Invuity, Inc.
Form 10-Q
August 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2015

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-37417

INVUITY, INC.

(Exact name of the registrant as specified in its charter)

Delaware	04-3803169
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

444 De Haro Street, San Francisco, California 94107

(Address of principal executive offices, Zip Code)

(415) 655-2100

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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 x (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares of the registrant s Common Stock outstanding as of June 30, 2015 was 13,305,015.

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PART I Financial Information

ITEM 1. Financial Statements.

INVUITY, INC.

Condensed Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 65,755	$ 6,048
Accounts receivable, net	3,237	2,798
Inventory	4,826	4,271
Prepaid expenses and other current assets	1,115	2,486
Total current assets	74,933	15,603
Restricted cash	1,125	1,125
Property and equipment, net	9,037	8,541
Other non-current assets		55
Total assets	$ 85,095	$ 25,324
Liabilities, Convertible Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,022	$ 1,075
Accrued and other current liabilities	5,094	4,162
Total current liabilities	7,116	5,237
Deferred rent	2,831	2,676
Convertible preferred stock warrant liability		136
Long-term debt related party	14,418	9,347
Total liabilities	24,365	17,396
Commitments and contingencies		
Convertible preferred stock, $0.001 par value 0 and 6,207,320 shares authorized at June 30, 2015 and December 31, 2014, respectively; 0 and 6,056,403 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		73,755
Stockholders equity (deficit):		

Preferred stock, $0.001 par value 10,000,000 and no shares authorized at June 30, 2015 and December 31, 2014, respectively; no shares issued and outstanding at June 30, 2015 and December 31, 2014		
Common stock, $0.001 par value 100,000,000 and 9,189,189 shares authorized at June 30, 2015 and December 31, 2014, respectively; 13,305,015 and 711,249 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	13	1
Additional paid-in capital	147,132	2,209
Accumulated deficit	(86,415)	(68,037)
Total stockholders equity (deficit)	60,730	(65,827)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 85,095	$ 25,324

See accompanying notes to unaudited condensed financial statements.

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INVUITY, INC.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue	$ 4,747	$ 2,816	$ 9,189	$ 4,970
Cost of goods sold	1,936	1,280	3,668	2,027
Gross profit	2,811	1,536	5,521	2,943
Operating expenses:				
Selling, general and administrative	9,820	5,339	18,743	9,913
Research and development	1,857	1,310	3,757	2,513
Total operating expenses	11,677	6,649	22,500	12,426
Loss from operations	(8,866)	(5,113)	(16,979)	(9,483)
Interest expense	(504)	(352)	(873)	(722)
Interest and other income (expense), net	24	9	(526)	37
Net loss and comprehensive loss	$ (9,346)	$ (5,456)	$ (18,378)	$ (10,168)
Net loss per common share, basic and diluted	$ (3.20)	$ (8.40)	$ (10.11)	$ (15.75)
Weighted-average shares used to compute net loss per common share, basic and diluted	2,919,823	649,511	1,817,673	645,681

See accompanying notes to unaudited condensed financial statements.

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INVUITY, INC.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (18,378)	$ (10,168)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	819	135
Stock-based compensation	561	323
Changes in fair value of convertible preferred stock warrant liability	472	(1)
Provision for doubtful accounts	89	57
Noncash interest expense	71	29
Accretion of premium on marketable securities		100
Changes in operating assets and liabilities:		
Accounts receivable	(528)	(339)
Inventory	(555)	98
Prepaid expenses and other current assets	1,386	(35)
Accounts payable	131	(227)
Accrued and other current liabilities	651	333
Deferred rent	126	(13)
Net cash used in operating activities	(15,155)	(9,708)
Cash flows from investing activities:		
Purchases of property and equipment	(2,695)	(214)
Purchases of marketable securities		(17,510)
Maturities of marketable securities		850
Increase in restricted cash		(1,090)
Net cash used in investing activities	(2,695)	(17,964)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	49,755	
Proceeds from issuance of long-term debt -related party, net of issuance costs	5,000	9,800
Payments of long-term debt		(2,500)
Proceeds from issuance of common stock upon exercise of stock options	33	27
Proceeds from issuance of convertible preferred stock, net of issuance costs	22,769	20,806
Net cash provided by financing activities	77,557	28,133

Net increase in cash and cash equivalents	59,707	461
Cash and cash equivalents, beginning of period	6,048	4,953
Cash and cash equivalents, end of period	$ 65,755	$ 5,414
Supplemental disclosures of cash flow information:		
Interest paid	$	$ 275
Interest paid to related party	$ 804	$ 427
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 82	$ 47
Initial public offering costs in accounts payable and accrued liabilities	$ 2,542	$
Reclassification of convertible preferred stock warrant liability to additional paid-in capital upon conversion of preferred stock warrants into common stock warrants	$ 608	$

See accompanying notes to unaudited condensed financial statements.

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INVUITY, INC.

Notes to Financial Statements

1. Organization and Description of Business

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

Reverse Stock Split

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

Initial Public Offering

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

Upon the effectiveness of the Amended and Restated Certificate of Incorporation of the Company on June 18, 2015, the number of shares of capital stock the Company is authorized to issue was increased to 110,000,000 shares, of which 100,000,000 shares are common stock and 10,000,000 shares are preferred stock. Both the common stock and preferred stock have a par value of $0.001 per share. There are no shares of preferred stock outstanding at June 30, 2015.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company s prospectus dated June 15, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended. The results for the three and six-months ended

June 30, 2015 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

Out-of-Period Adjustments

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

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INVUITY, INC.

Notes to Financial Statements (Continued)

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.

2. Summary of Significant Accounting Policies

Use of Estimates

The Company s financial statements have been prepared in conformity with 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 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 prior to the Company s IPO, and stock-based compensation. Actual results could differ from those estimates and assumptions.

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.

Fair Value of Financial Instruments

Carrying amounts of the Company s financial instruments, including cash equivalents, accounts receivable and accounts payable approximate fair value due to their relatively short maturities. As of June 30, 2015 and December 31, 2014, based on Level 2 inputs and the borrowing rates available to the Company for loans with similar terms and consideration of the Company s credit risk, the carrying value of the Company s long-term debt approximates its fair value.

Deferred Offering Costs

Deferred offering costs, primarily consisting of legal, accounting, printer and other direct fees and costs relating to the initial public offering, were capitalized. The deferred offering costs were subsequently offset against the Company s IPO proceeds upon the closing of the offering in June 2015. As of December 31, 2014, the Company had capitalized $40,000 in deferred offering costs in other non-current assets on the balance sheet.

Customer Concentration

Significant customers are those which represent 10% or more of the Company s total revenue for each period presented in the condensed statements of operations and comprehensive loss or 10% or more of the Company s net accounts receivable balance at each respective balance sheet date. For each significant customer, revenue as a percentage of total revenue was as follows:

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INVUITY, INC.

Notes to Financial Statements (Continued)

	Revenue				Accounts Receivable, net	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30,	December 31,
	2015	2014	2015	2014	2015	2014
Customers:						
Customer A	*	14%	*	15%	11%	12%
Customer B	*	*	*	*	*	12%

* Less than 10%

Convertible Preferred Stock Warrant Liability

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

Revenue Recognition

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

persuasive evidence of an arrangement exists;

the sales price is fixed or determinable;

collection of the relevant receivable is reasonably assured at the time of sale; and

delivery has occurred or services have been rendered.

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

Segment Reporting

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

Net loss per Common Share

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

Recent Accounting Pronouncements

In 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. On July 9, 2015, the FASB deferred the implementation of this standard by one year so that the guidance is effective for fiscal years and interim reporting periods beginning after December 15, 2017, at which time the Company may adopt the new standard under the full retrospective method or the modified retrospective method. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its financial statements and related disclosures.

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INVUITY, INC.

Notes to Financial Statements (Continued)

In April 2015, the FASB issued ASU 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 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.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 amends guidance on the measurement of inventory from lower of cost or market to net realizable value. The amendment applies to all inventory other than those measured by Last-In-First-Out (LIFO) and the Retail Inventory Method (RIM). The amendment is effective for fiscal years beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact, if any, that the adoption of ASU 2015-11 will have on its financial statements and related disclosures.

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 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 and cash equivalents and restricted cash.

Level 3 liabilities that were measured at fair value on a recurring basis consisted of the convertible preferred stock warrant liability, which was measured using the probability weighted expected return method that calculated the

probability of the Company going public or being acquired, and the option-pricing method for remaining private in the near to mid-term. The fair value of the convertible preferred stock warrants at December 31, 2014 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. At the end of each reporting period, the change in estimated fair value during the period is recorded in interest and other income (expense), net. 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 convertible preferred stock warrant liability was remeasured prior to the conversion of the warrants into common stock warrants using an option-pricing model and the following key assumptions: IPO price, expected life of 3.25 to 8.71 years, risk free interest rate of 1.01% to 2.01% and volatility of 35%. Upon completion of the IPO, the convertible preferred stock warrants were converted into common stock warrants and the fair value of the liability of $0.6 million was transferred to additional paid-in capital. The warrants are no longer subject to remeasurement.

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INVUITY, INC.

Notes to Financial Statements (Continued)

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):

	June 30, 2015			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds[(a)]	$ 63,769	$	$	$ 63,769
	$ 63,769	$	$	$ 63,769

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds[(a)]	$ 5,768	$	$	$ 5,768
	$ 5,768	$	$	$ 5,768
Liabilities				
Convertible preferred stock warrant liability	$	$	$ 136	$ 136
	$	$	$ 136	$ 136

(a) - Balances include $35,000 classified as non-current restricted cash as of June 30, 2015 and December 31, 2014.

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):

	Three Months ended June 30,		Six Months ended June 30,	
	2015	2014	2015	2014
Beginning balance	$ 640	$ 648	$ 136	$ 86
Issuance of convertible preferred stock warrants				572
Change in fair value recorded in interest and other income, net	(32)	9	472	(1)
Reclassification from liability to additional paid-in capital upon conversion to common stock warrants at the IPO	(608)		(608)	

Ending balance	$	$ 657	$	$ 657

4. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Raw materials	$ 702	$ 894
Work-in-process	642	768
Finished goods	3,482	2,609
Total inventory	$ 4,826	$ 4,271

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INVUITY, INC.

Notes to Financial Statements (Continued)

Prepaid Expenses and Other Current Assets

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

	June 30, 2015	December 31, 2014
Prepaid expenses	$ 803	$ 420
Tenant improvement allowance receivable	299	2,064
Other	13	2
Total prepaid expenses and other current assets	$ 1,115	$ 2,486

Property and Equipment, Net

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

	June 30, 2015	December 31, 2014
Computer equipment and software	$ 975	$ 633
Laboratory and manufacturing equipment	1,083	816
Furniture and fixtures	1,440	1,409
Leasehold improvements	6,889	6,541
Total property and equipment, gross	10,387	9,399
Less: accumulated depreciation and amortization	(1,350)	(858)
Total property and equipment, net	$ 9,037	$ 8,541

Depreciation and amortization expense was $421,000 and $68,000 for the three months ended June 30, 2015 and 2014, and $819,000 and $135,000 for the six months ended June 30, 2015 and 2014.

Accrued and Other Current Liabilities

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

	June 30, 2015	December 31, 2014
Accrued payroll-related expenses	$ 2,005	$ 1,599
Accrued independent sales agent commissions	276	227
Accrued professional fees	2,092	89
Accrued costs for property and equipment	5	1,453
Deferred rent	261	290
Accrued sales and marketing expenses	30	95
Other	425	409
Total accrued and other current liabilities	$ 5,094	$ 4,162

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INVUITY, INC.

Notes to Financial Statements (Continued)

5. Related Party Loan Agreement

In March 2015, the Company drew down the second tranche of $5.0 million from its $15.0 million loan agreement with HealthCare Royalty Partners (HCRP), a related party due to its equity ownership interest in the Company. 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. As of June 30, 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 June 30, 2015, the Company was in compliance with all covenants.

6. Credit Facility

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 June 30, 2015, the Company has not drawn down on the credit facility.

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INVUITY, INC.

Notes to Financial Statements (Continued)

7. Convertible Preferred Stock

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
Total	6,207,320	6,056,403	$ 73,755	$ 74,806

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

	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	As-Converted Shares
Series A	396,605	396,590	$ 2,646	396,590
Series B	493,385	478,718	8,141	568,615
Series C	1,586,392	1,566,352	17,412	1,666,248
Series D	2,028,236	2,016,929	24,750	2,034,709
Series E	1,702,702	1,597,814	20,806	1,642,002
Series F	1,654,594	1,596,212	22,769	1,671,168
Total	7,861,914	7,652,615	$ 96,524	7,979,332

As of June 30, 2015 there was no convertible preferred stock outstanding.

8. Stock Option Plans

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. 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 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 connection with the Board of Directors and stockholders approval of the 2015 Plan, all remaining shares available for future award under the 2005 Plan were transferred to the 2015 Plan, and the 2005 Plan was terminated.

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INVUITY, INC.

Notes to Financial Statements (Continued)

In April 2015, the Company s board of directors and stockholders approved the 2015 Equity Incentive plan (2015 Plan), effective June 11, 2015, covering incentive stock options, nonstatutory stock options and restricted stock awards that may be granted to employees, directors and consultants. The number of shares authorized for issuance under the 2015 Plan is 3,535,794 at June 30, 2015 of which 1,665,635 shares were available for grant. The number of shares available for issuance under the 2015 Plan will be increased on the first day of each fiscal year in an amount equal to at least (i) 1,494,272 shares; (ii) five percent of the outstanding shares on the last day of the immediately preceding fiscal year or (iii) such number of shares determined by the Company s board of directors. Incentive stock options may be granted to employees or directors holding more than 10% of the voting power of all classes of stock of the Company at an exercise price of no less than 110% of the fair value of the common stock on the grant date and to all other employees or directors at an exercise price of no less than 100% of the fair value of the common stock on the grant date. Nonstatutory stock options may be granted to employees, directors and consultants at an exercise price no less than 100% of the fair value of the common stock on the grant date. Employee stock options generally vest 25% upon one year of continued service to the Company, with the remainder in monthly increments over four additional years. Options expire no more than ten years after the date of grant. Any options under the 2015 Plan that expire or otherwise terminate will revert to the 2015 Plan and again become available for issuance. The 2015 Plan also includes the granting of restricted stock, restricted stock units, stock appreciation rights and performance units.

The following table summarizes stock option activity under the plans and related information:

		Options Outstanding		
	Options Available for Grant	Options Outstanding	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2014	315,876	1,379,503	$ 2.56	$ 9,483
Options authorized	1,851,517			
Options granted	(521,512)	521,512	$ 12.48	
Options exercised		(14,434)	$ 2.23	
Options forfeited	19,754	(19,754)	$ 3.26	
Balances at June 30, 2015	1,665,635	1,866,827	$ 5.33	$ 16,682
Options Exercisable at June 30, 2015		1,866,827	$ 5.33	$ 16,682
Options vested and expected to vest at June 30, 2015		1,754,832	$ 5.10	$ 16,060

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 fair value of the Company s common stock, as of June 30, 2015 and December 31, 2014.

During the three months ended June 30, 2015 and 2014, the Company granted options with a weighted average grant date fair value of $12.48 and $6.91 per share. During the six months ended June 30, 2015 and 2014, the Company granted options with a weighted average grant date fair value of $12.48 and $3.88 per share.

The aggregate intrinsic value of options exercised was $47,000 and $1,000 during the three months ended June 30, 2015 and 2014, and $60,000 and $24,000 during the six months ended June 30, 2015 and 2014. The total fair value of options vested was $381,000 and $178,000 for the three months ended June 30, 2015 and 2014, and $546,000 and $262,000 for the six months ended June 30, 2015 and 2014.

The weighted-average remaining contractual life of options outstanding was 8.0 and 7.8 years at June 30, 2015 and December 31, 2014. As of June 30, 2015 and December 31, 2014, the weighted-average remaining contractual life was 7.9 and 7.7 years, for vested and expected to vest options.

Early Exercise of Stock Options

The 2005 Plan allowed for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser s employment or services, at the price paid by the purchaser. The Company s right to repurchase these shares generally lapses 1/48 of the original grant date amount per month over four years. At June 30, 2015 and December 31, 2014, there were 13,603 and 17,566 shares of common stock outstanding subject to the Company s right of repurchase at a weighted-average price of $2.42 and $2.34 per share.

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INVUITY, INC.

Notes to Financial Statements (Continued)

Stock-Based Compensation

The fair value of share-based payments for option granted to employees and directors was estimated on the date of grant using the Black-Scholes option- pricing valuation model based on the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Expected term (in years)	5.0-6.32	6.0	5.0-6.32	6.0
Expected volatility	32.8%	38%	32.8%	38%
Risk-free interest rate	1.31-1.72%	1.93%	1.31-1.72%	1.91%-1.93%
Dividend yield				

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Expected term (in years)	8.1-9.1	8.0-9.8	8.1-9.1	8.0-10.0
Expected volatility	38%	38%	34-38%	38%-43%
Risk-free interest rate	1.9-3.03%	2.60%	1.79-3.03%	2.60%-2.72%
Dividend yield				

The following table summarizes stock-based compensation expense related to stock options for the three months and six months ended June 30, 2015 and 2014 included in the condensed statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Cost of revenue	$ 24	$ 3	$ 41	$ 4
Research and development	86	24	147	34
Selling, general and administrative	278	209	373	285
Total stock-based compensation expense	$ 388	$ 236	$ 561	$ 323

As of June 30, 2015, unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $3.4 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 3.5 years.

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INVUITY, INC.

Notes to Financial Statements (Continued)

9. 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 three months and six months ended June 30, 2015 and 2014 were not allocated to these participating securities. As the Company had net losses for all the periods presented, all potentially dilutive common securities were determined to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Numerator:				
Net loss	$ (9,346)	$ (5,456)	$ (18,378)	$ (10,168)
Denominator:				
Weighted-average common shares outstanding	2,934,315	672,407	1,833,709	666,896
Less: weighted-average unvested common shares subject to repurchase	(14,492)	(22,896)	(16,036)	(21,215)
Weighted-average shares used to compute net loss per common share, basic and diluted	2,919,823	649,511	1,817,673	645,681
Net loss per common share, basic and diluted	$ (3.20)	$ (8.40)	$ (10.11)	$ (15.75)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per share for the three months and six months ended June 30, 2015 and 2014 because their inclusion would be anti-dilutive:

	June 30,	
	2015	2014

Convertible preferred stock on an as-converted basis		6,246,196
Options to purchase common stock	1,866,827	1,181,970
Warrants to purchase common stock	137,007	3,532
Warrants to purchase convertible preferred stock on an as-converted basis		134,570
Total	2,003,834	7,566,268

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed financial statements and the related notes included in Item 1 of Part I of this report, and together with our audited financial statements and the related notes included in our Registration Statement on Form S-1 for the period ended December 31, 2014. Historic results are not necessarily indicative of future results. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ from these forward-looking statements as result of various factors including those discussed in the section titled Risk Factors included elsewhere in this Quarterly Report on Form 10-Q.

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 450 hospitals in the second quarter of 2015, as compared to approximately 240 hospitals in the same quarter of 2014. Based on the number of single-use units we have shipped as of June 30, 2015, we estimate that our devices have been used in approximately 109,000 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 39 as of December 31, 2014 to 44 as of June 30, 2015, and we expect to continue to expand our direct sales force and marketing organization to further penetrate and expand the market by demonstrating the benefits of our Intelligent Photonics technology platform to surgeons. Our direct sales force 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. Our currently marketed devices are commonly treated as general supplies utilized in surgery. As a result, the hospital or surgical center receives a single reimbursement from the third-party payor that is intended to

cover the overall cost of treatment, including the cost of devices used during the procedure, as well as the overhead cost associated with the facility where the procedure is performed. There is no separate reimbursement for our devices.

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

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For the six months ended June 30, 2015, our revenue was $9.2 million and we incurred a net loss of $18.4 million compared to revenue of $5.0 million and a net loss of $10.2 million for the six months ended June 30, 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 June 30, 2015, we had an accumulated deficit of $86.4 million. We have increased our number of employees from 88 on June 30, 2014 to 121 employees as of June 30, 2015.

Financial Operations Overview

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 sales force 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 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 inventories of products purchased in the fourth quarter. Revenue in the fourth quarter tends to be the highest as demand may be impacted by the desire of patients to spend their remaining balances in their flexible spending accounts or because they have met their annual deductibles under their health insurance plans. In addition, in the fourth quarter, our results can be impacted by the budgeting and buying patterns of hospitals and military facilities.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of material costs, manufacturing overhead, direct labor and third-party services, such as sterilization. Manufacturing overhead represents a significant portion of cost of goods sold and includes the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenue to decrease as our production volume increases and our production process becomes more efficient. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping cost, 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 and reduce outsourced manufacturing, thereby reducing our per unit manufacturing costs. However, our gross margin will likely fluctuate from quarter to quarter in the near term.

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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 for of the NASDAQ Global Market 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 expense R&D costs as they are incurred. We expect our R&D costs to increase in absolute dollars as we hire additional personnel to develop new devices and device enhancements.

Interest Expense

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

Interest and Other Income (Expense), Net

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

Critical accounting policies and estimates

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 U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions 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 estimates under different assumptions or conditions and any such differences may be material.

There have been no material changes in our critical accounting policies during the three and six months ended June 30, 2015, as compared to those disclosed in the *Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates* in our prospectus dated June 15, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

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Results of Operations

Comparison of the Three Months Ended June 30, 2015 and 2014

	Three Months Ended June 30,		$	%
	2015	2014	Change	Change
	(In thousands)			
Revenue	$ 4,747	$ 2,816	$ 1,931	69%
Cost of goods sold	1,936	1,280	656	51%
Gross profit	2,811	1,536	1,275	83%
Gross margin	59%	55%	4%	
Operating expenses:				
Selling, general and administrative	9,820	5,339	4,481	84%
Research and development	1,857	1,310	547	42%
Total operating expenses	11,677	6,649	5,028	76%
Loss from operations	(8,866)	(5,113)	(3,753)	73%
Interest expense	(504)	(352)	(152)	43%
Interest and other income, net	24	9	15	*
Net loss	$ (9,346)	$ (5,456)	$ (3,890)	71%

* *Not meaningful*

Revenue

Revenue increased $1.9 million, or 69%, to $4.7 million during the three months ended June 30, 2015, compared to $2.8 million during the three months ended June 30, 2014. The growth in revenue was attributable to an increase in unit sales, driven by the expansion of our direct sales force, which increased the number of customers to whom we sold devices. The number of our direct sales representatives increased from 39 as of June 30, 2014 to 44 as of June 30, 2015 and the number of customers purchasing our devices increased from approximately 240 in the second quarter of 2014 to approximately 450 in the second quarter of 2015. Our revenue for the three months ended June 30, 2015 was negatively impacted by a $0.3 million reversal of revenue that we had originally recorded in the fourth quarter of 2014 associated with sales to a distributor for military facilities. The distributor has returned the underlying inventory, we have terminated the relationship with the distributor involved, and we have started working with a new distributor for military accounts.

Revenue attributable to our reusable metal retractors increased 115% from $0.3 million during the three months ended June 30, 2014 to $0.7 million during the three months ended June 30, 2015, and represents 12% and 15% of our total revenue for the respective quarters. Revenue from our single-use products increased 74%, from $2.0 million during the three months ended June 30, 2014 to $3.5 million during the three months ended June 30, 2015 and represents 71% and 73% of our total revenue for the respective quarters.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $0.7 million, or 51%, to $1.9 million during the three months ended June 30, 2015, compared to $1.3 million during the three months ended June 30, 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. This increase in cost of goods sold is also attributable to an increase in the number of operations personnel and increased overhead related to our new leased facility in San Francisco.

Gross margin for the three months ended June 30, 2015 was 59%, compared to 55% for the three months ended June 30, 2014. In the three months ended June 30, 2014, a $0.4 million write-off of unrecoverable trunk stock inventory provided to direct sales representatives and independent sales agents resulted in an unfavorable impact to gross margin for the quarter. The gross margin for the three months ended June 30, 2015 was negatively affected by the Company s relocation into its new operating facility, where higher overhead costs, a temporary decrease in production output during the transition, and an increase in the allocation of quality and operations costs to manufacturing resulted in higher production costs.

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Selling, General and Administrative Expenses

SG&A expenses increased $4.5 million, or 84%, to $9.8 million during the three months ended June 30, 2015, compared to $5.3 million during the three months ended June 30, 2014. The increase in SG&A expenses was primarily attributable to a $1.1 million increase in personnel-related expenses (excluding sales commissions) as a result of increased headcount, a $0.6 million increase in commissions to direct sales representatives, a $0.1 million increase in independent sales agent commissions, 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 $0.3 million increase in depreciation expense primarily attributable to the new facility we lease starting in November 2014, a $0.3 million increase in consulting expenses, and a $0.5 million increase due to the increased rent associated with the new facility.

Research and Development Expenses

R&D expenses increased $0.5 million, or 42%, to $1.9 million during the three months ended June 30, 2015, compared to $1.3 million during the three months ended June 30, 2014. The increase in R&D expenses was primarily attributable to a $0.5 million increase in personnel-related expenses as a result of increased headcount.

Interest Expense

Interest expense increased $0.1 million to $0.5 million during the three months ended June 30, 2015, compared to $0.4 million during the three months ended June 30, 2014. The increase was due to the higher outstanding debt balance under our long-term loan with HealthCare Royalty Partners due to the additional $5.0 million borrowed in March 2015.

Comparison of the Six Months Ended June 30, 2015 and 2014

	Six Months Ended June 30,		$	%
	2015	2014	Change	Change
	(In thousands)			
Revenue	$ 9,189	$ 4,970	$ 4,219	85%
Cost of goods sold	3,668	2,027	1,641	81%
Gross profit	5,521	2,943	2,578	88%
Gross margin	60%	59%	1%	
Operating expenses:				
Selling, general and administrative	18,743	9,913	8,830	89%
Research and development	3,757	2,513	1,244	50%
Total operating expenses	22,500	12,426	10,074	81%
Loss from operations	(16,979)	(9,483)	(7,496)	79%
Interest expense	(873)	(722)	(151)	21%
Interest and other income (expense), net	(526)	37	(563)	*

Net loss	$ (18,378)	$ (10,168)	$ (8,210)	81%

* *Not meaningful*

Revenue

Revenue increased $4.2 million, or 85%, to $9.2 million for the six months ended June 30, 2015, compared to $5.0 million for the six months ended June 30, 2014. The growth in revenue was attributable to an increase in unit sales. The increase in units was driven by the expansion of our direct sales force, which increased the number of customers to whom we sold devices. Our revenue for the six months ended June 30, 2015 was negatively impacted by a $0.3 million reversal of revenue that we had originally recorded in the fourth quarter of 2014 associated with sales to a distributor for military facilities. The distributor has returned the underlying inventory, we have terminated the relationship with the distributor involved, and we have started working with a new distributor for military accounts.

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Revenue attributable to our reusable metal retractors increased 187% from $0.6 million during the six months ended June 30, 2014 to $1.6 million during the six months ended June 30, 2015, and represents 11% and 17% of our total revenue for the respective periods. Revenue from our single-use products increased 83%, from $3.5 million during the six months ended June 30, 2014 to $6.5 million during the six months ended June 30, 2015 and represents 71% and 70% of our total revenue for the respective periods.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $1.6 million, or 81%, to $3.7 million for the six months ended June 30, 2015, compared to $2.0 million for the six months ended June 30, 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. This increase in cost of goods sold is also attributable to an increase in the number of operations personnel and increased overhead 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 six months ended June 30, 2015 was 60%, compared to 59% for the six months ended June 30, 2014. The gross margin increased primarily due to a higher volume of sales during the first six months of 2015. In the six months ended June 30, 2014, a $0.4 million write-off of unrecoverable trunk stock inventory provided to direct sales representatives and independent sales agents resulted in an unfavorable impact to gross margin for the quarter. The gross margin for the six months ended June 30, 2015 was negatively affected by the Company s relocation into its new operating facility, where higher overhead costs, a temporary decrease in production output during the transition, and an increase in the allocation of quality and operations costs to manufacturing resulted in higher production costs.

Selling, General and Administrative Expenses

SG&A expenses increased $8.8 million, or 89%, to $18.7 million for the six months ended June 30, 2015, compared to $9.9 million for the six months ended June 30, 2014. The increase in SG&A expenses was attributable to a $2.5 million increase in personnel-related expenses (excluding sales commissions) as a result of increased headcount, a $1.2 million increase in commissions to direct sales representatives, a $0.3 million increase in independent sales agent commissions, a $1.4 million increase in marketing, advertising and promotion-related expenses, a $0.7 million increase in depreciation expense mainly due to the new facility, a $1.1 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 $0.3 million increase in travel and entertainment mainly due to an increase in the sales force, a $0.6 million increase in consulting expenses, and a $0.9 million increase due to the increased rent associated with the new facility.

Research and Development Expenses

R&D expenses increased $1.2 million, or 50%, to $3.8 million for the six months ended June 30, 2015, compared to $2.5 million for the six months ended June 30, 2014. The increase in R&D expenses was primarily attributable to a $1.0 million increase in personnel-related expenses as a result of increased headcount and a $0.2 million increase in consulting expenses.

Interest Expense

Interest expense increased $0.2 million, or 21%, to $0.9 million for the six months ended June 30, 2015, compared to $0.7 million for the six months ended June 30, 2014. The increase was due to the higher outstanding debt balance under our long-term loan with HealthCare Royalty Partners due to the additional $5.0 million borrowed in March 2015.

Interest and Other Income (Expense), Net

Interest and other income (expense), net changed $0.6 million to $0.5 million expense for the six months ended June 30, 2015, compared to income of $37,000 for the six months ended June 30, 2014. The change was primarily due to the fair value re-measurement and related increase of the liability related to our convertible preferred stock warrants.

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Liquidity and Capital Resources

Overview

As of June 30, 2015, we had cash and cash equivalents of $65.8 million and an accumulated deficit of $86.4 million, compared to cash and cash equivalents of $6.0 million and an accumulated deficit of $68.0 million as of December 31, 2014. Up to the time of our public offering, we had previously financed our operations primarily through sales of our convertible preferred securities, debt financings and the sale of our devices. We have 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. As of June 30, 2015 we have not borrowed on this facility and have $2.7 million available. In June 2015, we completed an initial public offering of our common stock for aggregate net proceeds of $47.2 million after underwriting discounts and commissions and offering costs incurred by us.

We believe that our existing cash and cash equivalents as of June 30, 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, 2016. Our expected future capital requirements may depend on many factors including customer expansion, the expansion of our sales force, 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 six months ended June 30, 2015 and 2014 (in thousands):

	Six Months Ended June 30,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	$ (15,155)	$ (9,708)
Investing activities	(2,695)	(17,964)
Financing activities	77,557	28,133

Net increase in cash and cash equivalents	$ 59,707	$ 461

Net Cash Used in Operating Activities

During the six months ended June 30, 2015, net cash used in operating activities was $15.2 million, which consisted of a net loss of $18.4 million, adjusted by non-cash charges of $2.0 million and a net change of $1.2 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of stock-based compensation of $0.6 million, depreciation and amortization of $0.8 million, a loss of $0.5 million on the remeasurement of our convertible preferred stock warrant liability, and an increase in the provision for doubtful accounts of $0.1 million. The increase in our net operating assets and liabilities was primarily due to a $1.4 million decrease in prepaid expenses and other current assets as a result of funds received related to the tenant allowance from our landlord on the De Haro facility, a $0.8 million increase in accounts payable and accrued liabilities as a result of an increase in our operations and related growth in headcount and an increase of $0.1 million in deferred rent related to our new facility lease. These increases in cash flows were partially offset by a $0.5 million increase in accounts receivable as a result of an increase in revenue and a $0.6 million increase in inventory to support the expected growth in future revenue.

During the six months ended June 30, 2014, net cash used in operating activities was $9.7 million, which consisted of a net loss of $10.2 million, adjusted by non-cash charges of $0.6 million. The non-cash charges were primarily comprised of depreciation and amortization of $0.1 million stock-based compensation of $0.3 million and accretion of premium on marketable securities of $0.1 million. The net change in our net operating assets and liabilities was primarily the result of a $0.3 million increase in accounts receivable as a result of increased revenue during the period, offset by a $0.1 million decrease in inventory and increase in net accounts payable and accrued liabilities of $0.1 million due to the growth in operations.

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Net Cash Used in Investing Activities

During the six months ended June 30, 2015, net cash used in investing activities was $2.7 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 six months ended June 30, 2014, net cash used in investing activities was $18.0 million, which consisted of $17.5 million for the purchase of marketable securities, $1.1 million increase in restricted cash in the period due to security deposit for the lease at 444 De Haro and $0.2 million of capital expenditures to purchase property and equipment, offset by $0.9 million in proceeds from the maturities of marketable securities.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2015, net cash provided by financing activities was $77.6 million, consisting of net cash proceeds of $49.8 million from the issuance of common stock from our initial public offering, $22.8 million from the issuance of convertible preferred stock, and net proceeds of $5.0 million from borrowings under our long-term debt facility.

During the six months ended June 30, 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.

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

During the three months ended June 30, 2015, there were no material changes to our contractual obligations and commitments described under Management s Discussion and Analysis of Financial Condition and Results of Operations in our prospectus dated June 16, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

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ITEM 3. 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 $6.0 million and $65.8 million as of December 31, 2014 and June 30, 2015, respectively, which consist of bank deposits and money market funds. The cash and cash equivalents are held for working capital purposes.

We do not enter into investments for trading or speculative purposes. Because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial statements.

As of December 31, 2014 and June 30, 2015, we had total outstanding net 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were not effective as described below.

Material Weakness in 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. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. 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 misstatement to our financial statements. However, this material weakness could result in a misstatement or our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected.

Management s Plan to Remediate the Material Weakness

We are in the process of implementing measures and processes 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 the financial personnel who perform the financial statement review do not have journal entry access.

We have formalized a process requiring financial personnel to review and approve journal entries that they have not prepared.

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

We have hired an experienced controller during the third quarter of 2015. We are also in the process of adding additional accounting personnel to our organization and ensuring proper segregation of duties amongst the accounting personnel.

The actions we are taking are subject to ongoing senior management review, as well as audit committee oversight. These remediation actions include designing reconciliation and review controls that will operate at a level of precision to ensure that the applicable controls will prevent or detect errors on a timely basis.

Changes in Internal Control Over Financial Reporting

Other than changes intended to remediate the material weakness noted above, there were no other changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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PART II OTHER INFORMATION

ITEM 1. 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.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, 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 $10.2 million and $18.4 million for the six months ended June 30, 2014 and 2015, respectively. As of June 30, 2015, our accumulated deficit was $86.4 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 six months ended June 30, 2015, our revenue was $7.2 million, $13.1 million and $9.2 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.

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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 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 sales force 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 sales force 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 44 as of June 30, 2015. Our operating results are dependent upon the sales and marketing efforts of our direct sales representatives. If our direct sales force fails to adequately promote, market and sell our devices, our sales may suffer.

As we launch new devices and increase our current marketing efforts with respect to existing devices and expand into new geographies, our future success will depend largely on our ability to continue to hire, train, retain and motivate

skilled sales personnel with significant technical knowledge of our devices. We have made, and intend to continue to make, a significant investment in recruiting and training sales representatives. There is significant competition for sales personnel 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 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, sales force 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:

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

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

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

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

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

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

surgeon and hospital acceptance of our devices;

the productivity of our sales representatives;

the introduction of new devices and technologies or acquisitions by us or our competitors;

fluctuations in our expenses associated with expanding our operations and operating as a public company;

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

buying patterns of the distributors that serve our military customers;

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supplier, manufacturing or quality problems with our devices; and

changes in our pricing policies or in the pricing policies of our competitors or suppliers.

For example, we are still learning about the buying patterns and timing of collections regarding sales to military facilities. Our revenue growth for the six months ended June 30, 2015 was negatively impacted by the reversal of revenue during the second quarter of 2015 of approximately $300,000 for revenue we had previously recorded in the fourth quarter of 2014 from our military distributor. We have since accepted return of the product, terminated our relationship with the distributor and are now working with a new distributor for military accounts.

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

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

A material portion of our total revenue in any given period may come from a relatively small number of customers. Sales to one customer accounted for 12% of our total revenue in each of 2013 and 2014, and sales to another customer accounted for 13% of our total revenue in 2013. We do not expect sales to these customers to increase significantly in the future, and as our revenue increases, we expect sales to these customers to decrease as a percent of revenue. There were no sales to any customer in excess of 10% of our total revenue for the six months ended June 30, 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.

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Although we could temporarily assemble some of these components internally, we may incur greater costs, delay production or divert attention from other critical projects until we find an alternate source. Any interruption or delay in obtaining components from our third-party suppliers, or our inability to obtain components from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing devices.

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

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions. In addition, because of the broad choice of devices we offer the many surgeon specialists who use our devices, we must maintain sufficient inventory on hand to ensure each order is filled when received. 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;
- 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;

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be fully FDA-compliant with marketing of new devices or modified devices;

provide adequate training to potential users of our devices; and

receive adequate coverage and reimbursement for procedures performed with our devices.

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

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

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

litigation costs;

distraction of management s attention from our primary business;

impairment of our business reputation;

the inability to commercialize our devices;

decreased demand for our devices or devices in development, if cleared or approved;

device recall or withdrawal from the market;

withdrawal of clinical trial participants;

substantial monetary awards to patients or other claimants; or

loss of revenue.

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

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

We believe that our continued success depends to a significant extent upon the efforts and abilities of our executive officers and other key personnel. Our executive officers and other key personnel are critical to the strategic direction and overall management of our company as well as our research and development process. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The loss of any of our executive officers and other key personnel could adversely affect our business, financial condition and operating results. Our current Chief Financial Officer, Michael Gandy, has informed us of his resignation from his position effective August 21, 2015. We have hired a new Chief Financial Officer, James Mackaness, who will begin his service with us on August 24, 2015. In addition, other 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, Vice President of Operations and Vice President of Marketing. 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.

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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 121 at June 30, 2015. We intend to continue to grow and may experience periods of rapid growth and expansion. Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems and other operational infrastructure. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. To achieve our revenue goals, we must continue to hire, train, retain and motivate skilled personnel.

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

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

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

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

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

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.

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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.

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

- difficulties in enforcing or defending intellectual property rights;
- pricing pressure that we may experience internationally;
- a shortage of high-quality sales people and distributors;
- third-party reimbursement policies that may require some of the patients who receive our devices to directly absorb medical costs or that may necessitate the reduction of the selling prices of our devices;
- competitive disadvantage with established businesses and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;

longer payment cycles;

foreign currency exchange rate fluctuations;

difficulties in maintaining consistency with our internal guidelines;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

the imposition of costly and lengthy new export licensing requirements;

the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and

the imposition of new trade restrictions.

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

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

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

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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 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.

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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.

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.

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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 six months ended June 30, 2015, our net cash used in operating activities was $15.2 million, and was $13.9 million and $19.8 million for the years ended December 31, 2013 and 2014, respectively. As of June 30, 2015, following our recent IPO, we had working capital of $67.8 million, which included $65.8 million in cash and cash equivalents. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the results of our commercialization efforts for our existing and future devices, including international expansion;
- the rate at which we continue to grow our direct sales force and increase our marketing activities;
- the establishment of high volume manufacturing;
- the need for additional capital to fund future development programs;
- the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property; and
- our success in entering into collaborative relationships with other parties.

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

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

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

As of June 30, 2015, we owed an aggregate principal amount of $15.0 million to HealthCare Royalty Partners, pursuant to a term loan agreement, which we refer to as the HCRP loan agreement.

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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 June 30, 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.

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.

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 overt time and can involve lengthy and detailed laboratory and clinical testing procedures and an extensive agency review process, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements depending on the complexity and novelty of the device. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

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

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

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

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

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

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

Before a new medical device, or a new intended use for, an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology

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

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

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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;
- 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.

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

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

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer s decision. Any modification to an FDA-cleared device that would significantly affect it safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties. Furthermore, the FDA s ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. Specifically, on July 9, 2012, the FDA Safety and Innovation Act of 2012 was enacted which, among other requirements, obligates the FDA to prepare a report for Congress on the FDA s approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently submitted this report and suggested that manufacturers continue to adhere to the FDA s 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA s continuing scrutiny of these issues remains unclear.

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

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA s Quality System Regulation, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic announced and unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate and prompt corrective action in response to an adverse Quality System inspection could result in, among other things, a partial or total shut-down of our manufacturing operations, significant fines, consent decrees, injunctions, untitled letters, warning letters, injunctions, customer notifications or repair, replacement, refunds, recall, detention or seizure of our products, suspension of marketing clearances and approvals, seizures or recalls of our

devices, operating restrictions, refusal to grant export approval for our products, refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products, withdrawing 510(k) clearances or pre-market approvals that have already been granted, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our devices and cause revenues to decline.

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

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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;

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 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;

the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which, pursuant to draft legislation being prepared by the German government, may make the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and

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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 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.

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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 government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals.

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

Risks Related to our Common Stock

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

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

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

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

changes in analysts estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts estimates;

legislation or regulatory policies, practices or actions affecting our business;

lawsuits threatened or filed against us;

the sale of our common stock or other securities in the future by us or our stockholders, including upon expiration of market standoff or contractual lock-up agreements;

developments or disputes concerning our intellectual property or other proprietary rights;

announcements related to patents issued to us or our competitors and to litigation;

recruitment or departure of key personnel, including changes in our board of directors and management;

changes in market valuation or earnings of our competitors;

the trading volume of our common stock;

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changes in the estimation of the future size and growth rate of our markets;

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and

developments in our industry.

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

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

Sales of a substantial amount of common stock in the public market, or the perception that these sales may occur, could adversely affect the market price of our common stock. As of June 30, 2015, we have 13,305,015 shares of common stock outstanding. This includes the 4,600,000 shares we sold in our IPO, which may be resold in the public market immediately, except for any shares held or purchased in this offering by our affiliates, as defined in Rule 144 under the Securities Act. The remaining 8,705,015 shares of common stock outstanding as of June 30, 2015 are 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 our prospectus dated June 15, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended. 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 our prospectus dated June 15, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, entitled Shares Eligible for Future Sale and Underwriting.

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 June 30, 2015, have the right, subject to some conditions, to require us file registration statements under the Securities Act covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders pursuant to a stockholders agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

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

plan and/or the option agreements entered into with option holders.

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

As of June 30, 2015, our directors and executive officers and stockholders holding more than 5% of our capital stock and their affiliates beneficially owned, in the aggregate, approximately 70.2% of our outstanding common stock. To the extent our existing stockholders purchase additional shares, this ownership concentration would increase. As a result, if these stockholders were to choose to act together, they would be able to control the management and affairs of our company and most matters and exercise significant influence over most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

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

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

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

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

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

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our

general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to maintain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

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

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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 are 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.

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.

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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.

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

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

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

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

a classified board of directors;

advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder s notice;

a supermajority stockholder vote requirement for amending certain provisions of our certificate of incorporation and bylaws;

the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;

allowing stockholders to remove directors only for cause and only with a supermajority stockholder vote;

a requirement that the authorized number of directors may be changed only by resolution of the board of directors;

allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;

a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent; and

limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. For more information, see the section of our prospectus dated June 15, 2015 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, entitled Description of Capital Stock.

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

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

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

We have never paid cash dividends and we currently intend to retain any future earnings and do not anticipate paying cash dividends in the foreseeable future. We are not legally or contractually required to pay dividends and both the HCRP loan agreement and the SVB credit facility contain restrictions on our ability to pay cash dividends. The declaration and payment of all future dividends, if any, will be at the sole discretion our board of directors, which retains the right to change our dividend policy at any time, and may be limited by our debt arrangements in place from time to time. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our common stock may be less valuable because stockholders must rely on sales of their common stock after price appreciation, which may never occur, to realize any future gains on their investment.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

The documents listed in the Exhibit Index of this Quarterly Report on Form 10-Q are herein incorporated by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Invuity, Inc.

Date: August 12, 2015

By: /s/ Philip Sawyer
Philip Sawyer
President and Chief Executive Officer

Date: August 12, 2015

By: /s/ Michael Gandy
Michael Gandy
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation
3.3	Amended and Restated Bylaws
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Invuity, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether

made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.