Invuity, Inc.
Form 10-Q
November 03, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10 Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016

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

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 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	(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

The number of shares of the registrant’s Common Stock outstanding as of November 1, 2016 was 16,930,376.

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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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 47,709	$ 46,296
Accounts receivable, net	5,149	3,619
Inventory	5,120	5,182
Prepaid expenses and other current assets	952	923
Total current assets	58,930	56,020
Restricted cash	1,090	1,090
Property and equipment, net	8,538	9,195
Other non-current assets	170	—
Total assets	$ 68,728	$ 66,305
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,800	$ 2,458
Accrued and other current liabilities	5,283	4,214
Short-term debt—related party	1,125	—
Total current liabilities	9,208	6,672
Deferred rent	2,751	2,810
Long-term debt—related party	13,462	14,480
Total liabilities	25,421	23,962
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value—10,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; no shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Common stock, $0.001 par value—100,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; 16,905,103 and 13,392,358 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	14	13
Additional paid-in capital	179,960	147,937
Accumulated deficit	(136,667)	(105,607)
Total stockholders' equity	43,307	42,343

Total liabilities, convertible preferred stock and stockholders' equity	$ 68,728	$ 66,305

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 8,478	$ 5,595	$ 23,106	$ 14,784
Cost of goods sold	2,219	2,035	6,416	5,605
Gross profit	6,259	3,560	16,690	9,179
Operating expenses:				
Research and development	2,471	2,042	7,412	5,799
Selling, general and administrative	12,134	10,180	38,885	29,020
Total operating expenses	14,605	12,222	46,297	34,819
Loss from operations	(8,346)	(8,662)	(29,607)	(25,640)
Interest expense	(505)	(504)	(1,514)	(1,377)
Interest and other income (expense), net	30	28	61	(499)
Net loss and comprehensive loss	$ (8,821)	$ (9,138)	$ (31,060)	$ (27,516)
Net loss per common share, basic and diluted	$ (0.56)	$ (0.69)	$ (2.19)	$ (4.84)
Weighted-average shares used to compute net loss per common share, basic and diluted	15,690,785	13,292,849	14,173,534	5,684,755

See accompanying notes to unaudited condensed financial statements.

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INVUITY, INC.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (31,060)	$ (27,516)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,481	1,258
Stock-based compensation	1,716	919
Changes in fair value of convertible preferred stock warrant liability	—	472
Provision for doubtful accounts	63	147
Noncash interest expense	107	107
Changes in operating assets and liabilities		
Accounts receivable	(1,593)	(633)
Inventory	61	(611)
Prepaid expenses and other assets	(199)	1,119
Accounts payable	327	30
Accrued and other current liabilities	1,145	696
Deferred rent	(59)	121
Net cash used in operating activities	(28,011)	(23,891)
Cash flows from investing activities		
Purchases of property and equipment	(884)	(3,181)
Change in restricted cash	—	35
Net cash used in investing activities	(884)	(3,146)
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	—	47,219
Proceeds from secondary offering, net of issuance costs	29,653	
Proceeds from issuance of long-term debt -related party, net of issuance costs	—	5,000
Proceeds from issuance of common stock upon exercise of stock options	655	36
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	22,769
Net cash provided by financing activities	30,308	75,024
Net increase in cash and cash equivalents	1,413	47,987
Cash and cash equivalents, beginning of period	46,296	6,048
Cash and cash equivalents, end of period	$ 47,709	$ 54,035
Supplemental disclosures of cash flow information		

Interest paid to related party	$ 1,406	$ 1,271
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 138	$ 12
Secondary offering issuance costs in accounts payable	$ 429	$ —
Reclassification of convertible preferred stock warrant liability to additional paid-in capital upon conversion of convertible preferred stock into common stock and additional paid-in capital	$ —	$ 96,524

See accompanying notes to unaudited condensed financial statements.

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NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Description of Business

Invuity, Inc. (the "Company") was incorporated in California on November 29, 2004 and reincorporated in Delaware in May 2015. The Company is a commercial-stage medical technology company that 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 manufacturing, development and management facilities are located in San Francisco, California.

Liquidity

The Company has incurred net losses from operations since inception and has an accumulated deficit of $136.7 million as of September 30, 2016. The Company expects to incur additional losses and negative cash flows for the foreseeable future. Management believes that its cash and cash equivalents at September 30, 2016 and additional borrowings available under its accounts receivable credit facility entered into in February 2015 will provide sufficient funds to enable the Company to meet its operating plan through at least the next twelve months. On July 1, 2016, the Company also filed a prospectus supplement for an at-the-market offering ("ATM Offering") of up to $25,000,000. However, if the Company's anticipated operating results are not achieved in future periods, additional debt or equity financing may need to be raised, or planned expenditures may need to be reduced.

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 of the financial position, results of operations and cash flows for the periods presented. 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 annual report for the year ended December 31, 2015 and filed with the U.S. Securities and Exchange Commission (the "SEC"). The accompanying year-end balance sheet was derived from the audited financial statements included in the annual report. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

Out-of-Period Adjustments

In the nine-months ended September 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

nine months ended September 30, 2015 and a corresponding decrease to accounts receivable. The distributor returned the underlying inventory, and the Company terminated the relationship with the distributor involved, and started working with a new distributor for military accounts.

In addition, during the nine months ended September 30, 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 nine months ended September 30, 2015 and a corresponding increase to the convertible preferred stock warrant liability.

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Management assessed the impact of these adjustments and did not believe the amounts were material to any prior period financial statements, and the impact of correcting these errors in the nine months ended September 30, 2015 was not material to those financial statements and were not expected to be material to the financial statements for the year ended December 31, 2015. As a result, the Company did not restate any prior period amounts.

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 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 a letter of credit related to the Company's facility lease in San Francisco, California.

Fair Value of Financial Instruments

The 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 September 30, 2016 and December 31, 2015, based on Level 2 inputs and the borrowing rates available to the Company for loans with similar terms and consideration of the Company's credit risk, the carrying value of the Company's long-term debt approximates its fair value.

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. As of and for the three and nine months ended September 30, 2016 and 2015, the Company had no customers that represented 10% or more of its revenue or accounts receivable balances.

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 remeasurement 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 initial public offering ("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.

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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.

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) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017.

In March 2016 the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net), to clarify certain aspects of the principal-versus-agent guidance in its new revenue recognition standard.

In April 2016 the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing to clarify on how to identify the performance obligations and the licensing implementation guidance in its new revenue recognition standard.

In May 2016 the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, to address certain issues identified by the TRG in

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the guidance on assessing collectability, presentation of sales tax, noncash consideration, and completed contracts and contracts modifications at transition.

The Company is in the process of determining the potential effects of this new guidance on its financial statements.

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

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern. The new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for the annual period ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. The Company is in the process of evaluating the impact of the adoption of this new guidance on its financial statements.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company is in the process of evaluating the impact of the adoption of this new guidance on its financial statements.

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

In March 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual periods beginning after December 15, 2016. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

In June 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-13, Measurement of Credit Losses on Financial Statements. This update provides financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The update replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for public entities for annual periods beginning after December 15, 2019. The Company is in the process of evaluating the impact of this new guidance on

its financial statements.

· In August 2016 the FASB issued Accounting Standards Update (ASU) No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the FASB

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Emerging Issues Task Force). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. This update addresses the following eight specific cash flow issues: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (COLIs) (including bank-owned life insurance policies (BOLIs)); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. ASU 2016-15 is effective for public entities for annual periods beginning after December 15, 2017. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

3. Fair Value Measurements

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

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

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

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

The Company's financial instruments consist of Level 1 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. Upon completion of the Company's 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.

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):

	September 30, 2016			
	Level 1	Level 2	Level 3	Total

Assets				
Money market funds	$ 46,832	$ —	$ —	$ 46,832
	$ 46,832	$ —	$ —	$ 46,832

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

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 was measured on a recurring basis until the Company's IPO in June 2015 (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Beginning balance	$ —	$ 136
Issuance of convertible preferred stock warrants	—	—
Change in fair value recorded in interest and other income (expense), net	—	472
Reclassification from liability to additional paid-in capital upon conversion to common stock warrants at the IPO	—	(608)
Ending balance	$ —	$ —

4. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$ 734	$ 1,000
Work-in-process	1,075	798
Finished goods	3,311	3,384
Total inventory	$ 5,120	$ 5,182

Property and Equipment, Net

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

	September 30, 2016	December 31, 2015
Computer equipment and software	$ 1,307	$ 1,341
Laboratory and manufacturing equipment	2,169	1,544
Furniture and fixtures	1,460	1,445
Leasehold improvements	7,212	7,106
Total property and equipment, gross	12,148	11,436
Less: accumulated depreciation and amortization	(3,610)	(2,241)
Total property and equipment, net	$ 8,538	$ 9,195

Depreciation and amortization expense was $0.5 million and $0.4 million for the three months ended September 30, 2016 and 2015, respectively and was $1.5 million and $1.3 million for the nine months ended September 30, 2016 and 2015, respectively.

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Accrued and Other Current Liabilities

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

	September 30, 2016	December 31, 2015
Accrued payroll-related expenses	$ 4,213	$ 3,052
Accrued independent sales agent commissions	163	158
Accrued professional fees	197	373
Accrued sales and marketing expenses	24	45
Deferred rent	261	261
Other	425	325
Total accrued and other current liabilities	$ 5,283	$ 4,214

5. Secondary Offering

On July 1, 2016, the Company filed a shelf registration statement on Form S-3 (Registration No. 333-212395) with the SEC to offer for sale up to an aggregate of $100,000,000 of common stock, preferred stock, depositary shares, warrants and/or units in one or more offerings and in any combinations. On that date, the Company also filed a prospectus supplement for an ATM Offering of up to $25,000,000. On August 2, 2016, the Company completed a secondary offering of 3,220,000 shares of its common stock at a price to the public of $10.00 per share, which included the exercise in full by the underwriters of their option to purchase an additional 420,000 shares of its common stock. The total net proceeds from this offering were $29.7 million, after deducting underwriting discounts and commissions and offering expenses of $0.6 million payable by the Company.

6. Stock Option Plans

In April 2015, the Company's board of directors and stockholders approved the 2015 Equity Incentive plan (the "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.

During the three and nine-months ended September 30, 2016, the Company granted to employees 21,400 and 756,950 options with a weighted average grant date fair value of $11.59 per share and $7.49 per share, respectively. In addition, the Company granted in May 2016, 144,500 options to the Board with a weighted average grant date fair value of $4.87 per share. There were 190,854 and 633,198 options granted to employees during the three and nine

months ended September 30, 2015, with a weighted average grant date fair value of $13.11 per share and $12.50 per share, respectively. For the three and nine-months ended September 30, 2015, the Company granted 16,121 and 75,291 options to the Board with a weighted average grant date fair value of $11.09 per share and $13.93 per share, respectively. The aggregate intrinsic value of options exercised was $0 and $0.5 million for the three and nine months ended September 30, 2016, and $11,000 and $71,000 for the three and nine months ended September 30, 2015, respectively.

The weighted-average remaining contractual life of options outstanding was 7.7 and 7.8 years at September 30, 2016 and December 31, 2015, respectively. For vested and expected to vest options, the weighted-average remaining contractual life was 7.7 years as of both September 30, 2016 and December 31, 2015.

In addition to options, the Company also granted restricted stock units (“RSUs”) including 10,000 RSUs to a consultant with an aggregate grant date fair value of $110,000 during the three months ended September 30, 2016. For the nine months ended September 30, 2016, the Company granted a total of 217,000 RSUs with an aggregate grant date fair value of $1.5 million. The RSUs have a range of vesting terms from a minimum of one month to a maximum of five years.

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Stock Based Compensation

The fair value of stock options granted to employees is amortized on a straight-line basis over the requisite service period of the award. Stock based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The Company recognized total employee –related stock compensation expense of $0.5 million and $1.6 million for the three months and nine months ended September 30, 2016, and $0.3 million and $0.8 million for the three months and nine months ended September 30, 2015, respectively. In addition, the Company recognized non-employee stock-based compensation expense of $46,000 and $88,000 for the three and nine months ended September 30, 2016, respectively, and $30,000 and $104,000 for the corresponding three month and nine month periods ended September 30, 2015, respectively.

The following table summarizes stock based compensation expense related to stock options and restricted stock units for the three months ended September 30, 2016 and 2015 included in the condensed statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of goods sold	$ 37	$ 25	$ 95	$ 66
Research and development	107	76	315	223
Selling, general and administrative	425	257	1,306	630
Total stock-based compensation expense	$ 569	$ 358	$ 1,716	$ 919

As of September 30, 2016, unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $4.6 million, which the Company expects to recognize on a straight line basis over a weighted average period of 3.4 years. Unrecognized compensation expense related to unvested RSUs, net of estimated forfeitures, was $0.7 million, which the Company expects to recognize on a straight line basis over a weighted average period of 4.4 years

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7. Net Loss per Common Share

As the Company generated net losses for all the periods presented, all potentially dilutive common securities are 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	$ (8,821)	$ (9,138)	$ (31,060)	$ (27,516)
Denominator:				
Weighted-average common shares outstanding	15,695,193	13,305,057	14,176,655	5,699,512
Less: weighted-average unvested common shares subject to repurchase	(4,408)	(12,208)	(3,121)	(14,757)
Weighted-average shares used to compute net loss per common share, basic and diluted	15,690,785	13,292,849	14,173,534	5,684,755
Net loss per common share, basic and diluted	$ (0.56)	$ (0.69)	$ (2.19)	$ (4.84)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per share for the three and nine months ended September 30, 2016 and 2015 because their inclusion would be anti dilutive:

	September 30,	
	2016	2015
Options to purchase common stock	2,453,373	2,018,739
Warrants to purchase common stock	137,007	137,007
Restricted Stock Units	127,000	—
Total	2,717,380	2,155,746

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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 Annual Report on Form 10-K for the period ended December 31, 2015. 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.

We also use our investor relations website as a channel of distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on our investor relations website. Information on or that can be accessed through our websites is not part of this Annual Report on Form 10-K.

Overview

We are a commercial-stage medical technology company pioneering the use of advanced photonics to provide surgeons with improved direct visualization of surgical cavities during minimally invasive and minimal access surgical procedures. We integrate our Intelligent Photonics technology platform into our single-use and reusable advanced surgical devices to address some of the critical intracavity illumination and visualization challenges facing surgeons today. We utilize our proprietary advanced photonics technology to develop optical waveguides that direct and shape thermally cool, brilliant light into broad, uniform and volumetric illumination of the surgical target. We believe that improving a surgeon's ability to see critical anatomical structures can lead to better clinical and aesthetic outcomes, improved patient safety and reduced surgical time and healthcare costs. Based on the number of single-use units we have shipped as of September 30, 2016, we estimate that our devices have been used in approximately 212,000 surgical procedures.

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

We currently sell our devices in the United States, primarily through a direct sales force. We had 65 direct sales representatives as of September 30, 2016, 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 advanced photonics technology platform to surgeons. Although our sales and marketing efforts are directed at surgeons because they are the primary users of our technology, the hospitals where surgical procedures are performed are our customers, as they typically are responsible for making the decisions to purchase our devices. Our currently marketed devices are commonly treated as general supplies utilized in surgery. As a result, the hospital or surgical center receives a single reimbursement from the third-party payor that is intended to cover the overall cost of treatment, including the cost of

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

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

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assembly or inspection, and certification. Finished products are stored at and distributed from our facility. We believe our facility is sufficient to support our operations and that suitable facilities would be available to us should our operations require it.

Components of Our Results of Operations

Revenue

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

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

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

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

Cost of Goods Sold and Gross Margin

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

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

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

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

Selling, General and Administrative Expenses

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

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

Interest Expense

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

Interest and Other Income (Expense), Net

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

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Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2016 and 2015

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Revenue				
Single use devices	$ 6,421	$ 4,074	$ 17,221	$ 10,528
Reusable retractors	1,398	875	4,001	2,482
Sales to 3rd party medical device manufacturers	369	306	1,078	1,035
Accessories	290	340	805	739
Total revenue	8,478	5,595	23,105	14,784
Cost of Revenue	2,219	2,035	6,416	5,605
Gross Profit	$ 6,259	$ 3,560	$ 16,689	$ 9,179
Gross Margin	73.8 %	63.6 %	72.2 %	62.1 %

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

Revenue increased $2.9 million, or 52%, to $8.5 million during the three months ended September 30, 2016, compared to $5.6 million during the three months ended September 30, 2015. Revenue for the nine months ended September 30, 2016 increased $8.3 million, or 56%, to $23.1 million compared to $14.8 million during the prior year period. The growth in revenue for both comparable periods was attributable to an increase in unit sales as a result of selling our products to new customers and also selling more units to existing customers. These increases were driven by the expansion of our direct sales force and the success of our marketing programs, notably our Hidden Scar for Breast Cancer Surgery. The number of our direct sales representatives increased from 52 as of September 30, 2015 to 65 as of September 30, 2016 and the number of customers ordering our devices increased from approximately 465 in the third quarter of 2015 to approximately 700 in the third quarter of 2016.

Cost of goods sold increased $0.1 million, or 9%, to $2.2 million during the three months ended September 30, 2016, compared to $2.0 million during the same period in 2015. Cost of goods sold for the nine months ended September 30, 2016 increased $0.8 million, or 14%, to $6.4 million compared to $5.6 million in the prior year period. 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 and was offset by increased efficiencies and reduced costs of manufacturing related to increased volumes of production.

Gross margin for the three months and nine months ended September 30, 2016 was 74% and 72% compared to 64% and 62% for the comparable periods in September 30, 2015. The increase in gross margin is primarily attributable to economies of scale as we manufacture larger quantities of product and therefore allocate a smaller portion of our overhead expenses to each product and due to the introduction of our Eikon LT retractor series at the beginning of 2016 which is quickly displacing its predecessor, the Eikon retractor series. The Eikon LT series is made from a non-conductive reinforced polymer which eliminates the risk of burns due to arcing from electrosurgical devices and is lighter in weight and has a lower material cost compared to our Eikon retractor and now represents 86% of Eikon sales.

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Operating Expenses

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016		2015		2016		2015	
	Amount (In thousands)	% of Revenue	Amount (In thousands)	% of Revenue	Amount (In thousands)	% of Revenue	Amount (In thousands)	% of Revenue
Operating Expenses								
Research and development	$ 2,471	29 %	$ 2,042	36 %	$ 7,412	32 %	$ 5,799	39 %
Selling general and administrative	12,134	143	10,180	182	38,885	168	29,020	196
Total operating expenses	$ 14,605	172 %	$ 12,222	218 %	$ 46,297	200 %	$ 34,819	235 %

Research and development expenses: expenses increased just over $0.4 million, or 21%, to $2.5 million during the quarter ended September 30, 2016, compared to $2.0 million during the quarter ended September 30, 2015. The increase in expenses was primarily attributable to an increase in personnel and consultant related costs of $0.5 million due to our expanding headcount. Research and development expenses increased $1.6 million, or 28%, to $7.4 million during the nine months ended September 30, 2016, compared to $5.8 million during the comparable period ended September 30, 2015. This increase in expenses was primarily attributable to an increase in personnel and consultant related costs of $1.5 million due to our expanding headcount plus an increase of $0.4 million relating to R&D activities for our next generation products, offset by $0.3 million in R&D manufacturing and various other allocations.

Selling, general and administrative expenses: expenses increased approximately $2.0 million, or 28%, to $12.1 million during the quarter ended September 30, 2016, compared to $10.2 million during the quarter ended September 30, 2015. The increase in expenses was primarily attributable to a $1.6 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 $0.4 million reserve against Eikon retractor trunk stock, and a $0.2 million increase in travel and entertainment, offset by a $0.8 million decrease in consulting and professional service fees. Selling, general and administrative expenses increased approximately $9.9 million, or 34%, to $38.9 million during the nine months ended September 30, 2016, compared to $29.0 million during the comparable period ended September 30, 2015. The year over year increase in expenses was primarily attributable to a $6.8 million increase in personnel-related expenses, excluding sales commissions, as a result of increased headcount, a $2.3 million increase in commissions to direct sales representatives, a $1.0 million increase in sales and marketing travel and entertainment expenses, and a $0.8 million reserve against Eikon retractor trunk stock, offset by a decrease of approximately $1.2 million in consulting, professional service fees, and various other allocations.

Interest expense, interest, and other income (expense):

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016		2015		2016		2015	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(In thousands)		(In thousands)		(In thousands)		(In thousands)	
Interest expense	$ (505)	(6) %	$ (504)	(9) %	$ (1,514)	(7) %	$ (1,377)	(9) %
Interest and other income (expense), net	30	0	28	1	61	0	(499)	(3)
Total	$ (475)	(6) %	$ (476)	(9) %	$ (1,453)	(6) %	$ (1,876)	(13) %

Interest expense remained constant during the quarter ended September 30, 2016, compared to the quarter ended September 30, 2015 and increased $0.1 million for the nine months ended September 30, 2016 compared to the prior period in 2015. In February 2015, we drew down the remaining $5.0 million from our loan with HealthCare Royalty Partners, or HCRP which resulted in the increase in interest expense year over year.

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Interest and other income (expense), net remained constant during the quarter ended September 30, 2016, compared to the quarter ended September 30, 2015 and changed by $0.6 million to income of $61,000 for the nine months ended September 30, 2016 from net expense of $0.5 million for the prior period. The change in interest and other income (expense), net was primarily related to the fair value re-measurement of the liability related to our outstanding convertible preferred stock warrants prior to our initial public offering ("IPO") in 2015. Upon completion of our IPO, the convertible preferred stock warrants were converted into common stock warrants and no further re-measurement of the liability was required.

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 nine months ended September 30, 2016, 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 Annual Report filed on Form 10-K filed with the SEC on March 25, 2016.

Liquidity and Capital Resources

As of September 30, 2016, our primary sources of liquidity were our cash and cash equivalents totaling $47.7 million and an accounts receivable credit facility with Silicon Valley Bank 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. On July 1, 2016, we also filed a prospectus supplement for an at-the-market offering ("ATM Offering") of up to $25,000,000.

As of September 30, 2016, we had an accumulated deficit of $136.7 million. We have financed our operations primarily through sales of our equity securities, debt financings and the sale of our devices.

Cash Flows

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

	Nine Months Ended September 30,	
(in thousands)	2016	2015
Net cash (used in) provided by:		
Operating activities	$ (28,011)	$ (23,891)
Investing activities	(884)	(3,146)
Financing activities	30,308	75,024
Net increase in cash and cash equivalents	$ 1,413	$ 47,987

During the nine months ended September 30, 2016, net cash used in operating activities was $28.0 million, which consisted of a net loss of $31.0 million adjusted by non-cash charges of $3.4 million and a net change of $0.3 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of stock-based compensation of $1.7 million, depreciation and amortization of $1.5 million, non-cash interest expense of $0.1 million and a provision for bad debt of $0.1 million. The decrease in our net operating assets and liabilities was primarily due to a $1.6 million increase in our accounts receivable balance related to increased customer sales and a $0.2 million decrease in prepaids and other assets as a portion of these assets were offset against the proceeds from our secondary offering in August 2016. These decreases in cash flows were partially offset by a $1.4 million increase in accrued liabilities and accounts payable as a result of our increase in operations and related growth in headcount.

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During the nine months ended September 30, 2015, net cash used in operating activities was $23.9 million, which consisted of a net loss of $27.5 million, adjusted by non-cash charges of $2.9 million and a net change of $0.7 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of stock-based compensation of $0.9 million, depreciation and amortization of $1.3 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 $1.1 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 $0.4 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 $0.6 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 nine months ended September 30, 2016, net cash used in investing activities was $0.9 million, which consisted of capital expenditures to purchase property and equipment in connection with our expanding operations.

During the nine months ended September 30, 2015, net cash used in investing activities was $3.1 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 nine months ended September 30, 2016, cash provided by financing activities was $30.3 million, which consisted of net cash proceeds of $29.7 million from a secondary offering completed on August 2, 2016 and $0.7 million from cash proceeds from the issuance of common stock upon the exercise of vested stock options.

During the nine months ended September 30, 2015, net cash provided by financing activities was $75.0 million, consisting of net cash proceeds of $47.2 million from the issuance of common stock from our IPO, $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.

We believe that our existing cash and cash equivalents as of September 30, 2016, and future borrowings available under our accounts receivable credit facility will be sufficient to meet our anticipated cash requirements for at least the next twelve months. Our expected future capital requirements may depend on many factors including customer sales, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our product portfolio. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary to relinquish some rights to our technologies or our devices, or grant licenses on terms that are not favorable to us.

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

Off-Balance Sheet Arrangements

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

Contractual Obligations

During the three and nine months ended September 30, 2016, 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 annual report dated December 31, 2015 filed with the SEC.

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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 $47.7 million and $46.3 million as of September 30, 2016 and December 31, 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 September 30, 2016 and December 31, 2015, we had total outstanding net debt of $14.6 million and $14.5 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 effective.

Changes in Internal Control Over Financial Reporting

There were no 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.

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

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 continue to incur losses in the future. If we do not achieve and sustain profitability, our financial condition and stock price could suffer.

We have experienced significant operating losses, and we expect to continue to incur operating losses for the next several years as we implement additional initiatives designed to grow our business, including, among other things, increasing sales and developing new devices. We incurred net losses of $37.6 million and $20.7 million for the years ended December 31, 2015 and 2014, respectively and net losses of $31.0 million and $27.6 million for the nine months ended September 30, 2016 and September 30, 2015, respectively. As of September 30, 2016, our accumulated deficit was $136.7 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital. To date, we have financed our operations primarily through the sale of equity securities, certain debt-related financing arrangements and from sales of our approved devices. We have devoted substantially all of our resources to research and development of our devices, sales and marketing activities and certain clinical and quality assurance initiatives. Our ability to generate sufficient revenue from our existing devices or from any of our device candidates in development, and to transition to profitability and generate consistent positive cash flows, is uncertain. We will need to generate significant sales to achieve profitability, and we might not be able to do so. If our revenue grows more slowly than we anticipate, or if our operating expenses are higher than we expect, we may not be able to achieve profitability as anticipated, or ever, our financial condition will suffer and our stock price could decline. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

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

We have focused heavily on the development and commercialization of devices using our Intelligent Photonics technology platform for the illumination of certain open minimally invasive and minimal access surgeries. For the nine months ended September 30, 2016 and the years ended December 31, 2015 and 2014, our revenues of $23.1 million, $21.0 million, and $13.1 million, respectively, were derived entirely from sales of devices incorporating our Intelligent Photonics technology. Because we expect our revenue to be derived entirely from sales of these devices for the foreseeable future, our ability to execute our growth strategy and become profitable will depend not only upon an increase in the number of hospitals using our devices, but also an increase in the number of specialties using our

devices within those hospitals in which our devices are utilized. If our advanced photonics technology, and the devices that incorporate it, fail to achieve and maintain wide market acceptance for any reason, our business may be adversely affected, as we will be severely constrained in our ability to fund our operations and develop and commercialize improvements to existing and new product lines.

We plan to introduce our PhotonBlade™ device in 2017 and there can be no assurance on the timing of introduction, level of market acceptance or revenue generated by this product.

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We recently announced that we have received FDA 510(k) clearance for PhotonBlade, a new device that integrates our Intelligent Photonics technology into an advanced energy device used for cutting and coagulation of soft-tissue during surgical procedures. We are currently in the process of establishing commercial production through third-party manufacturers and will begin early marketing activities through physician education programs. We have announced that we plan to initiate a limited launch of the PhotonBlade device in the first half of 2017 and incorporate feedback from initial users with a goal of launching the product more broadly in the middle of 2017. We cannot be assured that the products will be available from third-party manufacturers on the timeline we anticipate and that we will be able to establish long-term supply arrangements on pricing terms favorable to us. Additionally, we cannot be assured that PhotonBlade devices will achieve market acceptance. We will be required to devote significant resources to the launch and marketing of PhotonBlade devices and cannot be assured that these activities will generate revenue as anticipated. If we fail to generate revenue from PhotonBlade devices, or if that revenue grows more slowly than we expect, our business and financials will be adversely affected.

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

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

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

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

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

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

As we launch new devices and increase our current marketing efforts with respect to existing devices and expand into new geographies, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales personnel with significant technical knowledge of our devices. We have made, and intend to continue to

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

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

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

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

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

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

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

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

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

- surgeon and hospital acceptance of our devices;
- the productivity of our sales representatives;
- the introduction of new devices and technologies or acquisitions by us or our competitors;
- fluctuations in our expenses associated with expanding our operations and operating as a public company;
- the timing, expense and results of research and development activities and obtaining future regulatory clearances and approvals;
- supplier, manufacturing or quality problems with our devices; and
- changes in our pricing policies or in the pricing policies of our competitors or suppliers.

Additionally, we may experience seasonal variations in revenue. For example, our revenue tends to be the lowest in the first quarter as the result of the resetting of annual patient healthcare insurance plan deductibles and by hospitals and military facilities working off their inventories of products purchased in the fourth quarter. Revenue in the third quarter can be impacted by summer vacation season. 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. 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 nine months ended September 30, 2016 or for the year ended December 31, 2015. However, the loss of any of our key customers for any reason, or a change in our relationship with any of our key customers may cause a significant decrease in our total revenue.

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

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

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

In addition, we rely on single- and limited-source suppliers for several of our components and sub-assemblies. For example, the optical molding for our waveguides is provided by one supplier. These components are critical to our devices and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of these components or sub-assemblies used in our devices could involve significant time and cost.

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

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

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

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costs required to replace such inventory. For example, we introduced our Eikon LT retractor series at the beginning of 2016 which is quickly displacing its predecessor the Eikon Classic retractor series. The Eikon LT now represents more than 86% of Eikon sales and, as a result, we recorded reserves against inventory on hand to fill orders and trunk stock inventory held by our sales representatives for the Eikon Classic retractor series in the nine months ended September 30, 2016. We may need to write off inventory for other reasons as well.

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

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

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

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

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

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

provide adequate training to potential users of our devices; and

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

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

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

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

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

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

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

We believe that our continued success depends to a significant extent upon the efforts and abilities of our executive officers and other key personnel. Our executive officers and other key personnel are critical to the strategic direction and overall management of our company as well as our research and development process. All of our executive officers and other employees are at-will employees and, therefore, may terminate employment with us at any time with no advance notice. The loss of any of our executive officers and other key personnel could adversely affect our business, financial condition and operating results. Our former Chief Financial Officer, Michael Gandy, resigned effective August 21, 2015 and our new Chief Financial Officer, James Mackaness, began his service with us on August 24, 2015. Our Chief Business Officer and General Counsel, Brett Robertson, resigned effective March 31, 2016 and our VP of Marketing, Susan Martin, resigned effective April 19, 2016. 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.

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

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

We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. For example, we increased the number of employees from 102 at December 31, 2014 to 163 at September 30, 2016. We intend to continue to grow and may experience periods of rapid growth and expansion. Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems and other operational infrastructure. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. To achieve our revenue goals, we must continue to hire, train, retain and motivate skilled personnel.

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

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

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

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

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

In the first quarter of 2015, we transitioned all of our internal manufacturing, development and management activities to a new single location in San Francisco, California. Our facility and equipment would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire, vandalism and power outages, which

may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. While we have taken precautions to safeguard our facilities, including through insurance and health and safety protocols, the inability to perform those activities may result in the inability to continue manufacturing our devices during such periods and the loss of customers or harm to our reputation. We also possess insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

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

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

The sale and shipment of our devices across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act and anti-boycott laws, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

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

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

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

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

laws and business practices favoring local companies;

longer payment cycles;

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- foreign currency exchange rate fluctuations;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

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

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

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

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

We may in the future seek to acquire or invest in companies or technologies that we believe could complement or expand our platform, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets, be successful in entering into an agreement with any particular target, or obtain the expected benefits of any acquisition or investment.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

We also own trade secrets and confidential information that we try to protect by entering into invention assignment and confidentiality agreements with our employees and other parties. However, these agreements may not be honored or, if breached, we may not have sufficient remedies to protect our confidential or proprietary information. Further, our competitors may independently learn our trade secrets and develop similar or superior technologies. To the extent that our consultants, key employees or others apply technological information to our projects that they develop independently or others develop, disputes may arise regarding the ownership of proprietary rights to such information, and such disputes may not be resolved in our favor. If we are unable to protect our intellectual property adequately, our business and commercial prospects will suffer.

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

Our success depends, in part, on not infringing the patents or violating the proprietary rights of others. Significant litigation regarding patent rights occurs in the medical device industry. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our devices. Our competitors in both the

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

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

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

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

In addition, we may be required to indemnify our customers, distributors and OEM partners with respect to infringement by our devices of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors which may require us to initiate or defend protracted and costly litigation on

behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the devices they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our devices.

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Risks Related to Our Capital Structure

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

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we seek to continue to grow our business and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization efforts and our efforts to develop new technologies for surgical illumination and visualization, as well as technology complementary to our current devices. Our existing resources may not allow us to conduct all of these activities that we believe would be beneficial for our future growth. As a result, we may need to seek funds in the future and, if we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the nine months ended September 30, 2016, our net cash used in operating activities was $28.0 million, and was $31.2 million for the year ended December 31, 2015. As of September 30, 2016, we had working capital of $49.7 million, which included $47.7 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. In July 2016, in order to facilitate the raising of additional funds, we filed a shelf registration statement on Form S-3 (Registration No. 333-212395) that allows us to sell up to an aggregate of $100,000,000 of our common stock, preferred stock, warrants, depository shares and/or units. In July 2016, we also filed a prospectus supplement for an ATM Offering of up to $25,000,000. In August 2016, we sold 3,220,000 shares in a secondary offering pursuant to this shelf registration and a prospectus supplement. 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.

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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 September 30, 2016, we owed an aggregate principal amount of $15.0 million to HealthCare Royalty Partners, a holder of more than 5% of our capital stock, pursuant to a term loan agreement, which we refer to as the HCRP loan agreement.

In addition, in February 2015, we entered into a $7.5 million loan and security agreement with Silicon Valley Bank, which we refer to as the SVB credit facility. SVB has a first priority security in our cash and cash equivalents, accounts receivable and inventory, and HCRP has a second priority security in these assets and a first priority interest in our remaining assets. As of September 30, 2016, we had not drawn down on the SVB credit facility. Pursuant to the terms of the SVB credit facility, we can borrow up to 80% of certain qualified accounts receivables at a per annum interest rate equal to the prime rate as published by the Wall Street Journal, plus 75 basis points. In addition, the credit facility states that if we maintain a net cash balance, defined as unrestricted cash held with SVB less any borrowings on the revolving line of credit, of more than $3.0 million, then all collections will be deposited in our operating account. If the net cash balance is below $3.0 million, then all collections will be held in an SVB-controlled account and applied to reduce the loan balance.

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

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

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

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

As of December 31, 2015, we had net operating loss, or NOL, carryforwards for federal and state income tax purposes of approximately $95.2 million and $61.0 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in the future, our ability to utilize NOLs could be further limited by Section 382. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Section 382. Furthermore, we may be unable to use a substantial

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part of our NOLs if we do not attain profitability in an amount sufficient to offset such losses. Any limitation on using NOLs could result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income and state tax reporting purposes, which could materially and adversely affect our results of operations.

Risks Related to Government Regulation

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

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

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

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

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

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

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

- device design, development and manufacture;

- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;

premarketing clearance and approval;

record keeping;

device marketing, promotion and advertising, sales and distribution; and

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post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

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

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations, or MDRs, that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and sales of our devices may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. MDRs for our devices have been filed including: one report in 2014 relating to tissue irritation; two reports in 2015, one for device breakage and one for melting of our waveguide due to a fiber optic cable malfunction and nine reports in the first nine months of 2016. Of the nine MDRs in the first half of 2016, one was filed by Invuity and eight were filed by an OEM partner. All nine MDRs related to device breakage. The eight MDRs filed by the OEM partner related to four events, all of which we believe were caused by user error. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. The only Correction and Removal report that we have submitted to the FDA is in connection with the discontinued reusable aspiration device that we voluntarily recalled in 2012.

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

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

adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our devices;

operating restrictions, partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;

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withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

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

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

Surgeons may misuse our devices or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

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

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

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

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

harm our reputation with customers, and reduce our ability to achieve expected revenues.

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

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make

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

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We passed the most recent audit by the Food and Drug Branch of CDHS in February 2015, and the inspection revealed no minor or major issues. We were also subject to an FDA inspection in

April 2016 resulting in two observations, and the FDA has confirmed it will evaluate our corrective actions during its next inspection. However, we cannot assure you that we will pass future inspections or audits by the FDA or other regulatory bodies or that the FDA will consider the observations it previously identified to be closed out.

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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 Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “whistleblowers”, may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim;

the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value” to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for “knowing failures”) for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;

the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a

person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery

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provisions contained in the German Criminal Code, which, pursuant to draft legislation being prepared by the German government, may make the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and

analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with surgeons and other healthcare providers, some of whom receive stock or stock options as compensation for their services and/or recommend, purchase and/or use 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, sell certain of our devices outside of the United States and have already obtained the necessary regulatory approvals to sell certain of our devices outside of the United States. Sales of our devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates the exports of medical devices from the United States. Complying with international regulatory requirements can be an expensive and a time-consuming process and clearance or approval is not certain. The time required to obtain clearances or approvals, if required by other countries, may be longer than that required for FDA clearances or approvals, and requirements for

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States. On December 18, 2015, the President signed into law the Protecting Americans from Tax Hikes Act of 2015, which retroactively extends several expired tax provisions. Among the extended provisions is the Section 41 research credit for qualified research expenditures incurred through the end of 2015.

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 2025 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;

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

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

lawsuits threatened or filed against us;

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

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

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

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

changes in market valuation or earnings of our competitors;

the trading volume of our common stock;

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

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

developments in our industry.

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

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

Sales of a substantial amount of common stock in the public market, or the perception that these sales may occur, could adversely affect the market price of our common stock. As of September 30, 2016, we have 16,905,103 shares of common stock outstanding. This includes the 4,600,000 shares of our common stock we sold in our IPO in June 2015 and 3,220,000 shares of our common stock we sold in a secondary offering in August 2016, which may be resold in the public market immediately. In July 2016, in order to facilitate the raising of additional funds, we filed a shelf registration statement on Form S-3 (Registration No. 333-212395) that allows us to sell up to an aggregate of $100,000,000 of our common stock, preferred stock, warrants, depository shares and/or units. The shares we sold in a secondary offering in August 2016 were sold pursuant to this shelf registration and a prospectus supplement. In July 2016, we also filed a prospectus supplement for an ATM Offering of up to $25,000,000.

A significant portion of the holders of our common stock and warrants have the right, subject to some conditions, to require us to file registration statements under the Securities Act of 1933, as amended or the Securities Act covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders pursuant to a stockholders agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired. These registration rights terminate in June 2022.

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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 September 30, 2016, our directors and executive officers and stockholders holding more than 5% of our capital stock, and their affiliates, own a substantial majority of our outstanding common stock. To the extent our existing stockholders purchase additional shares, this ownership concentration would increase. As a result, if these stockholders were to choose to act together, they would be able to control the management and affairs of our company and most matters and exercise significant influence over most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or our assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

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

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

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

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

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

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

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

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

Maintaining effective internal control over financial reporting is necessary for us to produce reliable financial statements. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for fiscal 2016, provide a management report on the internal control over financial reporting.

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

We are an “emerging growth company” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company” as defined under the federal securities laws. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are

applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile or decline.

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We could be an emerging growth company until as late as December 31, 2020, although circumstances could cause us to lose that status at the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates is at least $700 million as of the last business day of our most recently completed second fiscal quarter , (ii) the end of the fiscal year in which we have total annual gross revenues of $1.0 billion or more during such fiscal year, or (iii) the date on which we issue more than $1.0 billion in non-convertible debt in a three-year period.

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

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

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

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

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

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

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

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, we are governed by the

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provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

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

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

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

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

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

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

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

On July 1, 2016, we filed a shelf registration statement on Form S-3 (Registration No. 333-212395) that allowed us to sell up to an aggregate of $100,000,000 of our common stock, preferred stock, warrants, depository shares and/or

units. In August 2016, we sold 3,220,000 shares of our common stock in a secondary offering pursuant to this shelf registration statement and prospectus supplement. We received net proceeds from this secondary offering of $29.7 million after deducting costs of approximately $0.6 million.

We continue to use the proceeds from the IPO and the secondary offering to: expand our sales and marketing activities, including our Hidden Scar™ marketing program; launch new products such as the Eikon LT; expand research and development efforts; and for working capital and general corporate purposes.

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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.

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: November 3, 2016 By: /s/ Philip Sawyer
Philip Sawyer
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2016 By: /s/ James Mackaness
James Mackaness
Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
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 being furnished and not filed with the SEC 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.