sup>	39,458	\$ 524,999.46
Valence CDK SPV, L.P. <sup>(5)</sup>	38,065	\$ 506,467.84
Entities affiliated with Legacy <sup>(6)</sup>	19,540	\$ 259,998.72
KPCB Holdings, Inc.	18,789	\$ 249,999.68
Robertson Revocable Trust <sup>(7)</sup>	14,875	\$ 197,917.37
Eric W. Roberts.	11,273	\$ 149,999.95
Lipps Family Ventures <sup>(8)</sup>	7,515	\$ 99,999.73

## Edgar Filing: Invuity, Inc. - Form S-1/A

<sup>(1)</sup> As a result of the Series E preferred stock financing, HealthCare Royalty Partners II, L.P. became a holder of more than 5% of the Company's outstanding capital stock.

**Table of Contents**

- (2) Reza Zadno, a member of our board of directors, is affiliated with InterWest Partners X, LP.
- (3) Eric W. Roberts, a member of our board of directors, is affiliated with CDK Associates, L.L.C.
- (4) Philip Sawyer, our Chief Executive Officer and President and a member of our board of directors, is affiliated with Helix Founders Fund, L.P.
- (5) Mr. Roberts, a member of our board of directors is affiliated with Valence CDK SPV, L.P.
- (6) Affiliates of Legacy holding our securities, whose shares are aggregated for purposes of reporting the above share ownership information, are Legacy Life Sciences, LLC, Covenant Properties, LLC and Heritage Holding Co. LLC. Immediately prior to the closing of the Series E preferred stock financing, the entities affiliated with Legacy were holders of more than 5% of our outstanding capital stock.
- (7) Brett Robertson, an executive officer, is related to Sanford Robertson, trustee of the Robertson Revocable Trust.
- (8) Randall A. Lipps, a member of our board of directors, is affiliated with the Lipps Family Ventures.

**Series D Preferred Stock Financing**

In June 2012, we issued an aggregate of 2,016,929 shares of our Series D convertible preferred stock at a price per share of \$12.395. The shares of Series D convertible preferred stock will convert into shares of common stock on a 1-to-1.0088217987 basis upon the completion of this offering, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share. The table below sets forth the number of shares of Series D convertible preferred stock sold to our directors, executive officers or holders of more than 5% of any class of our capital stock:

Name	Number of Shares of Series D Convertible Preferred Stock	Aggregate Purchase Price
Entities affiliated with Valence <sup>(1)</sup>	806,776	\$ 9,999,999.24
Wex Invuity Investors LLC <sup>(2)</sup>	500,201	\$ 6,199,999.77
InterWest Partners X, LP <sup>(3)</sup>	262,310	\$ 3,251,340.49
KPCB Holdings, Inc.	206,137	\$ 2,555,068.45
Entities affiliated with Legacy <sup>(4)</sup>	83,218	\$ 1,031,509.89
Helix Founders Fund, L.P. <sup>(5)</sup>	52,462	\$ 650,267.83
Philip Sawyer and Grace Sawyer <sup>(6)</sup>	1,613	\$ 19,999.50

- (1) Affiliates of Valence holding our securities, whose shares are aggregated for purposes of reporting the above share ownership information, are CDK Associates, L.L.C., Valence Advantage Life Sciences Fund II, L.P. and Valence Advantage Life Sciences Side Fund II, L.P. As a result of the Series D preferred stock financing, entities affiliated with Valence became holders of more than 5% of our outstanding capital stock.
- (2) As a result of the Series D preferred stock financing, Wex Invuity Investors LLC became a holder of more than 5% of our outstanding capital stock.
- (3) Reza Zadno, a member of our board of directors, is affiliated with InterWest Partners X, LP.
- (4) Affiliates of Legacy holding our securities, whose shares are aggregated for purposes of reporting the above share ownership information, are Legacy Life Sciences, LLC, Covenant Properties, LLC and Heritage Holding Co. LLC. Immediately prior to the closing of the Series D preferred stock financing, the entities affiliated with Legacy were holders of more than 5% of our outstanding capital stock.
- (5) Philip Sawyer, our Chief Executive Officer and President and a member of our board of directors, is affiliated with Helix Founders Fund, L.P.
- (6) Philip Sawyer, our Chief Executive Officer and President and a member of our board of directors, is related to Philip Sawyer and Grace Sawyer.

**Investor Rights Agreement**

In February 2015, in connection with the closing of our Series F convertible preferred stock financing, we entered into an amended and restated investor rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. In March 2015, we amended this agreement to increase the dollar threshold for agreements requiring the consent of our board of directors. Pursuant to the agreement, these holders are entitled to registration under the Securities Act of the shares of common stock issuable upon the conversion of our convertible preferred stock and upon the exercise of outstanding warrants. For a more detailed description of these registration

## **Table of Contents**

rights, see Description of Capital Stock Registration Rights. The agreement also provides certain additional rights to these holders, including with respect to access to financial information, inspection of our properties and, for certain investors, a right of first offer with respect to future sales by us of our equity securities (which right of first offer does not apply to this offering). All of the rights granted under the agreement, other than the registration rights, will terminate upon the closing of this offering.

### **Voting Agreement**

We are party to a voting agreement under which certain holders of our capital stock, including entities with which certain of our directors are affiliated, have agreed to vote their shares in a certain way on certain matters, including with respect to the election of directors, and certain holders have the right to have a designated representative present at meetings of our board of directors. Upon the closing of this offering, the voting agreement will terminate and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors or the voting of our capital stock.

### **Right of First Refusal and Co-Sale Agreement**

We are party to an amended and restated right of first refusal and co-sale agreement with certain holders of our capital stock, including entities with which certain of our directors are affiliated, which imposes restrictions on the transfer of our capital stock. Upon the closing of this offering, the right of first refusal and co-sale agreement will terminate and the restrictions on the transfer of our capital stock set forth in this agreement will no longer apply.

### **Employment Arrangements and Indemnification Agreements**

We have entered into employment and consulting arrangements with certain of our current executive officers. See Executive Compensation Executive Officer Employment Letters.

We have also entered into indemnification agreements with each of our directors and officers. The indemnification agreements and our certificate of incorporation and bylaws in effect upon the completion of this offering require us to indemnify our directors and officers to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties, fines and settlement amounts incurred by the director or officer in any action or proceedings, including any action or proceeding by or in right of us, arising out of the person's service as a director or officer. See Management Limitation on Liability and Indemnification Matters.

### **Stock Option Grants to Executive Officers and Directors**

We have granted stock options to our executive officers and our non-employee directors. See Executive Compensation and Management Director Compensation for stock options granted to our executive officers and non-employee directors.

**Table of Contents****Stock Option Repricing**

In April 2014, we amended certain of our outstanding stock options to reset their respective exercise prices to \$3.15 per share, the fair market value of our common stock as of April 30, 2014, as determined by our board of directors. Options repriced included all then current employee options with an exercise price higher than \$3.15 per share that remained outstanding and unexercised on April 30, 2014. Pursuant to this repricing, options to purchase 275,212 shares of common stock held by our directors and executive officers were repriced, as set forth below:

Name	Number of Shares Underlying Repriced Options
Philip Sawyer	130,200
Robert Gerberich	50,717
Michael Gandy	50,717
Brett Robertson	26,631
Alex Vayser	16,947

**Policies and Procedures for Related Party Transactions**

The audit committee of our board of directors has the primary responsibility for reviewing and approving transactions with related parties. Our audit committee charter will provide that the audit committee shall review and approve in advance any related party transactions.

**Indemnification of Directors and Officers**

Section 145 of the Delaware General Corporation Law authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors, and other corporate agents.

Immediately prior to the completion of this offering, as permitted by Section 102(b)(7) of the Delaware General Corporation Law, our amended and restated certificate of incorporation will include provisions that eliminate the personal liability of its directors and officers for monetary damages for breach of their fiduciary duty as directors and officers.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated certificate of incorporation and amended and restated bylaws will provide that:

We shall indemnify our directors and officers for serving in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such director or officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

We will not be obligated pursuant to the amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person, except with respect to



**Table of Contents**

proceedings authorized by our board of directors or brought to enforce a right to indemnification.

The rights conferred in the amended and restated certificate of incorporation and amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend the bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our policy is to enter into separate indemnification agreements with each of its directors and officers that provide the maximum indemnity allowed to directors and executive officers by Section 145 of the Delaware General Corporation Law and also to provide for certain additional procedural protections. We also maintain directors and officers insurance to insure such persons against certain liabilities.

These indemnification provisions and the indemnification agreements entered into between us and our officers and directors may be sufficiently broad to permit indemnification of our officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to the registration statement of which this prospectus is a part, provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act and otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

**Table of Contents**

**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information with respect to the beneficial ownership of our common stock at May 29, 2015, and as adjusted to reflect the sale of common stock in this offering, for:

each of our directors;

each of our named executive officers;

all of our current directors and executive officers as a group; and

each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Percentage ownership of our common stock Before Offering in the table is based on 8,701,683 shares of common stock issued and outstanding as of May 29, 2015, assuming the automatic conversion of our convertible preferred stock into common stock at a conversion rate based on the assumed initial public offering price of \$12.00 per share. The number of shares issuable upon conversion of the preferred stock is dependent upon the price at which our shares are sold to the public. For a description of the impact of changes in the offering price see Prospectus Summary The Offering. Percentage ownership of our common stock After Offering in the table is based on 12,701,683 shares of common stock issued and outstanding on May 29, 2015, which gives effect to the issuance of 4,000,000 shares of common stock in this offering and assumes no exercise of the underwriters option to purchase additional shares. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of common stock subject to options, warrants or other equity awards held by the person that are currently exercisable or exercisable within 60 days of May 29, 2015. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The table below excludes any shares of common stock that may be purchased in this offering.



**Table of Contents**

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Invuity, Inc., 444 De Haro St., San Francisco, CA 94107.

Name of Beneficial Owner+	Percentage of Shares Beneficially Owned		
	Shares Beneficially Owned	Before Offering	After Offering
<b>5% Stockholders:</b>			
Entities affiliated with the Wellington Entities <sup>(1)</sup>	1,459,698	16.8%	11.5%
Entities affiliated with HealthCare Royalty Partners II, L.P. <sup>(2)</sup>	1,245,455	14.2%	9.7%
Entities affiliated with InterWest Partners X, L.P. <sup>(3)</sup>	1,080,272	12.4%	8.5%
Entities affiliated with KPCB Holdings, Inc. <sup>(4)</sup>	961,699	11.1%	7.6%
Hadley Harbor Master Investors (Cayman) L.P. <sup>(5)</sup>	948,803	10.9%	7.5%
The Hartford Capital Appreciation Fund <sup>(6)</sup>	510,895	5.9%	4.0%
Entities affiliated with the Wexford Entities <sup>(7)</sup>	500,201	5.7%	3.9%
Entities affiliated with CDK Associates, L.L.C. <sup>(8)</sup>	448,653	5.2%	3.5%
<b>Named Executive Officers and Directors:</b>			
Philip Sawyer <sup>(9)</sup>	808,902	8.7%	6.1%
Paul O. Davison <sup>(10)</sup>	96,922	1.1%	*
Doug Heigel <sup>(11)</sup>	96,922	1.1%	*
Gregory B. Brown, M.D. <sup>(12)</sup>		*	*
William W. Burke <sup>(13)</sup>	44,306	*	*
Randall A. Lipps <sup>(14)</sup>	30,316	*	*
Gregory T. Lucier <sup>(15)</sup>	46,947	*	*
Eric W. Roberts <sup>(16)</sup>	380,208	4.4%	3.0%
Reza Zadno, Ph.D.		*	*
All executive officers and directors as a group (14 persons)	2,228,066	22.2%	15.9%

\* Represents beneficial ownership of less than one percent (1%).

+ Options to purchase shares of our capital stock included in this table are early exercisable, and to the extent such shares are early exercised but remain unvested as of a given date, such shares will remain subject to a right of repurchase held by us.

<sup>(1)</sup> Consists of (i) 948,803 shares held of record by Hadley Harbor Master Investors (Cayman) L.P. (Nominee: Italianflare & Co.) and (ii) 510,895 shares held of record by The Hartford Capital Appreciation Fund (Nominee: Cudd & Co.) (collectively referred to as the Wellington Entities). Wellington Management Company LLP (Wellington Management) is the investment adviser to several entities that own shares of Invuity, Inc. (each a Wellington Client), as reflected in the aggregate in the table and two of which are specifically named in the footnotes to the table of Principal Stockholders. Wellington Management Company LLP is an investment adviser registered under the Investment Advisers Act of 1940, as amended, and is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Company LLP and Wellington Management Group LLP may each be deemed to share beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of the shares indicated in the table, all of which are held of record by the entity named in the table or a nominee on its behalf. The business address of the entity named in the table is c/o Wellington Management Company LLP, 280 Congress Street, Boston, Massachusetts 02210. The business address of Wellington Management Company LLP and Wellington Management Group LLP is 280 Congress Street, Boston, Massachusetts 02210.

<sup>(2)</sup> Consists of (i) 1,158,564 shares held of record by HealthCare Royalty Partners II, L.P. (HCRPII) and (ii) 86,891 shares issuable pursuant to outstanding warrants held by HCRPII. HealthCare Royalty Management, LLC is the investment manager of HCRPII and therefore may be deemed to beneficially own the shares beneficially owned by HCRPII. Gregory B. Brown, MD, Todd C. Davis and Clarke B. Futch comprise the investment committee that, through HealthCare Royalty Management, LLC, is responsible for the voting and investment decisions relating to the shares beneficially owned by HCRPII. The reporting persons may be deemed to be a group as defined in Rule 13d-5(b) under the Securities Exchange Act of 1934, as amended, and each

footnotes continued on following page

**Table of Contents**

- member of such group may be deemed to beneficially own the ordinary shares beneficially owned by other members constituting such group. Each of Dr. Brown and Messrs. Davis and Futch disclaims beneficial ownership of such shares of common stock. The address for these entities is 300 Atlantic Street, Suite 600, Stamford, CT 06901.
- (3) Consists of 1,080,272 shares held of record by InterWest Partners X, L.P. (IW10). InterWest Management Partners X, LLC (IMP 10) is the General Partner of IW10 and has sole voting and investment power with respect to the shares held by IW10. The Managing Directors of IMP10 are Bruce A. Cleveland, Philip T. Gianos, W. Stephen Holmes, Nina Kjellson, Gilbert H. Kliman, Arnold L. Oronsky and Douglas A. Pepper. The Venture Members of IMP10 are Keval Desai and Khaled A. Nasr. Each of the Managing Directors and Venture Members of IMP10 share voting and investment power with respect to the shares held by IW10. Each of the Managing Directors and Venture Members disclaim beneficial ownership of the shares held by IW10 except to the extent of their pecuniary interest therein. The address for these entities is c/o InterWest Partners, 2710 Sand Hill Road, Suite 200, Menlo Park, CA 94025.
- (4) Consists of (i) 858,589 shares beneficially owned by Kleiner Perkins Caufield & Byers XII, LLC, or KPCB XII; (ii) 13,287 shares beneficially owned by KPCB XII Founders Fund, LLC, or KPCB XII FF; and (iii) 89,823 shares beneficially owned by individuals and entities associated with Kleiner Perkins Caufield & Byers. All shares are held for convenience in the name of KPCB Holdings, Inc. as nominee, for the accounts of such individuals and entities who each exercise their own voting and dispositive control over such shares. The Managing Member of KPCB XII and KPCB XII FF is KPCB XII Associates, LLC, or KPCB XII Associates. Brook H. Byers, L. John Doerr, Joseph Lacob, Raymond J. Lane, Theodore E. Schlein and Russ Siegelman, the Managers of KPCB XII Associates, exercise shared voting and dispositive control over the shares directly held by KPCB XII and KPCB XII FF. The principal business address for all entities and individuals affiliated with Kleiner Perkins Caufield & Byers is 2750 Sand Hill Road, Menlo Park, CA 94025.
- (5) The address for Hadley Harbor Master Investors (Cayman) L.P. is c/o Wellington Management Company LLP, 280 Congress Street, Boston, Massachusetts 02210.
- (6) The address for The Hartford Capital Appreciation Fund is c/o Wellington Management Company LLP, 280 Congress Street, Boston, Massachusetts 02210.
- (7) Consists of (i) 403,388 shares held of record by Wexford Spectrum Investors LLC and (ii) 96,813 shares held of record by Wex SP LLC (collectively referred to as the Wexford Entities). Wexford Capital LP (WC) is the investment manager of the Wexford Entities and Wexford GP LLC (WGP) is the General Partner of WC. As a result, and by virtue of the relationships described in this footnote, WC and WGP may be deemed to share beneficial ownership of the shares held by the Wexford Entities. In addition, as controlling persons of WGP, each of Joseph Jacobs and Charles E. Davidson may be deemed to share beneficial ownership of the shares held by the Wexford Entities. WC, WGP and Messrs. Jacobs and Davidson disclaim beneficial ownership of the shares held by the Wexford Entities except to the extent of their pecuniary interest therein. The address for these entities is 411 West Putnam Ave., Greenwich, CT 06830.
- (8) Consists of 448,653 shares held of record by CDK Associates, L.L.C. (CDK). Caxton Corporation is the manager of CDK. Bruce Kovner, as the controlling person of Caxton Corporation, may be deemed, by virtue of the relationships described in this footnote, to share beneficial ownership of the shares held by CDK. Mr. Kovner disclaims beneficial ownership of the shares held by CDK except to the extent of his pecuniary interest therein. The address for CDK is 731 Alexander Road, Building 2, Princeton, NJ 08540.
- (9) Consists of (i) 216,600 shares held of record by Helix Founders Fund, L.P. (HFF) and (ii) 592,302 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 410,995 shares were fully vested as of such date. HFF GP, LLC (HFFGP) is the General Partner of HFF and Helix Ventures, LLC (Helix Ventures) is the management company of HFF. Mr. Sawyer is a General Partner of Helix Ventures. As a result, and by virtue of the relationships described in this footnote, Mr. Sawyer may be deemed to share beneficial ownership of the shares held by HFF. Mr. Sawyer disclaims beneficial ownership of the shares held by HFF except to the extent of his pecuniary interest therein. The address for these entities is 1717 Embarcadero Road, Palo Alto, CA 94303.
- (10) Consists of 96,922 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 1,483 shares were fully vested as of such date.
- (11) Consists of 96,922 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 1,483 shares were fully vested as of such date.
- (12) The address for Gregory B. Brown, M.D. is 300 Atlantic Street, Suite 600, Stamford, CT 06901.
- (13) Consists of 44,306 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 2,461 shares were fully vested as of such date.
- (14) Consists of (i) 20,540 shares held of record by Randall A. Lipps, 9,842 shares of which have been issued upon early exercise of stock options and remain subject to further vesting as of 60 days following May 29, 2015, (ii) 7,722 shares held of record by Lipps Family Ventures, and (iii) 2,054 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, all of which were fully vested as of such date. Mr. Lipps shares beneficial ownership of the shares held of record by Lipps Family Ventures. The address for these entities is 39 Melanie Lane, Atherton, CA 94027.
- (15) Consists of (i) 18,245 shares held of record by RiverRoad Capital Partners, LLC and (ii) 28,702 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 8,675 shares were fully vested as of such date. Gregory T. Lucier is a Managing Member of RiverRoad Capital Partners, LLC. As a result, Mr. Lucier may be deemed to share beneficial ownership of the shares held of record by RiverRoad Capital Partners, LLC. The address for RiverRoad Capital Partners, LLC is 11988 El Camino Real, Suite 500, San Diego, CA 92130.
- (16) Consists of (i) 43,312 shares held of record by Eric W. Roberts, (ii) 326,086 shares held of record by Valence CDK SPV, L.P. (Valence CDK), and (iii) 10,810 shares issuable pursuant to outstanding stock options exercisable within 60 days of May 29, 2015, of which 6,531 shares were fully vested as of such date. Valence Life Sciences GP II, LLC (Valence) is the General Partner of Valence CDK and has sole voting and investment power with respect to the shares held by Valence CDK. Mr. Roberts is a Managing Member of Valence. As a result, and by virtue of the relationships described in this footnote, Mr. Roberts may be deemed to share beneficial ownership of the shares held by Valence CDK. Mr. Roberts disclaims beneficial ownership of the shares held by Valence CDK except to the extent of his pecuniary interest therein.

---

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

**General**

The following is a summary of the rights of our common stock and preferred stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws as they will be in effect immediately prior to the completion of this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Immediately prior to the completion of this offering, our authorized capital stock will consist of 110,000,000 shares, with a par value of \$0.001 per share, of which:

100,000,000 shares are designated as common stock; and

10,000,000 shares are designated as preferred stock.

The number of shares of our common stock to be issued upon the automatic conversion of all outstanding shares of our convertible preferred stock depends in part on the actual initial public offering price of our common stock in this offering. The terms of our Series D convertible preferred stock, Series E convertible preferred stock and Series F convertible preferred stock provide that the ratio at which each share of such series automatically converts into shares of our common stock in connection with this offering will increase if the initial public offering price is below \$12.395, \$13.3052 and \$14.3449 per share, respectively, which would result in additional shares of our common stock being issued upon conversion of the preferred stock as set forth below immediately prior to the closing of this offering.

As of March 31, 2015, and assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, we had outstanding 721,760 shares of common stock, 396,590 shares of Series A convertible preferred stock, each of which is convertible into one (1) share of common stock; 478,718 shares of Series B convertible preferred stock, each of which is convertible into 1.1877952253 shares of common stock; 1,566,352 shares of Series C convertible preferred stock, each of which is convertible into 1.0637813212 shares of common stock; 2,016,929 shares of Series D convertible preferred stock, each of which is convertible into 1.0088217987 shares of common stock; 1,597,814 shares of Series E convertible preferred stock, each of which is convertible into 1.0276626722 shares of common stock; and 1,596,212 shares of Series F convertible preferred stock, each of which is convertible into 1.0469621828 shares of common stock. Assuming the automatic conversion of all shares of our convertible preferred stock outstanding as of March 31, 2015 into common stock upon completion of this offering, as of March 31, 2015, we would have had 8,701,092 shares of common stock outstanding, held by approximately 97 stockholders, and no shares of preferred stock outstanding.

**Table of Contents**

However, the number of shares issuable upon conversion of our preferred stock depends, in part, on the actual initial public offering price of our common stock in this offering. For illustrative purposes only, the table below shows the number of shares of our common stock that would be issuable upon conversion of our Series D, Series E and Series F convertible preferred stock at various initial public offering prices, as well as the resulting total number of outstanding shares of our common stock after this offering, based on our shares outstanding as of March 31, 2015:

Assumed Public Offering Price (\$)	Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		Series F Convertible Preferred Stock		Total Common Stock Outstanding After this Offering (#)
	Approximate Conversion Ratio (#)	Shares of Common Stock Issuable upon Conversion (#)	Approximate Conversion Ratio (#)	Shares of Common Stock Issuable upon Conversion (#)	Approximate Conversion Ratio (#)	Shares of Common Stock Issuable upon Conversion (#)	
\$11.00	1.03187	2,081,189	1.04991	1,677,558	1.06836	1,705,321	12,817,281
\$11.50	1.02021	2,057,684	1.03867	1,659,588	1.05755	1,688,072	12,758,557
\$12.00	1.00882	2,034,709	1.02766	1,642,002	1.04696	1,671,168	12,701,092
\$12.50	1.00000	2,016,929	1.01689	1,624,785	1.03658	1,654,602	12,649,529
\$13.00	1.00000	2,016,929	1.00633	1,607,925	1.02641	1,638,358	12,616,425
\$13.50	1.00000	2,016,929	1.00000	1,597,814	1.01643	1,622,429	12,590,385
\$14.00	1.00000	2,016,929	1.00000	1,597,814	1.00664	1,606,808	12,574,764

In addition, as of March 31, 2015, we had outstanding options to acquire 1,359,142 shares of our common stock and warrants to acquire 140,539 shares of our common stock, assuming the conversion of warrants to purchase shares of convertible preferred stock into warrants to purchase shares of common stock, assuming a conversion rate based on the assumed initial offering price of \$12.00 per share, upon the completion of this offering.

**Common Stock**

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. Upon our liquidation, dissolution, or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of convertible preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

**Preferred Stock**

After the completion of this offering, no shares of preferred stock will be outstanding. Pursuant to our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. While providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, the issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing

**Table of Contents**

the liquidation rights of the common stock, or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

**Warrants**

As of March 31, 2015, a warrant to purchase 3,532 shares of our common stock at an exercise price of \$1.30 per share was outstanding. Upon the completion of this offering, the warrant will expire.

As of March 31, 2015, a warrant to purchase 14,660 shares of our Series B convertible preferred stock at an exercise price of \$17.2124 per share was outstanding. Upon the completion of this offering, the warrant will become exercisable for 17,413 shares of common stock. The warrant expires on September 15, 2018.

As of March 31, 2015, a warrant to purchase 20,033 shares of our Series C convertible preferred stock was outstanding at an exercise price of \$11.2314 per share. Upon the completion of this offering, the warrant will become exercisable for 21,310 shares of common stock. The warrant expires on December 17, 2020.

As of March 31, 2015, a warrant to purchase 11,294 shares of our Series D convertible preferred stock at an exercise price of approximately \$12.395 per share was outstanding. Upon the completion of this offering, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, the warrant will become exercisable for 11,393 of shares of common stock. The warrant expires on July 25, 2023.

As of March 31, 2015, a warrant to purchase 84,553 shares of our Series E convertible preferred stock was outstanding at an exercise price of \$13.3052 per share. Upon the completion of this offering, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, the warrant will become exercisable for 86,891 shares of common stock. The warrant expires on February 28, 2024.

The number of shares of common stock issuable upon exercise of our warrants after this offering as set forth above assumes an initial public offering price of \$12.00 per share. However, the number of shares of common stock issuable is dependent, in part, on the actual initial offering price of our common stock in this offering. For illustrative purposes only, the table below shows the number of shares of our common stock that would be issuable upon conversion of all outstanding warrants exercisable for shares of our Series D and Series E convertible preferred stock at various initial public offering prices and the resulting total number of outstanding shares of our common stock for which the warrant will become exercisable as a result:

Assumed Public Offering Price (\$)	Shares of Common Stock Issuable upon	Shares of Common Stock Issuable upon
	Conversion of Warrants to Purchase Series D Convertible Preferred Stock	Conversion of Warrants to Purchase Series E Convertible Preferred Stock
\$11.00	11,653	88,773
\$11.50	11,522	87,822
\$12.00	11,393	86,891
\$12.50	11,294	85,980
\$13.00	11,294	85,088
\$13.50	11,294	84,553
\$14.00	11,294	84,553

## **Table of Contents**

Each warrant has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the underlying shares at the time of exercise of the warrant after deduction of a number of shares equal in value to the aggregate exercise price. Each warrant contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The holders of the shares issuable upon exercise of our warrants are entitled to registration rights with respect to such shares as described in greater detail below under the heading **Registration Rights**.

### **Options**

As of March 31, 2015, options to purchase 1,359,142 shares of our common stock were outstanding under our 2005 Stock Incentive Plan, 818,536 of which were vested as of that date.

### **Registration Rights**

Certain holders of shares of our convertible preferred stock and warrants to purchase shares of our convertible preferred stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. These rights are provided under the terms of an investor rights agreement between us and the holders of these shares, which was entered into in connection with our convertible preferred stock financings, and include demand registration rights, short-form registration rights and piggyback registration rights. In any registration made pursuant to such investor rights agreement, all fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

The registration rights terminate seven years following the completion of this offering or, with respect to any particular stockholder, at such time after the effective date of the registration statement of which this prospectus is a part that such stockholder can sell all of its shares without restriction pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act.

#### ***Demand Registration Rights***

Following the completion of this offering, the holders of an aggregate of 7,979,332 shares of our common stock, including warrants to purchase 104,304 shares of our common stock, in each case assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, or their permitted transferees, will be entitled to demand registration rights. Subject to certain exceptions set forth in the investor rights agreement, we will be required, upon the written request of holders of at least 40% of the shares that are entitled to registration rights under the agreement, to register, as soon as practicable, all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investor rights agreement, and each registration must have an anticipated aggregate offering price in excess of \$5.0 million. We are not required to effect a demand registration earlier than 180 days after the effective date of this offering.

#### ***Short-Form Registration Rights***

Following the completion of this offering, the holders of an aggregate of 7,979,332 shares of our common stock, including warrants to purchase 137,007 shares of our common stock in each case assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, or their permitted transferees, will be entitled to short-form registration rights. If we are eligible to file a registration statement on Form S-3, these holders have the right, upon written request from holders of these shares, to have such shares registered by us if the proposed aggregate offering price of the shares to be registered by the holders requesting registration is at least \$1.0 million, subject to exceptions set forth in the investor rights agreement.

---

**Table of Contents**

***Piggyback Registration Rights***

The holders of an aggregate of 7,979,332 shares of our common stock, including warrants to purchase 137,007 shares of our common stock in each case assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, or their permitted transferees, are entitled to piggyback registration rights. If we register any of our securities for our own account, after the completion of this offering, the holders of these shares are entitled to include their shares in the registration. Subject to limitations set forth in the investor rights agreement, the underwriters of any underwritten offering, including this offering have the right to limit the number of shares or, in the case of this offering, to exclude altogether the shares to be registered by these holders for marketing reasons. If the underwriters for this offering do not determine to exclude any shares belonging to these holders for this offering, we intend to obtain a waiver of the piggyback registration rights in connection with this offering.

***Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws***

Our amended and restated certificate of incorporation and amended and restated bylaws to be effective immediately prior to the completion of this offering will contain provisions that could have the effect of delaying, deferring, or discouraging another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, could discourage takeovers, coercive or otherwise. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

***Undesignated Preferred Stock.*** As discussed above under Preferred Stock, our board of directors will have the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

***Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting.*** Our amended and restated certificate of incorporation will provide that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, the holders of a majority of our capital stock would not be able to amend the bylaws or remove directors without holding a meeting of stockholders called in accordance with the bylaws.

In addition, our amended and restated certificate of incorporation and amended and restated bylaws will provide that special meetings of the stockholders may be called only by the chairperson of the board, the chief executive officer, the president (in the absence of a chief executive officer), or our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

***Requirements for Advance Notification of Stockholder Nominations and Proposals.*** Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

***Board Classification.*** Our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system

## **Table of Contents**

of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

***Delaware Anti-Takeover Statute.*** We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

## **Transfer Agent and Registrar**

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent's address is 250 Royal Street, Canton MA 02021.

## **Exchange Listing**

We have applied to list our common stock on the NASDAQ Global Market under the symbol IVTY.



---

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Upon the completion of this offering, based on our shares outstanding as of March 31, 2015, a total of 12,701,092 shares of common stock will be outstanding, assuming the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock upon the completion of this offering at a conversion rate based on the assumed initial public offering price of \$12.00 per share. The number of shares issuable upon conversion of the preferred stock is dependent upon the price at which our shares are sold to the public. For a description of the impact of changes in the offering price see Prospectus Summary The Offering. Of these shares, all of the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act.

The remaining shares of common stock will be restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, the shares of common stock that will be deemed restricted securities after this offering will be available for sale in the public market as follows:

no shares will be available for sale until 180 days after the date of this prospectus, subject to certain limited exceptions provided for in the lock-up agreements; and

beginning 181 days after the date of this prospectus, 8,701,092 shares of common stock will become eligible for sale in the public market, of which 875,747 shares are expected to be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below.

**Rule 144**

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares at any time.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately 127,010 shares immediately after this offering; or

## **Table of Contents**

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

### **Rule 701**

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

### **Lock-Up Agreements**

In connection with this offering, our officers and directors, and substantially all of our stockholders, warrant holders and option holders, have each entered into a lock-up agreement with the underwriters of this offering that prohibits the sale of shares of our common stock by those parties, subject to limited exceptions, for a period of 180 days after the date of this prospectus without the prior written consent of Piper Jaffray & Co. and Leerink Partners LLC. Piper Jaffray & Co. and Leerink Partners LLC, on behalf of the underwriters, may, in their sole discretion, choose to release any or all of the shares of our common stock subject to these lock-up agreements at any time prior to the expiration of the lock-up period without notice. For more additional information, see [Underwriting No Sales of Similar Securities](#).

### **Registration Rights**

Upon the completion of this offering, the holders of 7,979,332 shares of common stock, including warrants to purchase 137,007 shares of common stock, in each case, assuming a conversion rate based on the assumed initial public offering price of \$12.00 per share, or their transferees, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See [Description of Capital Stock Registration Rights](#) for additional information.

### **Registration Statements on Form S-8**

Upon the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock subject to outstanding stock options and common stock issuable in the future under our stock option plans. Shares covered by such registration statement on Form S-8 will be eligible for sale in the public market, upon the expiration or release from the terms of the lock-up agreements and subject to vesting of such shares.

---

**Table of Contents**

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following is a general discussion of the material U.S. federal income tax consequences to non-U.S. holders with respect to their purchase, ownership and disposition of shares of our common stock purchased in this offering. This discussion is for general information only, is not tax advice, and does not purport to be a complete analysis of all potential tax considerations. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, (the Code), existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, in effect as of the date of this prospectus, all of which are subject to change, possibly with retroactive effect, or to differing interpretation. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of state, local or non-U.S. income taxes or any non-income taxes. This discussion also does not address the potential application of the alternative minimum tax, the tax on net investment income, or any specific tax consequences that may be relevant to a non-U.S. holder in light of such holder's particular circumstances and does not address the special tax rules applicable to particular non-U.S. holders, such as:

insurance companies;

tax-exempt organizations;

banks or other financial institutions;

brokers or dealers in securities, and traders in securities that use a mark-to-market method of accounting for their securities holdings;

partnerships or entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities;

regulated investment companies or real estate investment trusts;

tax-qualified retirement plans;

persons that own or are deemed to own more than 5% of our capital stock (except to the extent specifically set forth below);

controlled foreign corporations or passive foreign investment companies;

corporations that accumulate earnings to avoid U.S. federal income tax;

## Edgar Filing: Invuity, Inc. - Form S-1/A

owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;

certain former citizens or long-term residents of the United States; and

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and

---

**Table of Contents**

partners or members in such partnerships should consult their tax advisors. There can be no assurance that the Internal Revenue Service ( IRS ) will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock. We urge prospective investors to consult with their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, owning and disposing of shares of our common stock.

**Non-U.S. Holder Defined**

For purposes of this discussion, except as modified for estate tax purposes, a non-U.S. holder means a beneficial owner of our common stock, other than a partnership or other entity classified as a partnership for U.S. federal income tax purposes, that is not, for U.S. federal income tax purposes,:

an individual who is a citizen or resident of the United States;

a corporation, or other entity taxable as a corporation for U.S. federal tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;

an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (y) which has made a valid election to be treated as a U.S. person.

**Distributions on Our Common Stock**

We have not made any distributions on our common stock and we do not have any plans to make any distributions on our common stock. However, if we do make distributions on our common stock, those payments generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds both our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's capital, and will reduce such holder's basis in our common stock, but not below zero. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in Gain on Sale, Exchange or Other Disposition of Our Common Stock. Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States (and, if an applicable income tax treaty so provides, are also attributable to a permanent establishment or a fixed base maintained within the United States by such non-U.S. holder) are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder's country of residence.

In order to claim the benefit of a tax treaty or to claim exemption from withholding because dividends paid on our common stock are effectively connected with the conduct of a trade or business in the United States, a non-U.S. holder must provide a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E

---

## **Table of Contents**

for treaty benefits or IRS Form W-8ECI for effectively connected income, or such successor forms as the IRS designates, prior to the payment of dividends. These forms must be periodically updated. If a non-U.S. holder holds our common stock through a financial institution or other agent acting on such holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

### **Gain on Sale, Exchange or Other Disposition of Our Common Stock**

Subject to the discussion below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

the gain is effectively connected with a U.S. trade or business (and, if an applicable income tax treaty so provides, is also attributable to a permanent establishment or a fixed base maintained within the United States by such non-U.S. holder), in which case the graduated U.S. federal income tax rates applicable to U.S. persons will apply, and, if the non-U.S. holder is a foreign corporation, the additional branch profits tax described above in "Distributions on Our Common Stock" may also apply;

the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any; or

we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a United States real property holding corporation (a "USRPHC").

We believe that we have not been and are not currently, and we do not anticipate becoming in the future, a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we are or become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, as to which there can be no assurance, such common stock will be treated as U.S. real property interests only if a non-U.S. holder actually or constructively holds more than 5% of such regularly-traded common stock at any time during the shorter of the five-year period preceding such holder's disposition of, or such holder's holding period for, our common stock.

### **Federal Estate Tax**

Shares of our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will generally be included in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

### **Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid to each non-U.S. holder, their name and address, and the amount of tax withheld, if any. A similar report will be sent to each non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in such non-U.S. holder's country of residence.

## **Table of Contents**

Payments of dividends on or of proceeds from the disposition of our common stock may be subject to additional information reporting and backup withholding at a current rate of 28% unless a non-U.S. holder establishes an exemption, for example, by properly certifying its non-U.S. status on an IRS Form W-8BEN or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that such holder is a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

## **Foreign Accounts**

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends on and the gross proceeds from a sale or other disposition of our common stock, paid to a foreign financial institution (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and the gross proceeds from a sale or other disposition of our common stock paid to a non-financial foreign entity (as specifically defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transitional rules are expected to apply with respect to the gross proceeds from a sale or other disposition of our common stock on or after January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

*Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.*

**Table of Contents****UNDERWRITING**

Piper Jaffray & Co. and Leerink Partners LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

Underwriters	Number of Shares
Piper Jaffray & Co.	
Leerink Partners LLC	
Stifel, Nicolaus & Company, Incorporated	
William Blair & Company, L.L.C.	
<b>Total</b>	<b>4,000,000</b>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

**Discounts and Commissions**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$        per share. After the initial offering, the public offering price, concession or any other term of this offering may be changed. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
<b>Public Offering Price</b>	\$	\$	\$
<b>Underwriting Discount</b>	\$	\$	\$
<b>Proceeds, before expenses, to us</b>	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discount and commissions, are approximately \$3.5 million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount not to exceed \$20,000 as set forth in the underwriting agreement.



## **Table of Contents**

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares, described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased.

### **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 600,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less the underwriting discount and commissions. The underwriters may exercise this option solely for the purpose of covering overallocments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the table above bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

### **No Sales of Similar Securities**

We, our executive officers and directors and all of our other stockholders, optionholders and warrant holders have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable or exercisable for, or that represent the right to receive shares of our common stock, for 180 days after the date of the prospectus used to sell our common stock without first obtaining the written consent of Piper Jaffray & Co. and Leerink Partners LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;

sell any option or contract to purchase any shares of our common stock;

purchase any option or contract to sell any shares of our common stock;

grant any option, right or warrant to purchase any shares of our common stock;

make any short sale or otherwise transfer or dispose of any shares of our common stock;

enter into any swap or other agreement that transfers, in whole or in part, the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise; or

demand that we file a registration statement related to our common stock.

The restrictions in the preceding paragraph do not apply to transfers of securities:

as a bona fide gift or gifts;

## Edgar Filing: Invuity, Inc. - Form S-1/A

to an immediate family member or any trust for the direct or indirect benefit of the stockholder or an immediate family member of the stockholder;

if the stockholder is a corporation, partnership, limited liability company, investment fund, trust or other business entity (i) transfers to another corporation, partnership, limited liability company, investment fund, trust or other business entity that is a direct or indirect affiliate of the stockholder or (ii) distributions of shares of our common stock to limited

**Table of Contents**

partners, limited liability company members or stockholders of the stockholder, or to any investment fund or other entity that controls or manages the stockholder;

if the stockholder is a trust, to the beneficiary of such trust;

by testate succession or intestate succession; or

pursuant to the underwriting agreement;

provided, in the case of a transfer described in bullets one through five above, that such transfer does not involve a disposition for value, and each transferee agrees to be subject to the restrictions described in the immediately preceding paragraph and that no filing by any party under Section 16(a) of the Exchange Act, shall be required or shall be made voluntarily in connection with such transfer other than a required Form 5 filing filed within 45 days of December 31, 2015, in which case such Form 5 shall include a footnote describing the transaction being reported.

In addition, the transfer restrictions described above do not apply to:

the exercise of stock options granted pursuant to our equity plans or warrants described in this prospectus; provided that no filing by any party under Section 16(a) of the Exchange Act shall be required or shall be made voluntarily;

forfeitures to satisfy tax withholding obligations in connection with the conversion or exercise of our options or warrants; provided that if the stockholder is required to file a report under Section 16(a) reporting a reduction in beneficial ownership of shares of common stock, the stockholder will include a statement in such report to the effect that the purpose of the transfer was to cover tax withholding obligations;

transactions relating to shares of our common stock or other securities acquired in open market transactions on or after the date of this prospectus; provided that no filing by any party under Section 16(a) of the Exchange Act shall be required or shall be made voluntarily in connection with subsequent sales of our common stock acquired in such open market transactions;

transfers upon a termination of employment of shares of our common stock or any securities to us in connection with the repurchase of shares of our common stock issued pursuant to an employee benefit plan disclosed in this prospectus or pursuant to the agreements pursuant to which such shares were issued as disclosed in this prospectus;

transfers pursuant to a change of control of our company;

the conversion of the outstanding preferred shares into our common stock;

transfers of shares of our common stock or other securities by operation of law to a spouse, former spouse, domestic partner, former domestic partner, child or other dependent pursuant to a qualified domestic order or in connection with a divorce settlement; provided, that if the undersigned is required to file a report under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of our common stock, the stockholder shall include a statement in such report to the effect that the transfer occurred by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, as applicable; or

## Edgar Filing: Invuity, Inc. - Form S-1/A

the establishment of any 10b5-1 plan, provided that no sales of the stockholders common stock will be made under such plans for 180 days after the date of this prospectus.

## **Table of Contents**

### **Listing**

We have applied to list our common stock on the NASDAQ Global Market under the symbol IVTY. In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations among us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;

our financial information;

the history of, and the prospects for, our company and the industry in which we compete;

an assessment of our management, its past and present operations and the prospects for, and timing of, our future net sales;

the present state of our development; and

the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after this offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing shares of our common stock. However, the underwriters may engage in transactions that stabilize the price of our common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. Naked short sales are sales in excess of the overallotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of our common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have



## **Table of Contents**

repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the NASDAQ Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Electronic Offer, Sale and Distribution of Shares**

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, one or more of the underwriters may facilitate Internet distribution for this offering to certain of their Internet subscription customers. Any such underwriter may allocate a limited number of shares for sale to its online brokerage customers. An electronic prospectus is available on the Internet websites maintained by any such underwriter. Other than the prospectus in electronic format, the information on the websites of any such underwriter is not part of this prospectus.

### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **Selling Restrictions**

#### *European Economic Area*

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant

---

**Table of Contents**

Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

*United Kingdom*

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA )) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

*Canada*

The common stock may be sold only to purchasers purchasing as principal that are both accredited investors as defined in National Instrument 45-106 Prospectus and Registration Exemptions and permitted clients as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

*Hong Kong*

The common stock may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning





---

**Table of Contents**

of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

*Singapore*

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- (b) where no consideration is or will be given for the transfer; or
- (c) where the transfer is by operation of law.

*Switzerland*

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under

---

**Table of Contents**

art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ( CISA ). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common stock.

*United Arab Emirates*

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the UAE ), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority ( DFSA ), a regulatory authority of the Dubai International Financial Centre ( DIFC ). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The common shares may not be offered to the public in the UAE and/or any of the free zones.

The common shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

*France*

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the AMF ) for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;
2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and
3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

**Table of Contents**

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California. Latham & Watkins LLP, Costa Mesa, California is acting as counsel to the underwriters. An investment fund associated with Wilson Sonsini Goodrich & Rosati, Professional Corporation holds shares of our convertible preferred stock convertible into an aggregate of 2,016 shares of common stock, which represents less than 1% of our outstanding common stock.

**EXPERTS**

The financial statements as of December 31, 2013 and 2014 and for each of the two years in the period ended December 31, 2014 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements, and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at [www.invuity.com](http://www.invuity.com). Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

**Table of Contents**

INVUITY, INC.

INDEX TO FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Comprehensive Loss</u>	F-5
<u>Statements of Convertible Preferred Stock and Stockholders' Deficit</u>	F-6
<u>Statements of Cash Flows</u>	F-7
<u>Notes to the Financial Statements</u>	F-8

F-1

**Table of Contents**

**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' deficit, and cash flows present fairly, in all material respects, the financial position of Invuity, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014 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 13, 2015, except for the effects of the reverse stock split, as to which the date is May 27, 2015, and except for the effects of the Company's reincorporation in Delaware, as to which the date is May 28, 2015, both described in Note 1.

F-2

**Table of Contents****INVUITY, INC.****Balance Sheets**

(In thousands, except share data)

	December 31,		March 31,	Pro Forma as of
	2013	2014	2015	March 31,
			(unaudited)	2015
				(unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 4,953	\$ 6,048	\$ 25,251	
Short-term investments	853			
Accounts receivable, net	1,501	2,798	3,625	
Inventory	3,485	4,271	4,400	
Prepaid expenses and other current assets	563	2,486	1,391	
Total current assets	11,355	15,603	34,667	
Restricted cash	35	1,125	1,125	
Property and equipment, net	663	8,541	9,005	
Other non-current assets		55	1,354	
Total assets	\$ 12,053	\$ 25,324	\$ 46,151	
<b>Liabilities, Convertible Preferred Stock and Stockholders (Deficit) Equity</b>				
Current liabilities:				
Accounts payable	\$ 954	\$ 1,075	\$ 1,278	
Accrued and other current liabilities	1,455	4,162	5,159	
Long-term debt, current portion	460			
Total current liabilities	2,869	5,237	6,437	
Accrued interest payable	38			
Deferred rent		2,676	2,836	
Convertible preferred stock warrant liability	86	136	640	\$
Long-term debt, net of current portion	2,017			
Long-term debt, net of current portion related party		9,347	14,382	
Total liabilities	5,010	17,396	24,295	
Convertible preferred stock, \$0.001 par value 4,553,302, 6,207,320 and 7,861,914 (unaudited) shares authorized at December 31, 2013 and 2014 and March 31, 2015, respectively; 4,458,589, 6,056,403 and 7,652,615 (unaudited) shares issued and outstanding at December 31, 2013 and 2014 and March 31, 2015, respectively; aggregate liquidation preference of \$74,806 and \$97,704 (unaudited) at December 31, 2014 and March 31, 2015, respectively; no shares authorized, issued and outstanding, pro forma (unaudited)	52,949	73,755	96,524	
Stockholders (deficit) equity:				
Common stock, \$0.001 par value 7,027,027, 9,189,189 and 11,384,324 (unaudited) shares authorized at December 31, 2013 and 2014 and March 31, 2015, respectively; 656,184, 711,249 and 721,760 (unaudited) shares issued and outstanding at December 31, 2013 and 2014 and March 31, 2015, respectively; 8,701,092 shares issued and outstanding, pro forma (unaudited)	1	1	1	9
Additional paid-in capital	1,468	2,209	2,400	99,556
Accumulated deficit	(47,375)	(68,037)	(77,069)	(77,069)
Total stockholders (deficit) equity	(45,906)	(65,827)	(74,668)	\$ 22,496



## Edgar Filing: Invuity, Inc. - Form S-1/A

Total liabilities, convertible preferred stock and stockholders' deficit	\$ 12,053	\$ 25,324	\$ 46,151
--	-----------	-----------	-----------

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

F-3

**Table of Contents****INVUITY, INC.****Statements of Operations**

(In thousands, except share and per share data)

	Year Ended December 31,		Three Months Ended	
	2013	2014	2014	March 31, 2015 (unaudited)
Revenue	\$ 7,186	\$ 13,103	\$ 2,154	\$ 4,442
Cost of goods sold	2,294	4,871	747	1,731
Gross profit	4,892	8,232	1,407	2,711
Operating expenses:				
Selling, general and administrative	12,402	22,803	4,574	8,923
Research and development	4,445	5,181	1,203	1,900
Total operating expenses	16,847	27,984	5,777	10,823
Loss from operations	(11,955)	(19,752)	(4,370)	(8,112)
Interest expense	(284)	(1,402)	(370)	(369)
Interest and other income (expense), net	130	492	28	(551)
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
Net loss per common share, basic and diluted	\$ (19.15)	\$ (31.63)	\$ (7.34)	\$ (12.84)
Weighted-average shares used to compute net loss per common share, basic and diluted	632,407	653,195	641,810	703,637
Pro forma net loss per common share, basic and diluted (unaudited)		\$ (3.15)		\$ (1.07)
Pro forma weighted-average shares used to compute net loss per common share, basic and diluted (unaudited)		6,727,430		7,940,112

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

**Table of Contents**

## INVUITY, INC.

## Statements of Comprehensive Loss

(In thousands)

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
Other comprehensive loss:				
Unrealized loss on investments	(4)			
Total comprehensive loss	\$ (12,113)	(20,662)	\$ (4,712)	\$ (9,032)

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

**Table of Contents**

## INVUITY, INC.

## Statements of Convertible Preferred Stock and Stockholders Deficit

(In thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Shares	Amount				
Balance 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)
Balance 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)
Balance 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 at \$14.3449 per share, net of issuance costs of \$128 (unaudited)	1,596,212	22,769						
Exercise of common stock options (unaudited)			10,511		17			17
Vesting of early exercise options (unaudited)					1			1
Stock-based compensation expense (unaudited)					173			173
Net loss (unaudited)							(9,032)	(9,032)
Balance at March 31, 2015 (unaudited)	7,652,615	96,524	721,760	\$ 1	\$ 2,400		\$ (77,069)	\$ (74,668)

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

**Table of Contents****INVUITY, INC.****Statements of Cash Flows****(In thousands)**

	<b>Year Ended December 31,</b>		<b>Three Months Ended</b>	
	<b>2013</b>	<b>2014</b>	<b>2014</b>	<b>2015</b>
			<b>March 31,</b>	
			<b>(unaudited)</b>	
<b>Cash flows from operating activities</b>				
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	227	344	67	398
Stock-based compensation	279	663	87	173
Changes in fair value of convertible preferred stock warrant liability	(168)	(522)	(10)	504
Provision for (recovery of) doubtful accounts	(1)	87	57	26
Noncash interest expense (credit)	68	90	(11)	56
Accretion of premium on marketable securities	191	243	22	
Changes in operating assets and liabilities				
Accounts receivable	(677)	(1,384)	(55)	(853)
Inventory	(2,384)	(786)	(80)	(129)
Prepaid expenses and other current assets	(177)	(1,923)	130	1,110
Other non-current assets		(55)		
Accounts payable	413	143	(164)	(249)
Accrued and other current liabilities	441	1,034	67	924
Deferred rent		2,910	(6)	131
Net cash used in operating activities	(13,897)	(19,818)	(4,608)	(6,941)
<b>Cash flows from investing activities</b>				
Purchases of property and equipment	(468)	(6,791)	(66)	(1,467)
Purchases of marketable securities	(2,156)	(17,510)	(15,912)	
Sales of marketable securities		17,270		
Maturities of marketable securities	18,120	850	850	
Increase in restricted cash		(1,090)		
Net cash provided by (used in) investing activities	15,496	(7,271)	(15,128)	(1,467)
<b>Cash flows from financing activities</b>				
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		9,800	9,800	5,000
Payments of long-term debt	(3,016)	(2,500)	(2,500)	
Proceeds from issuance of common stock upon exercise of stock options	65	78	26	20
Proceeds from issuance of convertible preferred stock, net of issuance costs		20,806	20,806	22,769
Payments of initial public offering costs				(178)
Net cash (used in) provided by financing activities	(451)	28,184	28,132	27,611
Net increase in cash and cash equivalents	1,148	1,095	8,396	19,203
Cash and cash equivalents, beginning of period	3,805	4,953	4,953	6,048
Cash and cash equivalents, end of period	\$ 4,953	\$ 6,048	\$ 13,349	\$ 25,251
<b>Supplemental disclosures of cash flow information</b>				
Interest paid	\$ 165	\$ 275	\$ 275	\$
Interest paid to related party	\$	\$ 1,052	\$ 115	\$ 313
<b>Non-cash investing and financing activities</b>				

## Edgar Filing: Invuity, Inc. - Form S-1/A

Purchases of property and equipment in accounts payable and accrued liabilities	\$	31	\$	1,462	\$	67	\$	857
Initial public offering costs in accounts payable and accrued liabilities	\$		\$	30	\$		\$	1,176

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

F-7

---

**Table of Contents**

**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.

*Liquidity*

The Company has incurred net losses from operations since inception and has an accumulated deficit of \$68.0 million and \$77.1 million (unaudited) as of December 31, 2014 and March 31, 2015, respectively. The Company expects to incur additional losses and negative cash flows and, as a result will require additional capital to fund its operations and execute its business plan. Management plans to finance its operations in the future with additional equity and debt financing arrangements. In February and March 2015, the Company issued an aggregate of 1,596,212 shares of Series F convertible preferred stock for \$22.9 million in net proceeds (see Note 14). Management believes that its cash and cash equivalents of \$25.3 million (unaudited) as of March 31, 2015 and borrowings available under the accounts receivable credit facility entered into in February 2015 (see Note 14), will provide sufficient funds to enable the Company to meet its operating plan through at least December 31, 2015. However, if the Company's anticipated operating results are not achieved in future periods, management believes that planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the Company's operations.

*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.

*Reincorporation in Delaware*

On May 28, 2015, the Company reincorporated in Delaware and established the par value of each share of common and convertible preferred stock to be \$0.001. In connection with the reincorporation, common stock and additional paid-in capital amounts in these financial statements have been adjusted to reflect the par value of common stock. All share information included in these financial statements has been adjusted to reflect this reincorporation.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Use of Estimates*

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). The preparation of the 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

---

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

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, convertible preferred stock and related warrants, common stock, and stock-based compensation. Actual results could differ from those estimates and assumptions.

*Out-of-period and Other Adjustments*

In 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 expected to be material to the financial statements for the year ending 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.

*Unaudited Pro Forma Balance Sheet Information*

The unaudited pro forma balance sheet information as March 31, 2015 presents the Company's balance sheet information as though all of the Company's outstanding convertible preferred stock had automatically converted into shares of common stock upon the completion of a qualifying initial public offering of the Company's common stock (an IPO). In addition, the pro forma balance sheet information assumes the reclassification of the convertible preferred stock warrant liability to stockholders' equity upon completion of an IPO, as the warrants to purchase convertible preferred stock will be converted into common stock warrants. The unaudited pro forma balance sheet information does not assume any proceeds from the proposed IPO.

*Unaudited Interim Financial Statements*

The accompanying balance sheet as of March 31, 2015, the statements of operations, comprehensive loss and cash flows for the three months ended March 31, 2014 and 2015, and the statements of convertible preferred stock and stockholders' deficit as of March 31, 2015, are unaudited. The financial data and other information disclosed in these notes to the financial statements related to March 31, 2015, and the three months ended March 31, 2014 and 2015, are also unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's financial position as of March 31, 2015, and the results of its operations and cash flows for the three months ended March 31, 2014 and 2015. The results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015, or for any other interim period or for any future year.



---

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

*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, 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, net. Unrealized gains and losses and realized gains and losses on sale of short-term investments were insignificant for the years ended December 31, 2013 and 2014. The Company did not hold any short-term investments as of December 31, 2014 and March 31, 2015.

*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 \$11,000, \$98,000 and \$42,000 (unaudited) as of December 31, 2013 and 2014 and March 31, 2015, respectively. The Company did not have any write-offs relating to uncollectible accounts receivable for the years ended December 31, 2013 and 2014. The Company has written off \$84,000 (unaudited) as uncollectible accounts receivable to the allowance for doubtful accounts during the three months ended March 31, 2015.

*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, 2014 and March 31, 2015, 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.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)***Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk at December 31, 2014 and March 31, 2015 consist primarily of cash, which is held primarily by one domestic financial institution and exceeds federally insured limits, cash equivalents, and available for sale securities. 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		Revenue		Accounts Receivable, net		
	Year Ended December 31,	Year Ended December 31,	Three Months Ended March 31,	Three Months Ended March 31,	December 31,	December 31,	March 31,
	2013	2014	2014	2015	2013	2014	2015
			(unaudited)				(unaudited)
<b>Customers:</b>							
Customer A	12%	12%	16%	*	11%	12%	*
Customer B		*	*	*		12%	10%
Customer C	13%	*	*	*	*		

\* 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 sold and establish a new cost basis for the inventory.

*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.	



---

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

*Deferred Initial Public Offering Costs*

Deferred initial public offering costs, primarily consisting of legal, accounting, printer and other direct fees and costs relating to the initial public offering, are capitalized. The deferred initial public offering costs will be offset against the Company's planned initial public offering proceeds upon the closing of the offering. In the event the offering is terminated, all of the deferred initial public offering costs will be expensed. As of December 31, 2014 and March 31, 2015, the Company capitalized \$40,000 and \$1.4 million (unaudited), respectively, of deferred initial public offering costs within other non-current assets on the balance sheets.

*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 are contingently redeemable are 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 are subject to re-measurement at each balance sheet date and the change in fair value, if any, is recognized as interest and other income, net in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of (i) exercise or expiration of the warrants, or (ii) the completion of an IPO, at which time all convertible preferred stock warrants will be converted into warrants to purchase common stock and the liability will be reclassified to additional paid-in capital.

*Comprehensive Loss*

Comprehensive loss represents all changes in stockholders' deficit except those resulting from and distributions to stockholders. The Company's unrealized gains or losses on short-term investments represent the only component of other comprehensive loss that is excluded from the reported net loss and has been 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

Edgar Filing: Invuity, Inc. - Form S-1/A

delivery has occurred or services have been rendered.

F-12

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

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. A warranty liability was not recorded for the periods presented in these financial statements as the estimated future warranty costs were insignificant based on the Company's historical experience.

*Medical Device Excise Tax*

In accordance with the Patient Protection and Affordable Care Act, effective January 1, 2013, the Company began to incur a 2.3% excise tax on sales of medical devices in the United States. The medical device excise tax is included in cost of goods sold in the statements of operations for the years ended December 31, 2013 and 2014 and for the three months ended March 31, 2014 and 2015.

*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.

---

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

*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.

*Unaudited Pro Forma Net Loss per Common Share*

The unaudited pro forma basic and diluted net loss per common share has been computed to give effect to the conversion of the shares of convertible preferred stock into common stock as if such conversion had occurred at the earlier of the beginning of the period or the date of issuance, if later. Also, the numerator in the pro forma basic and diluted net loss per common share calculation has been adjusted to remove gains or losses resulting from the remeasurement of the convertible preferred stock warrant liability as it will be reclassified to additional paid-in capital upon the completion of an IPO of the Company's common stock. The unaudited pro forma net loss per common share does not include the shares to be sold and related proceeds to be received from an IPO.

*Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board ( FASB ) issued *Accounting Standards Update ( ASU ) 2014-09, Revenue from Contracts with Customers* ( ASU 2014-09 ). Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for fiscal years and interim reporting periods beginning after December 15, 2016, at which time the Company may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ( ASU 2014-15 ). ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2014-15 on its financial statements and related disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest-Imputation of Interest* ( ASU No. 2015-03 ). ASU No. 2015-03 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 that debt liability, consistent with debt discounts. The recognition and measurement guidance of debt issuance costs is not affected by the amendments in this update. The standard will be effective for the

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

Company beginning in the first quarter of 2016 and requires the Company to apply the new guidance on a retrospective basis on adoption. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

**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 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, 2013, the Company's Level 2 investments include corporate bonds that are based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, and issuer spreads. 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, 2013			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds <sup>(a)</sup>	\$ 4,563	\$	\$	\$ 4,563
Corporate debt		853		853
	\$ 4,563	\$ 853	\$	\$ 5,416
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$	\$	\$ 86	\$ 86
	\$	\$	\$ 86	\$ 86





**Table of Contents**

## INVUITY, INC.

## Notes to Financial Statements (Continued)

	December 31, 2014			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds <sup>(a)</sup>	\$ 5,768	\$	\$	\$ 5,768
	\$ 5,768	\$	\$	\$ 5,768
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$	\$	\$ 136	\$ 136
	\$	\$	\$ 136	\$ 136

  

	March 31, 2015 (unaudited)			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds <sup>(a)</sup>	\$ 19,768	\$	\$	\$ 19,768
	\$ 19,768	\$	\$	\$ 19,768
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$	\$	\$ 640	\$ 640
	\$	\$	\$ 640	\$ 640

<sup>(a)</sup> Balances include \$35,000 classified as non-current restricted cash as of December 31, 2013 and 2014 and March 31, 2015 (unaudited). 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):

	Year ended December 31,		Three Months ended March 31, 2015 (unaudited)
	2013	2014	
Beginning balance	\$ 232	\$ 86	\$ 136
Issuance of convertible preferred stock warrants	22	572	
Change in fair value recorded in interest and other income (expense), net	(168)	(522)	504
Ending balance	\$ 86	\$ 136	\$ 640



**Table of Contents**

## INVUITY, INC.

## Notes to Financial Statements (Continued)

**4. BALANCE SHEET COMPONENTS***Inventory*

Inventory consisted of the following (in thousands):

	December 31,		March 31,
	2013	2014	2015
			(unaudited)
Raw materials	\$ 1,421	\$ 894	\$ 698
Work-in-process	189	768	569
Finished goods	1,875	2,609	3,133
Total inventory	\$ 3,485	\$ 4,271	\$ 4,400

*Prepaid expenses and other current assets*

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

	December 31,		March 31,
	2013	2014	2015
			(unaudited)
Prepaid expenses	\$ 547	\$ 420	\$ 702
Tenant improvement allowance receivable		2,064	670
Other	16	2	19
Total prepaid expenses and other current assets	\$ 563	\$ 2,486	\$ 1,391

*Property and Equipment, Net*

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

	December 31,		March 31,
	2013	2014	2015
			(unaudited)
Computer equipment and software	\$ 249	\$ 633	\$ 691
Laboratory and manufacturing equipment	608	816	948
Furniture and fixtures	245	1,409	1,387
Leasehold improvements	257	6,541	6,909
Total property and equipment, gross	1,359	9,399	9,935
Less: accumulated depreciation and amortization	(696)	(858)	(930)

## Edgar Filing: Invuity, Inc. - Form S-1/A

Total property and equipment, net	\$ 663	\$ 8,541	\$ 9,005
-----------------------------------	--------	----------	----------

Depreciation and amortization expense was \$227,000 and \$344,000 during the years ended December 31, 2013 and 2014, respectively, and \$67,000 (unaudited) and \$398,000 (unaudited) for the three months ended March 31, 2014 and 2015, respectively.

F-17

**Table of Contents****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,		March 31,
	2013	2014	2015 (unaudited)
Accrued payroll-related expenses	\$ 941	\$ 1,599	\$ 1,874
Accrued independent sales agent commissions	153	227	329
Accrued professional fees	138	89	1,068
Accrued costs for property and equipment		1,453	793
Accrued sales and marketing expenses		95	351
Deferred rent	56	290	261
Other	167	409	483
 Total accrued and other current liabilities	 \$ 1,455	 \$ 4,162	 \$ 5,159

**5. COMMITMENTS AND CONTINGENCIES***Operating Leases*

The Company leases laboratory and office space in San Francisco, California, under a non-cancelable operating lease entered into in 2007 and expiring on January 31, 2016. In September 2013, the Company paid a security deposit of \$90,000 that will be applied against the rent due under this lease in various periods from July 2014 until the expiration of the lease. In May 2014, the Company entered into a new non-cancelable facility lease agreement to relocate its operations to a larger facility in San Francisco. The lease commencement date was November 1, 2014 and the lease expires on October 31, 2024. At the inception of the 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, 2014 and March 31, 2015. The balance of the security deposit related to the first leased facility was \$90,000 and \$67,000 at December 31, 2013 and 2014, respectively, and \$45,000 (unaudited) at March 31, 2015, and was recorded in prepaid expenses and other current assets.

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 costs incurred in connection with qualified costs as of December 31, 2014. The Company has recorded \$2.1 million and \$0.7 million (unaudited) as a receivable from the landlord for the reimbursement for costs incurred and not reimbursed as of December 31, 2014 and March 31, 2015, respectively, which has been recorded in prepaid expenses and other current assets.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

The following table summarizes the Company's future minimum lease payments as of December 31, 2014 (in thousands):

<b>Year ending December 31:</b>	
2015	\$ 2,053
2016	2,053
2017	2,114
2018	2,178
2019	2,243
Thereafter	11,821
<b>Total</b>	<b>\$ 22,462</b>

The Company's rent expense was \$315,000 and \$570,000 for the years ended December 31, 2013 and 2014, respectively and \$61,000 (unaudited) and \$529,000 (unaudited) for the three month periods ended March 31, 2014 and 2015, 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 California corporate law. The Company currently has directors' and officers' insurance.

**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. The first term loan (Tranche I) in the amount of \$2.8 million was issued by SVB upon the signing of the loan agreement and the second term loan (Tranche II) in the amount of \$2.1 million was issued in September 2011. Tranches I and II were repayable in monthly installments over three years from the issuance date, with the first six payments being interest only. Interest was payable at the U.S. Treasury note to maturity for a term equal to the Treasury Note Maturity as reported in the Federal Reserve Statistical Release H.15-Select Interest Rates under the heading "U.S. Government Securities/Treasury Constant Maturities" on the funding date of the applicable loan plus a margin of 5.52% per annum. The loan and security agreement contains restrictions on the Company's ability to pay cash dividends.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

In connection with Tranche I, in December 2010, the Company granted SVB a warrant to purchase 20,033 shares of Series C convertible preferred stock at \$11.2314 per share. The warrant was recorded as a liability on the balance sheet on the date of issuance at its fair value of \$141,000 and recorded as a reduction in the carrying value of the debt. This debt discount was amortized to interest expense over the term of the agreement. See Note 8 for further discussion regarding the warrants.

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 Tranches I and II 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 is prepaid on or before 18 months after its funding date. At December 31, 2013, the outstanding balance of the term loan was \$2.5 million. The loan was repaid in February 2014.

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. See Note 8 for further discussions regarding the warrants.

**7. 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, for an aggregate principal amount of up to \$15.0 million in two separate tranches. The Company drew down the first tranche of \$10.0 million upon execution of the loan agreement and repaid the outstanding balance of the Tranche III loan payable to SVB of \$2.7 million. The second tranche of \$5.0 million (unaudited) 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.



**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

As of December 31, 2014 and March 31, 2015, 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, 2014 and March 31, 2015, 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. See Note 8 for further discussion regarding the warrants. 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 using the effective interest method over the term of the loan.

Future payments due under the Company's loan agreements as of December 31, 2014 are as follows (in thousands):

<b>Year ending December 31:</b>	
2015	\$ 1,250
2016	1,250
2017	2,203
2018	3,034
2019	3,734
Thereafter	4,313
	15,784
Less: Amount representing interest	(5,784)
Less: Amount representing debt discount	(653)
	\$ 9,347

Future payments due under the Company's loan agreements as of March 31, 2015, which includes the \$5.0 million (unaudited) additional borrowings in March 2015, are as follows (in thousands):

<b>Year ending December 31 (unaudited):</b>	
2015 (remaining nine months)	\$ 1,405
2016	1,875
2017	3,305
2018	4,547
2019	5,602
Thereafter	6,469
	23,203
Less: Amount representing interest	(8,203)
Less: Amount representing debt discount	(618)
	\$ 14,382



---

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)****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 warrant is fully exercisable and expires upon the earliest to occur of: (a) the close of business on March 17, 2020, (b) a liquidation, dissolution, or winding up of the Company, or (c) the closing of a firm commitment underwritten public offering. 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 with the following assumptions: no dividend yield, an estimated life equal to ten years, a risk-free interest rate of 3.73%, and volatility of 50%. The warrants remain outstanding at December 31, 2014 and March 31, 2015.

*Preferred Stock Warrants*

In September 2008, the Company issued a warrant to purchase a total of 14,660 shares of Series B convertible preferred stock at an exercise price of \$17.2124 per share to a third party in conjunction with a loan. The warrant is fully exercisable and expires upon the earliest to occur of: (a) the close of business on September 15, 2018, or (b) a merger as defined in the loan agreement. The Company recorded the warrant as a liability on the balance sheet at its fair value of \$150,000 on the date of issuance using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, an estimated life equal to ten years, a risk-free interest rate of 3.61%, and volatility of 49%. The fair value of the Series B warrant was \$23,000, \$5,000 and \$43,000 (unaudited) at December 31, 2013 and 2014 and March 31, 2015, respectively.

In December 2010, the Company issued a warrant to purchase 20,033 shares of Series C convertible preferred stock at an exercise price of \$11.2314 per share to SVB in conjunction with the Tranche I loan. The warrant was immediately exercisable and expires upon the earliest to occur of: (a) the close of business on December 17, 2020, or (b) an acquisition as defined in the loan agreement. The Company recorded the warrant as a liability on the balance sheet at its fair value of \$141,000 on the date of issuance using the Black Scholes option-pricing model with the following assumptions: no dividend yield, an estimated life equal to ten years, a risk-free interest rate of 3.29%, and volatility of 48%. The fair value of the Series C warrant was \$41,000, \$51,000 and \$100,000 (unaudited) at December 31, 2013 and 2014 and March 31, 2015, respectively.

In July, 2013, the Company issued a warrant to purchase 11,294 shares of Series D convertible preferred stock at an exercise price of \$12.395 per share to SVB in conjunction with the Tranche III loan. The warrant was immediately exercisable and expires upon the earliest to occur of: (a) the close of business on July 25, 2023, or (b) an acquisition as defined in the loan agreement. The Company recorded the warrant as a liability on the balance sheet at its fair value of \$23,000 on the date of issuance using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, an estimated life equal to ten years, a risk-free interest rate of 2.90%, and volatility of 43%. The fair value of the Series D warrant was \$22,000, \$15,000 and \$59,000 (unaudited) at December 31, 2013 and 2014 and March 31, 2015, respectively.

In February 2014, the Company issued a warrant to purchase 84,553 shares of Series E convertible preferred stock at an exercise price of \$13.3052 per share to HCRP, a related party, in conjunction with a loan. The warrant is immediately exercisable and expires upon the earliest to occur of: (a) February 28, 2024, or (b) an acquisition as defined in the warrant agreement. The Company recorded the warrant as a liability on the balance sheet at its fair value of \$572,000 on the date of issuance using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, an estimated life equal to ten

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

years, a risk-free interest rate of 2.71%, and volatility of 38%. The fair value of the Series E warrant was \$65,000 at December 31, 2014 and \$438,000 (unaudited) at March 31, 2015.

The key assumptions used in the Black-Scholes option-pricing model for the valuation of the convertible preferred stock warrants at December 31, 2013 were: estimated life of 4.8 to 9.6 years, volatility of 43%, risk free rate of 1.58% to 2.90%, and no dividend yield. The fair value of the convertible preferred stock warrants at December 31, 2014 and March 31, 2015 was determined using a hybrid method of the option-pricing model and a probability of various liquidity events required to trigger the conversion of the convertible preferred stock warrants. The scenarios included merger and acquisition events ranging in time to liquidity event of one to three years, an IPO occurring within six months to two years, and dissolution of the Company. The scenarios were weighted based on the Company's estimate of each event occurring in deriving the estimated fair value of \$136,000 and \$640,000 (unaudited) as of December 31, 2014 and March 31, 2015, respectively.

The Company recorded a gain of \$168,000 and \$522,000 for the years ended December 31, 2013 and 2014, respectively, and a gain of \$10,000 (unaudited) and a loss of \$504,000 (unaudited) for the three months ended March 31, 2014 and 2015, representing the change in the fair value of the convertible preferred stock warrant liability during the periods.

**9. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT***Convertible Preferred Stock*

Convertible preferred stock as of December 31, 2013 consisted of the following (in thousands, except share data):

	December 31, 2013			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
Series A	405,224	396,590	\$ 2,646	\$ 2,715
Series B	501,147	478,718	8,141	8,240
Series C	1,602,962	1,566,352	17,412	17,592
Series D	2,043,969	2,016,929	24,750	25,000
Total	4,553,302	4,458,589	\$ 52,949	\$ 53,547

Convertible preferred stock as of December 31, 2014 consisted of the following (in thousands, except share data):

	December 31, 2014			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
Series A	396,605	396,590	\$ 2,646	\$ 2,715
Series B	493,385	478,718	8,141	8,240
Series C	1,586,392	1,566,352	17,412	17,592
Series D	2,028,236	2,016,929	24,750	25,000
Series E	1,702,702	1,597,814	20,806	21,259

Edgar Filing: Invuity, Inc. - Form S-1/A

Total	6,207,320	6,056,403	\$ 73,755	\$ 74,806
-------	-----------	-----------	-----------	-----------

F-23

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

Convertible preferred stock as of March 31, 2015 consisted of the following (in thousands, except share data):

	March 31, 2015 (unaudited)			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
Series A	396,605	396,590	\$ 2,646	\$ 2,715
Series B	493,385	478,718	8,141	8,240
Series C	1,586,392	1,566,352	17,412	17,592
Series D	2,028,236	2,016,929	24,750	25,000
Series E	1,702,702	1,597,814	20,806	21,259
Series F	1,654,594	1,596,212	22,769	22,898
<b>Total</b>	<b>7,861,914</b>	<b>7,652,615</b>	<b>\$ 96,524</b>	<b>\$ 97,704</b>

Significant provisions of the convertible preferred stock are as follows:

**Voting** Each share is entitled to voting rights equivalent to the number of shares of common stock into which such share can be converted. Holders of the common stock voting as a separate class are entitled to elect two out of the nine members of the Board of Directors; holders of Series A, Series B, Series C, Series D and Series E convertible preferred stock voting as separate classes are each entitled to elect one out of the nine members of the Board of Directors; and holders of the majority of the outstanding shares of common stock and preferred stock, voting as a single class and on an as-converted to common stock basis, are entitled to elect two out of the nine members of the Board of Directors. Certain corporate actions require approval of holders of at least 65% of the then outstanding shares of preferred stock, voting together as a single class on an as-converted to common stock basis. In addition, certain corporate actions require the approval of at least 66 and 2/3% of the outstanding Series D convertible preferred stock or Series E convertible preferred stock, as applicable, voting as separate classes.

**Conversion** Each share of Series A, Series B, Series C, Series D, Series E and Series F convertible preferred stock is convertible at the holder's option at any time into the number of fully paid and nonassessable shares of common stock determined by dividing the original issue price of \$6.8450, \$17.2124, \$11.2314, \$12.395, \$13.3052 and \$14.3449 respectively, by the conversion price of \$6.8450, \$14.4911, \$10.558, \$12.395, \$13.3052 and \$14.3449, respectively, and is subject to adjustments for stock splits, stock dividends and dilution. Each share of preferred stock automatically converts into the number of shares of common stock into which such shares are convertible at the then applicable conversion ratio (i) immediately prior to the completion of the sale of shares of common stock in a public offering with a price of not less than \$14.3449 per share, resulting in at least \$40.0 million of gross proceeds to the Company or (ii) upon the receipt by the Corporation of a written request for such conversion from the holders of at least 65% of the Series A, Series B, Series C, Series D and Series E convertible preferred stock then outstanding (voting as a single class and on an as-converted basis), or with respect to the Series F preferred stock, the vote of the holders of a majority of the Series F preferred stock then outstanding. The Series A, Series D, Series E and Series F convertible preferred stock are convertible into common stock on a one-for-one basis. The Series B and Series C convertible preferred stock are convertible into common stock on a one-for-1.1878 and one-for-1.0638 basis, respectively.

If the Company shall issue, after the date upon which any share of Series F convertible preferred stock was first issued, any additional stock for a consideration per share less than, in case of Series A, \$6.8450

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

per share, in the case of Series B, \$10.558 per share, in the case of Series C, \$10.558 per share, in the case of Series D, \$12.395 per share, in the case of Series E, \$13.3052 per share and in the case of Series F, \$14.3449 per share, then the conversion price for such series of convertible preferred stock shall be adjusted as described below.

Such conversion price shall be adjusted by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately prior to such issuance based on a fully diluted basis, plus the number of shares of common stock that the aggregate consideration received by the Company for such issuance would purchase at such conversion price; and the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, plus the number of shares of additional stock so issued.

**Dividends** Holders of Series A, Series B, Series C, Series D, Series E and Series F convertible preferred stock are entitled to noncumulative dividends of \$0.4107, \$1.032744, \$0.673881, \$0.7437, \$0.798312 and \$0.860694 respectively, per share per annum, if and when declared by the Board of Directors. These dividends are to be paid in advance of any distributions to common stockholders. No dividends have been declared through March 31, 2015, and the payment of cash dividends is restricted under the terms of the loan agreement with HCRP.

**Liquidation Preferences** In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Series F are entitled to receive, prior and in preference to holders of Series A, Series B, Series C, Series D and Series E convertible preferred stock and common stock, an amount equal to \$14.3449 per share, plus any and all declared but unpaid dividends. After this, the holders of Series E are entitled to receive, prior and in preference to holders of Series A, Series B, Series C and Series D convertible preferred stock and common stock, an amount equal to \$13.3052 per share, plus any declared and unpaid dividends. If upon occurrence of such an event, the assets and funds to be distributed among the holders of Series E are insufficient to permit the payment to such holders, the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Series E. Upon completion of the distribution to the holders of Series E, holders of Series A, Series B, Series C and Series D convertible preferred stock are entitled to receive prior and in preference to holders of common stock, an amount equal to \$6.8450, \$17.2124, \$11.2314 and \$12.395 per share for Series A, Series B, Series C and Series D convertible preferred stock, respectively, plus any declared but unpaid dividends. If upon occurrence of such an event, after payment in full of preferential amounts due to holders of Series E convertible preferred stock, the assets and funds to be distributed among the holders of Series A, Series B, Series C and Series D convertible preferred stock are insufficient to permit the payment to such holders, the entire remaining assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Series A, Series B, Series C and Series D convertible preferred stock. All remaining legally available assets of the Company are to be distributed pro rata to the holders of common stock. A liquidation may be deemed to be occasioned by or to include (i) a consolidation or merger of the Company with or into any other corporation in which the Company's stockholders of record as constituted immediately prior to such transaction will, immediately after such transaction, fail to hold at least 50% of the voting power of the result of the surviving corporation; or (ii) a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company (an Acquisition). In the event of an Acquisition, each holder of convertible preferred stock shall be entitled to receive the greater of the liquidation preference described above or the amount of cash, securities or other property to which the holder would be entitled to receive with respect to their shares if the convertible preferred stock had been converted into common stock immediately prior to such Acquisition.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)***Other Matters*

The Company and certain of its preferred and common stockholders have entered into an amended and restated investor rights agreement and an amended and restated right of first refusal and co-sale agreement, respectively. Among other things, the investor rights agreement provides the holders who are party to the agreement with registration rights and, in the event the Company proposes to make certain sales of its equity securities, provides major investors (as defined therein) with a right of first offer. Among other things, the right of first refusal and co-sale agreement provides the Company and certain of its preferred and common stockholders with a right of first refusal, and stockholders with a right of co-sale in certain circumstances in which other stockholders propose to sell equity securities of the Company.

The Company has classified the convertible preferred stock as temporary equity on the balance sheets as the shares can be redeemed upon the occurrence of certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

*Common Stock*

The Company had reserved shares of common stock, on an as-converted basis, for future issuance as follows:

	December 31,		March 31,
	2013	2014	2015 (unaudited)
Convertible preferred stock	4,648,382	6,246,196	7,842,408
Options issued and outstanding	911,403	1,379,503	1,359,142
Shares available for future stock option grants	503,906	315,876	682,971
Warrants to purchase common stock	3,532	3,532	3,532
Convertible preferred stock warrants	50,017	134,570	134,570
Total	6,117,240	8,079,677	10,022,623

**10. STOCK OPTION PLAN**

Pursuant to the Company's 2005 Stock Incentive Plan ( "2005 Plan" ), options and restricted stock may be granted to employees, directors and consultants of the Company. The number of shares authorized for issuance under the 2005 Plan is 1,915,340 shares at December 31, 2014 and 2,272,585 (unaudited) as of March 31, 2015, of which 315,876 and 682,971 (unaudited) shares were available for grant at December 31, 2014 and March 31, 2015, respectively. Any options under the 2005 Plan that expire or otherwise terminate will revert to the 2005 Plan and again become available for issuance.

Options granted under the Company's 2005 Plan may be either incentive stock options or nonstatutory stock options. Incentive stock options may be granted to employees with exercise prices of no less than



**Table of Contents**

## INVUITY, INC.

## Notes to Financial Statements (Continued)

100% the fair value of the common stock on the grant date and nonstatutory options 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 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.

In the event of stock splits and stock dividends, the Board of Directors may increase or decrease proportionately the number of shares and the exercise (purchase) price per share deliverable to the 2005 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 under the 2005 Plan and related information:

	Options Available for Grant	Options Outstanding	Options Outstanding Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value (in thousands)
<b>Balances at December 31, 2012</b>	671,182	767,825	\$ 2.41	
Options granted	(193,844)	193,844	\$ 4.32	
Options exercised		(23,698)	\$ 2.74	
Options forfeited	26,568	(26,568)	\$ 3.10	
<b>Balances at December 31, 2013</b>	503,906	911,403	\$ 2.79	\$ 640
Options authorized	335,135			
Options granted	(631,320)	631,320	\$ 3.15	
Options exercised		(55,065)	\$ 1.43	
Options forfeited	108,155	(108,155)	\$ 3.47	
<b>Balances at December 31, 2014</b>	315,876	1,379,503	\$ 2.57	\$ 9,483
Options authorized (unaudited)	357,245			
Options exercised (unaudited)		(10,511)	\$ 1.89	
Options forfeited (unaudited)	9,850	(9,850)	\$ 3.04	
<b>Balances at March 31, 2015 (unaudited)</b>	682,971	1,359,142	\$ 2.57	\$ 11,596
Options exercisable December 31, 2014		1,379,503	\$ 2.57	\$ 9,483
Options vested and expected to vest December 31, 2014		1,299,466	\$ 2.53	\$ 8,978
Options exercisable March 31, 2015 (unaudited)		1,359,142	\$ 2.57	\$ 11,596
Options vested and expected to vest March 31, 2015 (unaudited)		1,291,804	\$ 2.54	\$ 11,059



**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the Board of Directors, as of December 31, 2014 and March 31, 2015.

During the years ended December 31, 2013 and 2014, the Company granted options with a weighted-average grant date fair value of \$4.32 and \$5.99 per share, respectively. During the three months ended March 31, 2014, the Company granted options with a weighted average grant date fair value of \$3.15 per share (unaudited). No options were granted during the three months ended March 31, 2015.

The aggregate intrinsic value of options exercised was \$24,000 and \$310,000 in the years ended December 31, 2013 and 2014, respectively, and \$23,000 (unaudited) and \$79,000 (unaudited) during the three months ended March 31, 2014 and 2015, respectively. The total fair value of options vested during the period was \$299,000 and \$335,000 for the years ended December 31, 2013 and 2014, respectively, and \$161,000 (unaudited) for the three months ended March 31, 2015.

The weighted-average remaining contractual life of options outstanding was 6.9 years and 7.8 years at December 31, 2013 and 2014, respectively. The weighted-average remaining contractual life of options outstanding was 7.6 years (unaudited) at March 31, 2015. As of December 31, 2014 and March 31, 2015 the weighted-average remaining contractual life was 7.7 years and 6.5 years (unaudited), respectively, for vested and expected to vest options.

The options outstanding, vested and currently exercisable by exercise price under the 2005 Plan at December 31, 2014 are as follows:

Exercise Price	Options Outstanding and Exercisable			Options Vested	
	Number of Options	Weighted-Average Remaining Contractual Life (years)	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)
\$0.19	21,032	1.0	21,032	\$ 0.19	1.0
\$1.30	349,733	5.7	349,280	\$ 1.30	5.7
\$1.48-1.67	54,683	6.6	48,150	\$ 1.65	6.5
\$2.22-2.78	35,936	7.7	26,143	\$ 2.35	7.5
\$3.15	909,747	9.0	332,203	\$ 3.15	8.1
\$4.81	8,372	8.2	7,380	\$ 4.81	8.2
	1,379,503	7.8	784,188	\$ 2.14	6.7

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

The options outstanding, vested and currently exercisable by exercise price under the 2005 Plan at March 31, 2015 are as follows:

Exercise Price	Options Outstanding and Exercisable		(unaudited)		Options Vested	
	Number of Options	Weighted-Average Remaining Contractual Life (years)	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price Per Share
\$0.19	21,032	0.7	21,032	\$ 0.19	0.7	
\$1.30	349,733	5.5	349,647	\$ 1.30	5.5	
\$1.48-1.67	45,000	6.2	40,927	\$ 1.64	6.1	
\$2.22-2.78	35,936	7.4	27,967	\$ 2.35	7.3	
\$3.15	899,069	8.6	370,843	\$ 3.15	7.9	
\$4.81	8,372	7.9	8,120	\$ 4.81	7.9	
	1,359,142	7.6	818,536	\$ 2.20	6.6	

*Early Exercise of Stock Options*

The 2005 Plan allows 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, 2013 and 2014, there were 17,972 and 17,566 shares of common stock outstanding, respectively, subject to the Company's right of repurchase at a weighted-average price of \$2.59 and \$2.34 per share, respectively. As of March 31, 2015, there were 16,272 (unaudited) shares of common stock outstanding subject to the Company's right of repurchase at a weighted-average price of \$2.37 (unaudited) per share.

*Employee Stock-Based Compensation*

Stock-based compensation expense recognized during the years ended December 31, 2013 and 2014, includes compensation expense for stock-based awards granted to employees based on the grant date fair value of \$266,000 and \$606,000, respectively. Stock-based compensation expense recognized during the three months ended March 31, 2014 and 2015, includes compensation expense for stock-based awards granted to employees based on the grant date fair value of \$82,000 (unaudited) and \$163,000 (unaudited), respectively.

As of December 31, 2014, there were total unamortized compensation costs of \$2.0 million related to unvested stock options which the Company expects to recognize over a period of approximately 3.0 years. As of March 31, 2015, there were total unamortized compensation costs of \$1.7 million (unaudited) related to unvested stock options which the Company expects to recognize over a period of approximately 3.0 years.

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

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

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.

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. The fair value of employee stock options was estimated using the assumptions below. Each of these inputs is subjective and its determination generally requires significant judgment.

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015 <sup>(A)</sup>
Expected term (in years)	6.0	6.0	6.0	(unaudited)
Expected volatility	43%	35% 38%	38%	
Risk-free interest rate	1.08% 1.82%	1.80% 1.93%	1.91%	
Dividend yield	0%	0%	0%	

(A)No stock options were granted during the three months ended March 31, 2015.

**Fair Value of Common Stock** 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 has 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.

**Expected Term** The expected term represents the period that the share-based awards are expected to be outstanding. The Company used 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** Because the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants. When selecting comparable publicly traded companies in a similar industry on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' common stock during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

**Risk-Free Interest Rate** The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

**Dividend Yield** The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)***Non-Employee Stock-Based Compensation*

During the years ended December 31, 2013 and 2014, the Company granted options to purchase 11,615 and 9,239 shares, respectively, of common stock to consultants for research and development and general and administrative services. No options were granted during the three months ended March 31, 2015. As of December 31, 2014 and March 31, 2015, none of the consultants' options had been exercised, and 36,846 options remained outstanding with a weighted-average exercise price of \$2.98 per share.

The fair value of non-employee awards is estimated at the time the services are delivered and is remeasured at each reporting date using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,		Three Months Ended March 31,					
	2013		2014		2014		2015	
					(unaudited)			
Expected term (in years)	8.0	9.6	8.0	9.3	8.0	10.0	8.1	9.1
Expected volatility	43%		35%		43%		34%	
Risk-free interest rate	1.76%	2.90%	2.21%	2.72%	2.72%		1.79%	1.86%
Dividend yield	0%		0%		0%		0%	

Stock-based compensation expense related to non-employee awards was \$13,000 and \$57,000 during the years ended December 31, 2013 and 2014, respectively. Stock-based compensation expense related to non-employee awards was \$5,000 (unaudited) and \$10,000 (unaudited) during the three months ended March 31, 2014 and 2015, respectively.

*Total Stock-Based Compensation*

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

	Year Ended December 31,		Three Months Ended			
	2013		March 31,			
	2014		2014		2015	
			(unaudited)			
Cost of goods sold	\$	4	\$	23	\$	17
Selling, general and administrative		233		547		95
Research and development		42		93		61
Total stock-based compensation expense	\$	279	\$	663	\$	173

**11. INCOME TAXES**

The Company has incurred net operating losses for the years ended December 31, 2013 and 2014, therefore has no provision for income taxes recorded for such years. For the years ended December 31, 2013 and 2014, the Company generated losses before taxes in the United States of \$12.1 million and



**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

\$20.7 million, respectively and no foreign income or losses. The Company's deferred tax assets continue to be fully offset by a valuation allowance.

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

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
Tax at statutory federal rate	34.0%	34.0%
State taxes, net of federal benefit	4.9	3.8
Tax credits	1.0	1.3
Change in valuation allowance	(40.1)	(37.8)
Other	0.2	(1.3)
Provision for income taxes	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):

	<b>December 31,</b>	
	<b>2013</b>	<b>2014</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 17,364	\$ 23,574
Research and development	626	782
Accrued liabilities and other	509	590
Stock-based compensation	194	259
Fixed assets	95	100
Tenant improvement allowance		970
Total deferred tax assets	18,788	26,275
Valuation allowance	(18,788)	(26,275)
Net deferred tax assets	\$	\$

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 \$4.9 million and \$7.5 million for the years ended December 31, 2013 and 2014, respectively, and there were no releases of the valuation allowance in these years.

As of December 31, 2014, the Company had net operating loss ( NOL ) carryforwards (before tax effects) for federal and state income tax purposes of \$60.9 million and \$53.8 million, respectively. These federal and state NOL carryforwards will begin to expire in 2026 and 2016, respectively, if not utilized. In addition, the Company has federal and state research and development tax credit carryforwards of \$591,000 and \$684,000, 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

F-32

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)**

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, 2013 and 2014 is as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
Balance at beginning of year	\$ 157	\$ 209
Additions for tax positions taken in current year	52	69
Reductions for tax positions taken in prior years		(17)
Balance at end of year	\$ 209	\$ 261

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 significant change to its unrecognized tax benefits over the next 12 months. The unrecognized tax benefits may increase or change during the year for items that arise in the ordinary course of business.

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, 2013 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.

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)****12. NET LOSS PER COMMON SHARE**

The Company computes net income (loss) per share of common stock in conformity with the two-class method required for participating securities. The Company considers all series of the Company's convertible preferred stock to be participating securities as the holders of the convertible preferred stock are entitled to receive a noncumulative dividend on a pari passu basis in the event that a dividend is paid on common stock. In accordance with the two-class method, earnings allocated to convertible preferred stock are excluded from the computation of net income per common share, basic and diluted. The holders of all series of convertible preferred stock do not have a contractual obligation to share in the losses of the Company. As such, the Company's net losses for the years ended December 31, 2013 and 2014 and the three months ended March 31, 2014 and 2015 were not allocated to these participating securities. As the Company had net losses for the years ended December 31, 2013 and 2014, and the three months ended March 31, 2014 and 2015, all potential common shares were determined to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2013 and 2014 and for the three months ended March 31, 2014 and 2015 (in thousands, except share and per share data):

	Year Ended December 31,		Three Months Ended March 31, (Unaudited)	
	2013	2014	2014	2015
<b>Numerator:</b>				
Net loss	\$ (12,109)	\$ (20,662)	\$ (4,712)	\$ (9,032)
<b>Denominator:</b>				
Weighted-average common shares outstanding	633,146	673,573	661,325	720,874
Less: weighted-average unvested common shares subject to repurchase	(739)	(20,378)	(19,515)	(17,237)
Weighted-average shares used to compute net loss per common share, basic and diluted	632,407	653,195	641,810	703,637
Net loss per common share, basic and diluted	\$ (19.15)	\$ (31.63)	\$ (7.34)	\$ (12.84)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the years ended December 31, 2013, December 31, 2014 and three months ended March 31, 2014 and 2015 because their inclusion would be anti-dilutive:

	Years ended December 31,		Quarter ended March 31, (unaudited)	
	2013	2014	2014	2015
Convertible preferred stock on an as-converted basis	4,648,382	6,246,196	6,246,196	7,842,408
Options to purchase common stock	911,403	1,379,503	1,316,819	1,359,142
Warrants to purchase common stock	3,532	3,532	3,532	3,532
Warrants to purchase convertible preferred stock on an as-converted basis	50,017	134,570	134,570	134,570
Total	5,613,334	7,763,801	7,701,117	9,339,652

**Table of Contents****INVUITY, INC.****Notes to Financial Statements (Continued)****13. PRO FORMA NET LOSS PER COMMON SHARE (UNAUDITED)**

The following table sets forth (in thousands, except share and per share amounts) the computation of the Company's unaudited pro forma basic and diluted net loss per common share after giving effect to the automatic conversion of convertible preferred stock using the as-if converted method into common stock as though the conversion had occurred at the beginning of the period presented or date of issuance, if later. Also, the numerator in the pro forma basic and diluted net loss per common share calculation has been adjusted to remove gains or losses resulting from the remeasurement of the convertible preferred stock warrant liability as it will be reclassified to additional paid-in capital upon the completion of an IPO of the Company's common stock.

	Year Ended December 31, 2014	Three Months Ended March 31, 2015 (unaudited)
Net loss	\$ (20,662)	\$ (9,032)
Less: Change in fair value of convertible preferred stock warrant liability	(522)	504
Net loss used in computing pro forma net loss per common share, basic and diluted	\$ (21,184)	\$ (8,528)
Weighted-average shares used to compute net loss per common share, basic	653,195	703,637
Pro forma adjustment to reflect assumed conversion of convertible preferred stock	6,074,235	7,236,475
Weighted-average shares used to compute pro forma net loss per common share, basic and diluted	6,727,430	7,940,112
Pro forma net loss per common share, basic and diluted	\$ (3.15)	\$ (1.07)

**14. SUBSEQUENT EVENTS**

In February and March 2015, the Company entered into the Series F Preferred Stock Purchase Agreement with new and existing investors and issued an aggregate of 1,596,212 shares of Series F convertible preferred stock at a price of \$14.3449 per share for net proceeds of \$22.9 million. The holders of the Series F convertible preferred stock are entitled to receive non-cumulative dividends at a rate of \$0.860694 per share when and if declared by the board of directors. In connection with the issuance of the Series F convertible preferred stock, the Company amended its articles of incorporation and revised the conditions under which all series of the Company's convertible preferred stock would automatically convert into common stock. Based on the revised terms, the Company's convertible preferred stock will automatically convert into common stock upon the earlier of (i) an IPO with gross proceeds of not less than \$40.0 million to the Company and in which the per share price is at least \$14.3449; or (ii) with respect to the Series A, Series B, Series C, Series D and Series E convertible preferred stock, the vote of the holders of at least 65% of the Series A, Series B, Series C, Series D and Series E convertible preferred stock, voting together as a single class on an as-converted to common stock basis, or (iii) with respect to the Series F convertible preferred stock, the vote of the holders of a majority of the Series F convertible preferred stock then outstanding. Shares of Series F convertible preferred stock convert into shares of common stock on a one-for-one basis.

**Table of Contents**

**INVUITY, INC.**

**Notes to Financial Statements (Continued)**

In February 2015, the Company entered into an accounts receivable credit facility with 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 customary 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 March 13, 2015, the Company has not drawn down on the credit facility.

On May 27, 2015, the Company effected a 1-for-18.5 reverse stock split. On May 28, 2015, the Company reincorporated in Delaware. Refer to Note 1 for further details.

The Company has reviewed and evaluated subsequent events through March 13, 2015, the date the financial statements were available to be issued. For the reissuance of the financial statements, the Company has reviewed and evaluated subsequent events through May 29, 2015.

**15. SUBSEQUENT EVENTS (UNAUDITED)**

In April and May 2015, the Company granted options to purchase 521,512 shares of common stock to employees, directors and consultants, with a weighted-average exercise price of \$12.48 per share.

On May 27, 2015, the Company effected a 1-for-18.5 reverse stock split. On May 28, 2015, the Company reincorporated in Delaware. Refer to Note 1 for further details.

The Company has reviewed and evaluated subsequent events through May 12, 2015, the date these unaudited interim financial statements were available to be issued. For the reissuance of these unaudited interim financial statements, the Company has reviewed and evaluated subsequent events through May 29, 2015.

**Table of Contents**

**Table of Contents**

**Table of Contents****PART II****Information Not Required in Prospectus****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses to be paid by the Registrant, other than underwriting discounts and commissions, upon completion of this offering. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	\$ 8,553
FINRA filing fee	11,540
Exchange listing fee	125,000
Printing and engraving	310,000
Legal fees and expenses	1,725,000
Accounting fees and expenses	1,282,000
Transfer agent and registrar fees	5,000
Miscellaneous	32,907
<b>Total</b>	<b>\$ 3,500,000</b>

**Item 14. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors, and other corporate agents.

Immediately prior to the completion of this offering, as permitted by Section 102(b)(7) of the Delaware General Corporation Law, the Registrant's amended and restated certificate of incorporation will include provisions that eliminate the personal liability of its directors and officers for monetary damages for breach of their fiduciary duty as directors and officers.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, the amended and restated certificate of incorporation and amended and restated bylaws of the Registrant will provide that:

The Registrant shall indemnify its directors and officers for serving the Registrant in those capacities or for serving other business enterprises at the Registrant's request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

The Registrant may, in its discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

The Registrant is required to advance expenses, as incurred, to its directors and officers in connection with defending a proceeding, except that such director or officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.



## Edgar Filing: Invuity, Inc. - Form S-1/A

The Registrant will not be obligated pursuant to the amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person, except with respect to proceedings authorized by the Registrant's board of directors or brought to enforce a right to indemnification.

The rights conferred in the amended and restated certificate of incorporation and amended and restated bylaws are not exclusive, and the Registrant is authorized to enter into indemnification agreements with its directors, officers, employees and agents and to obtain insurance to indemnify such persons.

II-1

---

**Table of Contents**

The Registrant may not retroactively amend the bylaw provisions to reduce its indemnification obligations to directors, officers, employees, and agents.

The Registrant's policy is to enter into separate indemnification agreements with each of its directors and officers that provide the maximum indemnity allowed to directors and executive officers by Section 145 of the Delaware General Corporation Law and also to provide for certain additional procedural protections. The Registrant also maintains directors and officers insurance to insure such persons against certain liabilities.

These indemnification provisions and the indemnification agreements entered into between the Registrant and its officers and directors may be sufficiently broad to permit indemnification of the Registrant's officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification by the underwriters of the Registrant and its officers and directors for certain liabilities arising under the Securities Act and otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to the Registrant's directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. Please read

Item 17. Undertakings for more information on the position of the Securities and Exchange Commission regarding such indemnification provisions.

**Item 15. Recent Sales of Unregistered Securities.**

During the last three years, the Registrant issued the following unregistered securities:

*Warrants*

In July 2013, the Registrant issued a warrant to purchase 11,294 shares of its Series D convertible preferred stock to one accredited investor at an exercise price of \$12.395 per share.

In February 2014, the Registrant issued a warrant to purchase 84,553 shares of its Series E convertible preferred stock to one accredited investor at an exercise price of \$13.3052 per share.

*Sales of Convertible Preferred Stock*

In June 2012, the Registrant sold an aggregate of 2,016,929 shares of its Series D convertible preferred stock to a total of 26 accredited investors at a purchase price of \$12.395 per share, for aggregate proceeds of approximately \$25,000,000.

In February 2014, the Registrant sold an aggregate of 1,597,814 shares of its Series E convertible preferred stock to a total of 21 accredited investors at a purchase price of \$13.3052 per share, for aggregate proceeds of approximately \$21,260,000.

In February 2015, the Registrant 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 Registrant 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.

**Table of Contents**

*Option and Common Stock Issuances*

From May 29, 2012 through June 11, 2015, pursuant to the terms of its 2005 Stock Incentive Plan, the Registrant granted to its officers, directors, employees, consultants and other service providers options to purchase an aggregate of 1,572,494 shares of its common stock at exercise prices ranging from \$2.59 to \$15.91 per share.

From May 29, 2012 through June 11, 2015, pursuant to the terms of its 2005 Stock Incentive Plan, the Registrant issued and sold to its officers, directors, employees, consultants and other service providers an aggregate of 95,855 shares of its common stock upon the exercise of options at exercise prices ranging from \$1.30 to \$4.81 per share, for aggregate proceeds of approximately \$173,931.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant 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 Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

**Item 16. Exhibits and Financial Statement Schedules.**

**(a) Exhibits.**

We have filed the exhibits listed on the accompanying Exhibit Index of this registration statement.

**(b) Financial Statement Schedules.**

All financial statement schedules are omitted because the information called for is not required or is shown either in the financial statements or in the notes thereto.

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**Table of Contents**

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in San Francisco, California, on June 11, 2015.

Invuity, Inc.

By: */s/ Philip Sawyer*  
**Philip Sawyer**  
**President and Chief Executive Officer**

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<i>/s/ Philip Sawyer</i> <b>Philip Sawyer</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	June 11, 2015
<i>/s/ Michael Gandy</i> <b>Michael Gandy</b>	Chief Financial Officer (Principal Accounting and Financial Officer)	June 11, 2015
* <b>Gregory B. Brown</b>	Director	June 11, 2015
* <b>William W. Burke</b>	Director	June 11, 2015
* <b>Randall A. Lipps</b>	Director	June 11, 2015
* <b>Gregory T. Lucier</b>	Director	June 11, 2015
* <b>Eric W. Roberts</b>	Director	June 11, 2015
* <b>Reza Zadno</b>	Director	June 11, 2015

By: */s/ Michael Gandy*  
 Michael Gandy  
 Attorney-in-fact

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
1.1**	Form of Underwriting Agreement.
3.1**	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect.
3.2**	Form of Amended and Restated Certificate of Incorporation of the Registrant to be effective upon closing of the offering.
3.3**	Bylaws of the Registrant as currently in effect.
3.4**	Form of Amended and Restated Bylaws of the Registrant to be effective upon closing of the offering.
4.1**	Specimen Common Stock certificate of the Registrant.
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.
4.3**	Warrant to purchase shares of Series B convertible preferred stock issued to Lighthouse Capital Partners VI, L.P., dated September 15, 2008.
4.4**	Warrant to purchase shares of Series C convertible preferred stock issued to Silicon Valley Bank, dated December 17, 2010.
4.5**	Warrant to purchase shares of Series D convertible preferred stock issued to Silicon Valley Bank, dated July 25, 2013.
4.6**	Warrant to purchase shares of Series E convertible preferred stock issued to HealthCare Royalty Partners II, L.P., dated February 28, 2014.
5.1**	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1**	Form of Indemnification Agreement for directors and executive officers.
10.2+**	Invuity, Inc. 2005 Stock Incentive Plan and form of agreement thereunder, as currently in effect.
10.3+**	Executive Incentive Compensation Plan of the Registrant to be effective upon closing of the offering.
10.4+**	2015 Equity Incentive Plan and forms of agreements thereunder to be effective upon closing of the offering.
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)
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, and currently in effect.
10.7**	Loan and Security Agreement, dated as of February 11, 2015, by and between the Registrant and Silicon Valley Bank.
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, and currently in effect.
10.9+**	Executive Employment Agreement, dated May 15, 2015, by and between the Registrant and Philip Sawyer.
10.10+**	Executive Employment Agreement, dated May 19, 2015, by and between the Registrant and Doug Heigel.
10.11+**	Executive Employment Agreement, dated May 19, 2015, by and between the Registrant and Paul O. Davison.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2**	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1**	Power of Attorney (included in page II-5 to the registration statement on Form S-1 filed on April 17, 2015).
24.2**	Power of Attorney for William W. Burke.

\*\* Previously filed.

+ Indicates a management contract or compensatory plan or arrangement.