

Invuity, Inc.  
Form 10-Q  
August 03, 2018  
Table of Contents

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 June 30, 2018

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      (I.R.S. Employer  
other  
jurisdiction of Identification No.)

incorporation  
or  
organization)

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 July 31, 2018 was 24,073,678.

---

Table of Contents

TABLE OF CONTENTS

	Page No.
<u>PART I Financial Information</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	1
<u>Condensed Balance Sheets</u>	1
<u>Condensed Statements of Operations and Comprehensive Loss</u>	2
<u>Condensed Statements of Cash Flows</u>	3
<u>Notes to Condensed Financial Statements</u>	4
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Qualitative and Quantitative Disclosures About Market Risk</u>	22
<u>Item 4. Controls and Procedures</u>	23
<u>PART II Other Information</u>	
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	52
<u>Item 3. Defaults Upon Senior Securities</u>	52
<u>Item 4. Mine Safety Disclosures</u>	52
<u>Item 5. Other Information</u>	52
<u>Item 6. Exhibits</u>	54
<u>SIGNATURES</u>	55

Table of Contents

## PART I—Financial Information

## ITEM 1. Financial Statements.

## INVUITY, INC.

## Condensed Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,327	\$ 17,962
Short-term investments	8,602	3,040
Restricted cash - current	181	181
Accounts receivable, net	6,668	7,421
Inventory, net	8,534	7,436
Prepaid expenses and other current assets	1,621	1,274
Total current assets	40,933	37,314
Restricted cash	727	727
Property and equipment, net	6,868	7,169
Other long-term assets	201	285
Total assets	\$ 48,729	\$ 45,495
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,502	\$ 3,598
Accrued and other current liabilities	5,629	5,179
Deferred revenue - short term	54	—
Long-term debt, current portion	4,615	—
Short-term debt	5,411	5,859
Total current liabilities	19,211	14,636
Deferred rent	2,468	2,569
Deferred revenue - long term	86	36
Long-term debt, net of current portion	24,632	29,116
Total liabilities	46,397	46,357
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value—10,000,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value—100,000,000 shares authorized at June 30, 2018 and December 31, 2017; 24,073,537 and 17,179,258 shares issued and outstanding at June 30, 2018 and December 31, 2017	24	17
Additional paid-in capital	208,589	185,255

Edgar Filing: Invuity, Inc. - Form 10-Q

Accumulated deficit	(206,281)	(186,134)
Total stockholders' equity (deficit)	2,332	(862)
Total liabilities and stockholders' equity (deficit)	\$ 48,729	\$ 45,495

See accompanying notes to unaudited condensed financial statements.

The year-end condensed balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

1

---

Table of Contents

## INVUITY, INC.

## Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	\$ 10,501	\$ 9,768	\$ 20,006	\$ 18,791
Cost of goods sold	4,073	3,015	6,996	5,114
Gross profit	6,428	6,753	13,010	13,677
Operating expenses:				
Research and development	2,145	2,410	4,027	4,839
Selling, general and administrative	12,498	14,204	27,610	29,057
Total operating expenses	14,643	16,614	31,637	33,896
Loss from operations	(8,215)	(9,861)	(18,627)	(20,219)
Interest expense	(794)	(527)	(1,568)	(1,014)
Interest income	109	53	164	110
Other expense, net	(50)	(52)	(116)	(178)
Loss on extinguishment of debt	—	—	—	(2,303)
Net loss and comprehensive loss	\$ (8,950)	\$ (10,387)	\$ (20,147)	\$ (23,604)
Net loss per common share, basic and diluted	\$ (0.37)	\$ (0.61)	\$ (0.95)	\$ (1.39)
Weighted-average shares used to compute net loss per common share, basic and diluted	24,047,256	16,986,074	21,102,254	16,972,280

See accompanying notes to unaudited condensed financial statements.

Table of Contents

INVUITY, INC.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended	
	June 30,	2017
	2018	2017
Cash flows from operating activities		
Net loss	\$ (20,147)	\$ (23,604)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	748	1,009
Stock-based compensation	1,609	1,421
Amortization of debt discount	131	38
Provision for (recovery of) doubtful receivable accounts	22	(82)
Loss on extinguishment of debt	—	2,302
Payment of original issue discount	—	(782)
Accretion of premium (discount) on marketable securities	(30)	4
Changes in operating assets and liabilities:		
Accounts receivable	835	262
Inventory	(1,098)	(508)
Prepaid expenses and other current assets	(264)	386
Accounts payable	(131)	716
Accrued and other current liabilities	351	(441)
Deferred rent	(101)	(71)
Net cash used in operating activities	(18,075)	(19,350)
Cash flows from investing activities		
Purchases of property and equipment	(413)	(558)
Purchases of marketable securities	(8,586)	(9,462)
Purchase of distribution license	—	(250)
Maturities of marketable securities	3,050	10,742
Net cash (used in) provided by investing activities	(5,949)	472
Cash flows from financing activities		
Proceeds from (payments of ) revolving credit facility	(448)	3,518
Proceeds from common stock offerings, net of offering costs	21,700	57
Proceeds from issuance of long-term debt, net of issuance costs	—	19,701
Payments of long-term debt - related party	—	(14,193)
Proceeds from issuance of common stock upon exercise of stock options	136	240
Prepayment penalty on long-term debt	—	(1,950)
Net cash provided by financing activities	21,388	7,373
Net decrease in cash and cash equivalents and restricted cash	(2,636)	(11,505)
Cash and cash equivalents and restricted cash, at beginning of period	18,871	29,390
Cash and cash equivalents and restricted cash, at end of period	\$ 16,235	\$ 17,885
Reconciliation of cash, cash equivalents and restricted cash as shown in the condensed statements of cash flows		

Edgar Filing: Invuity, Inc. - Form 10-Q

Cash and cash equivalents	\$ 15,327	\$ 16,795
Restricted cash classified as current assets	181	181
Restricted cash classified as long term assets	727	909
Total cash, cash equivalents and restricted cash	\$ 16,235	\$ 17,885
Supplemental disclosures of cash flow information		
Interest paid to related party	\$ —	\$ 980
Cash paid for interest	\$ 1,247	\$ —
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable and accrued liabilities at period end	\$ 25	\$ 16
Common stock offering costs in accounts payable and accrued liabilities	\$ 128	\$ —

See accompanying notes to unaudited condensed financial statements.



Table of Contents

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

In this Quarterly Report on Form 10-Q, references to “Invuity,” “we,” “us,” “our” and the “Company” refer to Invuity, Inc., unless expressly indicated or the context otherwise requires

1. Organization and Description of Business

Invuity, Inc. 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 minimal access procedures. The Company’s manufacturing, development and management facilities are located in San Francisco, California.

Liquidity and Going Concern

The Company has incurred net losses from operations since inception, including \$20.1 million in the six months ended June 30, 2018, and has an accumulated deficit of \$206.3 million as of June 30, 2018. In March 2018, the Company issued and sold a total of 6,800,000 shares of its common stock at \$3.50 per share, resulting in total net proceeds of approximately \$21.7 million. The Company has \$23.9 million in cash and cash equivalents and short-term investments, and \$34.7 million in net debt outstanding at June 30, 2018.

The Company is required to comply with a financial covenant relating to certain quarterly minimum Net Revenue (as defined in the debt agreements) requirements on a trailing twelve-month basis. See Note 5 for further details. As of June 30, 2018, the Company was not in compliance with this covenant. As disclosed in Note 10, the Company entered into an Amendment No. 3 to the Credit and Security Agreement (“Term Loan”) with MidCap Financial Trust (“MidCap”) to revise the financial covenant. After the execution of the amendment, the Company was in compliance with the revised covenant. The amendment also added a minimum cash covenant if the Company does not meet a minimum Net Revenue requirement on a trailing twelve month basis for the remainder of 2018. The minimum Net Revenue requirement is \$41.5 million for the period ending September 30, 2018, \$42.5 million for the period ending December 31, 2018, \$45.7 million for the period ending March 31, 2019, and \$47.7 million for the period ending June 30, 2019. In addition, the Company must comply with a minimum cash covenant of \$5.0 million that is triggered if Net Revenue is not in excess of \$45.0 million on a trailing twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter. The Company expects to incur additional losses and negative cash flows for the foreseeable future as the Company continues to invest in its sales and marketing efforts and research and development activities to continue to grow its business.

The Company believes that its cash, cash equivalents and short-term investments as of June 30, 2018, and expected sales from its products together with additional funding available under the Company’s revolving credit facility will not provide sufficient funds to enable the Company to meet its projected operating requirements for the next twelve months from the issuance of these financial statements.

The Company intends to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to support its operating and capital needs. If the Company is not able to perform according to the Company’s 2018

operating plan, the Company's available capital resources may be consumed more rapidly than currently expected, and therefore may be required to raise additional funds sooner than anticipated. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Without additional funds, the Company will be forced to delay, scale back or eliminate some of its sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations.

The uncertainty around the achievement of the Company's plans to mitigate the risk of going concern raises substantial doubt about the Company's ability to continue as a going concern for a one year period from the issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## Table of Contents

### 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 on Form 10-K for the year ended December 31, 2017 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 Company’s Annual Report on Form 10-K for the year ended December 31, 2017. The results for the three months and six months ended June 30, 2018 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

### 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, short-term investments, accounts receivable and accounts payable, approximate fair value due to their relatively short maturities. As of June 30, 2018 and December 31, 2017, 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

Edgar Filing: Invuity, Inc. - Form 10-Q

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 year ended December 31, 2017 and as of and for the three and six months ended June 30, 2018 and 2017, the Company had no customers that represented 10% or more of its revenue or accounts receivable balances.

5

---

## Table of Contents

### Changes in Significant Accounting Policies

Except for the accounting policies for revenue recognition and deferred commissions that were updated as a result of adopting Topic 606, there have been no changes to our significant accounting policies described in the Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 5, 2018, that have had a material impact on the Company's condensed financial statements and related notes.

### 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 accounts for a contract with a customer when there's approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance, collectability of consideration is probable and the risks and rewards of ownership are transferred.

In certain circumstances, the Company enters into arrangements in which multiple performance obligations are provided to customers. Under multiple performance obligations arrangements, the Company accounts for individual products and services separately if they are distinct, that is, if a product or service is separately identifiable from other items in the bundled package and if a customer can benefit from it on its own or with other resources that are readily available to the customer. The consideration (including any discounts) is allocated between separate products and services in a bundle based on their individual stand-alone selling price ("SSP"). The SSP is determined based on observable prices at which the Company separately sells the products and services.

The Company does not offer rights of return or price protection and does not provide credits or incentives, which may be required to be accounted for as variable consideration when estimating the amount of revenue to be recognized. With the exception of PhotonVue®, whereby customers can purchase service contracts for future periods of time, the Company has no post-delivery obligations other than the standard warranty for the Company's products.

### Single use devices

Single use device revenues include the Company's single use products, such as the PhotonGuide® (which is used in conjunction with our reusable retractors), Photonsaber® F, the Photonsaber® Y, and the PhotonBlade®. Revenues from the sale of single use devices are recognized when the Company transfers the risks and rewards of ownership to the customer. The Company's products do not require installation being readily available for use upon transfer of physical possession.

### Reusable retractors

Reusable retractor revenues include the Company's reusable products, such as the Eikon® LT, the Breisky, and the Breiten®. Revenues from the sale of reusable retractors are recognized when the Company transfers the risks and rewards of ownership to the customer. The Company's products do not require installation being readily available for use upon transfer of physical possession.

### Sales to 3rd party medical device manufacturers

At times, the Company sells uniquely modified products to 3rd party medical device manufacturers. The products are modified based on the specifications provided by 3rd party medical device manufacturers, who then incorporate these parts into products sold to their customers. Revenues from the sale to 3rd party medical device manufacturers are recognized when the Company transfers the risks and rewards of ownership to the 3rd party manufacturers. The Company's products do not require installation being readily available for use upon transfer of physical possession.

6

---

## Table of Contents

### Other

Other revenues include revenues from sales of accessories and service agreements. Revenues for sales of accessories, such as cables and trays, are recognized when the accessories are delivered to the customer and control is transferred. Revenues from service agreements are accounted for ratably over the term of the service agreement.

### Segment Reporting

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The majority of the Company's assets are maintained in the United States. The Company derives its revenue primarily from sales to customers in the United States, based upon the billing address of the customer. The Company started selling in Asia in June 2017 and in Europe and Australia in June 2018. The Company had \$20,000 and \$141,000 in total international sales for the three months ended March 31, 2018 and June 30, 2018, and \$0.2 million in total international sales for the six months ended June 30, 2018.

### 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.

### Contract Balances

The timing of revenue recognition, billings and cash collections results in accounts receivables and deferred revenues on the Condensed Balance Sheet. Service contracts are usually billed upon initial purchase with the PhotonVue® system, resulting in a contract liability. These contract liabilities are reported as deferred revenues on the Condensed Balance Sheet at the end of each reporting period.

### Recent Accounting Pronouncements

- In May 2014, the Financial Accounting Standards Board (the "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.

## Edgar Filing: Invuity, Inc. - Form 10-Q

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 Transition Resource Group, (the “TRG”) in the guidance on assessing collectability, presentation of sales tax, noncash consideration, and completed contracts and contracts modifications at transition.



Table of Contents

The adoption of ASC 606, using the modified retrospective approach in the first quarter of 2018 did not have a material impact on the Company's financial statements.

- In February 2016, the FASB issued ASU No. 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 Company expects to adopt the guidance on January 1, 2019. The Company is in the process of evaluating the impact of this new guidance on its financial statements, and expects the balance sheet to include a right of use asset and liability related to its lease arrangements.
- In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Statements (Topic 326). 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 No. 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 ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the FASB 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 No. 2016-15 is effective for public entities for annual periods beginning after December 15, 2017. The Company adopted this standard in the first quarter of 2018. As a result of the adoption, the Company reclassified \$2.0 million of Loss from debt extinguishment from Operating cash outflows in the three months ended March 31, 2017 to financing cash outflows on the Condensed Statements of Cash Flows.
- In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The amendments in this update expand the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments in this Update are effective for private entities for

## Edgar Filing: Invuity, Inc. - Form 10-Q

fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. 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

8

---

Table of Contents

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

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

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

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

The Company's financial instruments consist of Level 1 and 2 assets. Level 1 assets consist primarily of highly liquid money market funds that are included in cash, cash equivalents, and restricted cash. Commercial paper and corporate debt securities are classified in Level 2 of the fair value hierarchy because these valuation inputs are observable or market-corroborated.

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

	June 30, 2018			Total
	Level 1	Level 2	Level 3	
Assets				
Money market funds	\$ 6,253	\$ —	\$ —	\$ 6,253
Commercial paper	—	12,642	—	12,642
Corporate debt securities	—	1,348	—	1,348
	\$ 6,253	\$ 13,990	\$ —	\$ 20,243
	December 31, 2017			Total
	Level 1	Level 2	Level 3	
Assets				
Money market funds	\$ 13,071	\$ —	\$ —	\$ 13,071
Commercial paper	—	3,763	—	3,763
Corporate debt securities	—	1,753	—	1,753
	\$ 13,071	\$ 5,516	\$ —	\$ 18,587

As of June 30, 2018 and December 31, 2017, the carrying value of the Company's short-term investments approximates their fair value.

#### 4. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Raw materials	\$ 1,968	\$ 1,606
Work-in-process	2,701	1,860
Finished goods	3,865	3,970
Total inventory	\$ 8,534	\$ 7,436

Table of Contents

## Prepaid Expenses and Other Current Assets

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

	June 30, 2018	December 31, 2017
Prepaid expenses	\$ 1,570	\$ 1,252
Other	51	22
Total prepaid expenses and other current assets	\$ 1,621	\$ 1,274

## Property and Equipment, Net

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

	June 30, 2018	December 31, 2017
Computer equipment and software	\$ 1,606	\$ 1,368
Laboratory and manufacturing equipment	3,116	3,008
Furniture and fixtures	1,550	1,516
Leasehold improvements	7,201	7,155
Assets in progress	188	167
Total property and equipment, gross	13,661	13,214
Less: accumulated depreciation and amortization	(6,793)	(6,045)
Total property and equipment, net	\$ 6,868	\$ 7,169

Depreciation and amortization expense was \$0.4 million for the three months ended June 30, 2018, and \$0.5 million for the three months ended June 30, 2017. Depreciation and amortization expense was \$0.7 million for the six months ended June 30, 2018, and \$1.0 million for the six months ended June 30, 2017.

## Accrued and Other Current Liabilities

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

	June 30, 2018	December 31, 2017
Accrued payroll-related expenses	\$ 3,885	\$ 3,777
Accrued independent sales agent commissions	298	181
Accrued professional fees	830	501
Deferred rent	261	261
Other	355	459
Total accrued and other current liabilities	\$ 5,629	\$ 5,179

As part of a corporate restructuring program the Company implemented in May 2018, the Company recorded \$0.9 million in severance expense, of which \$0.6 million is included in the total Accrued payroll-related expenses of \$3.9 million for the six months ended June 30, 2018. The remaining severance payments of \$0.6 million are expected to be fully disbursed by January 2019.

5. Debt

MidCap credit and security agreement:

On March 10, 2017, the Company entered into a credit and security agreement with MidCap as agent, for up to \$30.0 million in term loans. Under the terms of the agreement, the Company borrowed the first term loan of \$20.0 million (“Tranche 1”) at closing. The Tranche 1 term loan accrues interest at a floating rate equal to 6.50% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. Interest shall accrue on the date of the commencement of funding and is payable in arrears on the first day of each month. Principal was payable in 36 equal monthly installments beginning April 1, 2019, subject to extension to October 1, 2019, if the Company achieves a certain revenue target, until paid in full on March 1, 2022. The Company used \$17.2 million of the \$20.0 million Tranche 1 term loan to pay off in

Table of Contents

full the outstanding \$15.0 million loan with Health Care Royalty Partners (“HCRP”). The Company also terminated its accounts receivable credit facility with Silicon Valley Bank which was never drawn down. The transaction was accounted for as a debt extinguishment and a loss of \$2.3 million was accounted for as loss on extinguishment of debt in the income statement. The loss amount includes a \$1.8 million prepayment fee paid to HCRP, a \$150,000 fee paid to Silicon Valley Bank for termination of the accounts receivable facility and a \$0.3 million non-cash expense related to unamortized issuance costs. The facility terminates in full on March 1, 2022, unless terminated earlier. As of June 30, 2018, the Company had drawn down \$5.4 million under the revolving credit facility.

In connection with the term loan facility, the Company agreed to issue to each lender warrants to purchase shares of the Company’s common stock upon the drawdown of each tranche in an aggregate amount equal to 2.0% of the amount drawn, divided by the exercise price per share for that tranche. In connection with the Tranche 1 term loan, the Company issued warrants to purchase an aggregate of 50,618 shares of the Company’s common stock, at an exercise price equal to \$7.90 per share. These warrants, which were recorded within stockholders’ equity, were fair valued at \$279,000 upon issuance using a Black-Scholes valuation model. The assumptions used in the Black-Scholes model consisted of a 10 year contractual term, interest free rate of 2.58%, dividend yield of 0.0% and volatility of 60.0%. The fair value was recorded as a discount to the initial \$20.0 million term loan and will be amortized as interest expense over the term of the agreement, which is approximately five years. In connection with the Tranche 2 term loan, the Company issued warrants to purchase an aggregate of 47,790 shares of the Company’s common stock, at an exercise price equal to \$8.37 per share. These warrants, which were recorded within stockholders’ equity, were fair valued at \$278,000 upon issuance using a Black-Scholes valuation model. The assumptions used in the Black-Scholes model consisted of a 10 year contractual term, interest free rate of 2.24%, dividend yield of 0.0% and volatility of 60.0%. The fair value was recorded as a discount to the initial \$10.0 million term loan and will be amortized as interest expense over the term of the agreement, which is approximately five years

On September 26, 2017, the Company entered into an Amendment No. 2 to the Term Loan with MidCap and borrowed the second term loan of \$10.0 million (“Tranche 2”). The Tranche 2 term loan accrues interest at a floating rate equal to 6.50% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. Interest shall accrue on the date of the commencement of funding and is payable in arrears on the first day of each month. Principal was payable in 36 equal monthly installments beginning April 1, 2019, subject to extension to October 1, 2019, if the Company achieved a certain revenue target, until paid in full on March 1, 2022.

The Company also entered into a separate Credit and Security Agreement (Revolving Loan) with MidCap on March 10, 2017 that provided for a revolving credit facility of up to \$10.0 million based on the eligible accounts receivable and inventory balances, as amended on September 26, 2017. The Company could increase the total commitments under the revolving credit facility by up to an additional \$10.0 million, subject to the Company meeting certain conditions. Loans under the revolving credit facility accrued interest at a floating rate equal to 3.25% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. Interest was payable in arrears on the first day of each month subsequent to the draw down date.

The term loan facility and the revolving credit facility are secured by substantially all of the Company’s assets, including intellectual property. In addition, under the terms of the agreement, the Company is required to meet certain covenants which if the Company is unable to meet, or if the Company does not make its payments, the Company may be found in default and all obligations may be accelerated and become immediately due and payable upon the sole election of the lenders. The Company must also comply with a financial covenant relating to certain quarterly minimum Net Revenue requirements on a trailing twelve month basis. As of June 30, 2018, the Company was not in compliance with this covenant. Additionally, the credit and security agreement with MidCap, includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, and material adverse effect events. If an event of default occurs, MidCap may require immediate repayment of all amounts due.

On July 31, 2018, the Company entered into an Amendment No. 3 to the Term Loan, (the “Term Loan Amendment”). For the Term Loans and the Revolving Loan, the financial covenant, relating to certain quarterly minimum net revenue requirements on a trailing twelve-month basis, was revised. In addition, the amendment also added a minimum cash covenant if the Company does not meet a minimum Net Revenue requirement on a trailing twelve month basis for the remainder of 2018. The minimum Net Revenue requirement is \$41.5 million for the period ending September 30, 2018, \$42.5 million for the period ending December 31, 2018, \$45.7 million for the period ending March 31, 2019, and \$47.7 million for the period ending June 30, 2019. In addition, the Company must comply with a minimum cash covenant of \$5.0 million that is triggered if Net Revenue is not in excess of \$45.0 million on a trailing



## Table of Contents

twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter. For the term loan, the exit fee was increased from 6.5% to 7.0% of the total amount of all term loans and the repayment schedule was revised such that principal on each term loan advance is now payable in 39 equal monthly installments beginning January 1, 2019 until paid in full on March 1, 2022. In connection with the Term Loan Amendment, the Company also entered into an Amendment No. 3 to Revolving Loan (the “Revolving Loan Amendment”). For the Revolving Loan, the total commitments were increased from \$10.0 million to \$15.0 million. After the execution of the amendment, the Company was in compliance with the revised covenant.

### 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 months ended June 30, 2018 and 2017, the Company granted 8,840 options and 125,525 options, respectively, to employees and consultants, with a weighted average grant date fair value of \$3.62 per share and \$7.32 per share, respectively. During the six months ended June 30, 2018 and 2017, the Company granted 325,340 and 734,705 options, respectively, to employees and consultants, with a weighted average grant date fair value of \$4.11 per share and \$6.65 per share, respectively. The options granted in 2017 included 268,000 options granted to certain executive officers with a market-based condition. The 268,000 options were valued at an aggregate value of \$0.7 million using the Monte Carlo Simulation model, which will be amortized over three years from the date of grant.

The aggregate intrinsic value of options exercised was \$30,000 for the three months and \$45,000 for the six months ended June 30, 2018, respectively, and was \$0.3 million for both of the three and six months ended June 30, 2017. The weighted-average remaining contractual life of options outstanding was 5.6 and 7.0 years at June 30, 2018 and December 31, 2017, respectively. For vested and expected to vest options, the weighted-average remaining contractual life as of June 30, 2018 and December 31, 2017, was 5.6 and 7.0 years, respectively.

For the three months ended June 30, 2018, the Company granted 171,230 restricted stock units (“RSUs”) to non-employee board members (“Outside Directors”) with a grant date fair value, in the aggregate, of approximately \$0.6 million. Under the Company’s Restricted Stock Unit Deferral Program for Outside Directors, Outside Directors may elect to defer the receipt of shares upon vesting of RSUs granted under the 2015 Plan. A deferral election will apply to the entirety of the particular RSU award and no partial elections may be made. A deferral election is irrevocable once made. In the event an Outside Director makes a deferral election, the shares of common stock underlying the deferred RSUs will not be distributed to such Outside Director until the earlier of his or her separation of service as a board member or upon a “Change in Control” (as defined in the 2015 Plan) of the Company. Three out of five of the Company’s Outside Directors elected to defer receipt of the RSUs granted to them on the date of the Company’s 2018 Annual Meeting (the “2018 Annual meeting”) under the 2015 plan. The Company also granted 60,000 RSUs to the Interim President and Chief Executive Officer, with a grant date fair value, in the aggregate, of approximately \$0.2 million.

For the six months ended June 30, 2018, the total RSUs granted were 522,665 with a fair value of \$1.9 million, including RSUs granted to Outside Directors described above and 272,985 RSUs granted to executive officers with a fair value of \$1.1 million. The RSUs granted to executive officers have a four-year term and vest 25% annually, with the exception of the RSUs granted as part of the new Interim President and Chief Executive Officer’s employment agreement that vest 100% after one year. The RSUs granted to Outside Directors on the date of the 2018 Annual Meeting will vest 100% on the one year anniversary of the 2018 Annual Meeting, with the exception of any RSUs that an Outside Director elected to defer, which RSUs generally will vest 100% on the first anniversary of the date that the Outside Director elected to defer such RSUs.

For the three months ended June 30, 2017, the Company granted approximately 72,000 RSUs to Outside Directors with a grant date fair value, in the aggregate, of \$0.5 million. The RSUs granted to Outside Directors on the date of the 2017 Annual Meeting will vest 100% on the earlier of the 2018 Annual Meeting of Stockholders or the one year anniversary of the 2017 Annual Meeting, with the exception of any RSUs that an Outside Director elected to defer, which RSUs generally will vest 100% on the first anniversary of the date that the Outside Director elected to defer such RSUs. As previously noted, under the Company's Restricted Stock Unit Deferral Program for Outside Directors, Outside Directors may elect to defer the receipt of shares upon vesting of RSUs granted under the 2015 Plan. Three out of four

Table of Contents

of the Company's Outside Directors elected to defer receipt of the RSUs granted to them on the date of the Company's 2017 Annual Meeting (the "2017 Annual Meeting") under the 2015 Plan.

For the six months ended June 30, 2017, the total RSUs granted were 153,000 with a fair value of \$1.0 million, including the RSUs granted to Outside Directors described above and 71,500 RSUs granted to executive officers with a fair value of \$0.5 million. The RSUs granted to executive officers have a four-year term and vest 25% annually.

## 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 expenses of \$0.6 million and \$1.6 million for the three and six months ended June 30, 2018, respectively, and \$0.7 million and \$1.3 million for the three months and six months ended June 30, 2017, respectively.

In addition, the Company recognized non-employee stock-based compensation expense of \$29,000 and \$48,000 for the three and six months ended June 30, 2018, respectively, and \$44,000 and \$111,000 for the three and six months ended June 30, 2017, respectively.

The following table summarizes stock based compensation expense related to stock options and restricted stock units included in the condensed statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of goods sold	\$ 59	\$ 51	\$ 113	\$ 96
Selling, general and administrative	481	475	183	1,007
Research and development	90	173	1,313	318
Total stock-based compensation expense	\$ 630	\$ 699	\$ 1,609	\$ 1,421

As of June 30, 2018, unrecognized compensation expense related to unvested options was \$6.9 million, which the Company expects to recognize on a straight line basis over a weighted average period of 2.6 years. Unrecognized compensation expense related to unvested RSUs was \$2.7 million, which the Company expects to recognize on a straight line basis over a weighted average period of 2.1 years.

## 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	\$ (8,950)	\$ (10,387)	\$ (20,147)	\$ (23,604)
Denominator:				
Weighted-average common shares outstanding	24,047,256	16,986,628	21,102,254	16,973,473

Edgar Filing: Invuity, Inc. - Form 10-Q

Less: weighted-average unvested common shares subject to repurchase	—	(554)	—	(1,193)
Weighted-average shares used to compute net loss per common share, basic and diluted	24,047,256	16,986,074	21,102,254	16,972,280
Net loss per common share, basic and diluted	\$ (0.37)	\$ (0.61)	\$ (0.95)	\$ (1.39)

13

---

Table of Contents

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per share because their inclusion would be anti dilutive:

	June 30, 2018	June 30, 2017
Options to purchase common stock	2,696,767	2,949,908
Restricted stock units	620,315	250,447
Warrants to purchase common stock	235,415	187,625
Total	3,552,497	3,387,980

## 8. Commitments and Contingencies

On February 27, 2017, a purported stockholder class action titled *Paciga v. Invuity, Inc., et al.*, Case No. 3:17-cv-01005, was filed in the United States District Court for the Northern District of California against the Company, its Chief Executive Officer, and its Chief Financial Officer. The complaint alleges that the defendants made false or misleading statements to investors regarding the Company's business prospects. The complaint purports to assert claims for violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and the Securities Exchange Commission Rule 10b-5 on behalf of a purported class consisting of all purchasers of the Company's common stock between July 19, 2016 and November 3, 2016, and seeks unspecified compensatory damages, attorney fees and costs, and other relief. On May 30, 2017, the Court appointed Mike Paciga as lead plaintiff. The lead plaintiff filed an amended complaint on July 31, 2017. Defendants filed a motion to dismiss on September 14, 2017, and the lead plaintiff filed his opposition to the motion on October 30, 2017. Defendants filed a reply brief on December 4, 2017. The Company intends to defend the litigation vigorously. Based on information currently available, the Company has determined that the amount of any possible loss or range of possible loss is not reasonably estimable.

In December 2016, Medtronic, which competes with us across multiple product lines, filed a civil complaint in the State Court of Minnesota against us, alleging tortious interference with contract, and two of our former sales employees, alleging breach of contract, misappropriation of trade secrets and breach of duty of loyalty. The complaint seeks unspecified monetary damages. In April 2018, we entered into an agreement with Medtronic, pursuant to which we agreed to pay \$1.0 million to Medtronic, which was paid during the quarter. Medtronic agreed to dismiss this complaint.

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

## 9. Disaggregation of Revenues

The Company disaggregates its revenues by product categories, as the Company believes this best depicts how the nature, amount, timing, and uncertainty of revenues and cash flows are affected by economic factors. See details in the tables below.

Edgar Filing: Invuity, Inc. - Form 10-Q

	Three Months Ended		Six Months Ended	
	June 30, 2018	2017	June 30, 2018	2017
	(In thousands)		(In thousands)	
Revenue				
Single use devices	\$ 9,245	\$ 8,289	\$ 17,826	\$ 15,337
Reusable retractors	848	926	1,547	2,049
Sales to third party medical device manufacturers	86	278	86	827
Other	322	275	547	578
Total revenue	\$ 10,501	\$ 9,768	\$ 20,006	\$ 18,791

10. Subsequent Events

Debt Covenants:

As of June 30, 2018, the Company was not in compliance with the financial covenant relating to the Term Loan and the Revolving Loan with MidCap. On July 31, 2018, the Company entered into an Amendment No. 3 to the Term

## Table of Contents

Loan and to the Revolving Loan to revise the financial covenant. After the execution of the amendment, the Company was in compliance with the revised covenant. See Note 5, “Debt”, of the Notes to Condensed Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10 Q for more details.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the Term Loan Amendment and the Revolving Loan Amendment, copies of which are attached hereto as Exhibits 10.1 and 10.2, respectively, and incorporated herein by reference.

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

The following discussion and analysis 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 Quarterly Report on Form 10 Q, 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, 2017. 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 materially from those anticipated in these forward-looking statements as a 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 Quarterly Report on Form 10 Q.

### Overview

We are a leading medical technology company focused on developing and marketing advanced surgical devices to improve the ability of physicians to perform minimal access surgery through smaller and hidden incisions. Our patented Intelligent Photonics® technology delivers enhanced visualization which facilitates surgical precision, efficiency and safety. In addition, we utilize comprehensive strategic marketing programs to create stronger institutional partnerships. Clinical applications include women's health, encompassing breast cancer and breast reconstruction surgery, gynecology and thyroid surgery. Additional applications include procedures for electrophysiology, spine, orthopedic, cardiothoracic, and general surgery.

We channel our development through two broad categories of innovation. First, we integrate our Intelligent Photonics® technology platform into our single-use and reusable advanced surgical devices to address some of the critical intracavity illumination and visualization challenges facing surgeons today. We utilize this proprietary technology to develop optical waveguides, called PhotonGuides®, which 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.

Our second broad category of innovation for minimally invasive and minimal access surgical procedures is in the development and commercialization of a novel, advanced energy platform. In September 2016, we received U.S. Food and Drug Administration, or FDA, 510(k) clearance of PhotonBlade®, a dynamic precision illuminator with enhanced energy delivery. PhotonBlade® is a first-of-its-kind device, delivering directed, thermally cool illumination at the precise point of surgical treatment in conjunction with a novel advanced energy platform allowing for precise tissue cutting and coagulation with minimal tissue damage. As such, PhotonBlade® represents a new category of Intelligent

Photonics® and strategically expands our current product portfolio. After a preliminary market launch in March 2017, we fully launched the PhotonBlade® in September 2017.

We sold our devices to approximately 935 hospitals in the second quarter of 2018, as compared to approximately 825 hospitals in the second quarter of 2017. Based on the number of single-use units we have shipped as of June 30, 2018, we estimate that our devices have been used in approximately 433,000 surgical procedures cumulative from inception.



## Table of Contents

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 minimal access procedures and enable new advanced surgical techniques. Our manufacturing involves the combined utilization of our internal manufacturing resources and expertise, approved suppliers and contract manufacturers. We outsource the manufacture of components, subassemblies and certain finished devices that are produced to our specifications and shipped to our facilities in San Francisco, California for final assembly or inspection, and certification. Finished products are stored at and distributed from our facility. In January, 2018, we secured additional space for storage and distribution, and believe these facilities are sufficient to support our operations and that suitable facilities would be available to us should our operations require it.

On May 1, 2018, we implemented a corporate restructuring program to streamline our company and increase productivity in our commercial operations and product development process. As a result, we recorded \$0.9 million in severance expense of which \$0.6 million is included in the total Accrued payroll-related expenses of \$3.9 million for the six months ended June 30, 2018. The remaining severance payments of \$0.6 million are expected to be fully disbursed by January 2019.

## Components of Our Results of Operations

### Revenue

Substantially all of our revenue is 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. In June 2017, we started selling into Asia and in June 2018, we started selling into Europe and Australia. Our international efforts to date have primarily involved training and supplying our distributors demonstration inventory. We had \$20,000 and \$141,000 in total international sales for the three months ended March 31, 2018 and June 30, 2018, and \$0.2 million in total international sales for the six months ended June 30, 2018.

We consider revenue derived from our single-use products to be the most important part of our business. Therefore, our focus is on procedure adoption. 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 are targeting our sales and marketing efforts to surgeons for the following women's health clinical applications: breast cancer and breast reconstruction surgery, gynecology and thyroid surgery. Additional applications include procedures for electrophysiology, spine, orthopedic, cardiothoracic and general surgery. Although we have made progress towards our goals there are still many areas for growth. To achieve these goals, we are focused on the following initiatives to continue to drive revenue growth:

- Leveraging our unique marketing programs that align with hospital initiatives including safety, patient outcomes and patient satisfaction, for example our Hidden Scar Surgery Program and Safety Program;
- Cross selling within our initial target markets and developing adjacent surgical specialties to broaden the three core categories to Women's health, spine/orthopedic and electrophysiology; and.
- Introducing new products to support our ability to expand our clinical applications including the launch of our Adapt product line, consisting of PhotonGuide® Adapt and Adapt-compatible retractors.

We have experienced seasonality during 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. The third quarter is similarly negatively impacted by lower procedure rates typically associated with vacation plans of both patients and surgeons. 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.

## Table of Contents

### 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. However, we expect overhead costs as a percentage of revenue to decrease over time as our production volume increases and our production process becomes more efficient. In addition, new product launches typically have higher costs due to less efficient manufacturing process costs and higher material costs due to lower production volumes. 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. Gross margin on our current product portfolio may increase over the long term as our production volume increases and we are able to spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs; however this positive trend has been offset by new product introductions, notably the PhotonBlade® and PhotonVue®, as new products are produced at low volumes which may result in lower margins as component costs are usually higher at lower volumes. Therefore, our gross margin will likely fluctuate from quarter to quarter in the near term.

### 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 salaries, healthcare benefits, bonuses, stock-based compensation expense, consulting services, laboratory materials and supplies, and an allocation of related facilities costs. In the near term, we expect R&D expense to decline as a result of our recent corporate restructuring program and then remain fairly constant in absolute dollars as we look to increase our operating efficiencies while expanding our product lines.

### Selling, General and Administrative Expenses

Our selling, general and administrative, or SG&A, expenses consist primarily of personnel costs including salaries, healthcare benefits, sales commissions, bonuses and stock compensation for sales, executives, and administrative personnel. Other significant SG&A expenses include independent sales agent commissions, conferences, trade shows, promotional activities including trunk stock expenses associated with the sales team demonstrating our products, and professional fees for legal and accounting services, consulting fees, insurance costs and travel expenses.

In the near term, we expect SG&A expenses to decrease as a result of our recent corporate restructuring program. Over the longer term, we expect SG&A to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our planned revenue growth in addition to supporting a dynamically growing company.

### 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 Income and Other Expense, Net

Interest income and other expense, net consists primarily of interest income earned on our cash, cash equivalents and marketable securities offset by tax expenses, and the fair value re-measurement related to our outstanding common stock warrants, which have been accounted for as a discount to our MidCap debt and will be marked-to-market at each future reporting period.

17

---

Table of Contents

## Loss on Extinguishment of Debt

Loss on extinguishment of debt consists primarily of prepayment penalties associated with the early payment of our loan with HCRP in addition to the write-off of original debt issuance costs and debt discount associated with this loan agreement.

## Results of Operations

## Comparison of the Three Months and Six Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Revenue				
Single use devices	\$ 9,245	\$ 8,289	\$ 17,826	\$ 15,337
Reusable retractors	848	926	1,547	2,049
Sales to third party medical device manufacturers	86	278	86	827
Other	322	275	547	578
Total revenue	\$ 10,501	\$ 9,768	\$ 20,006	\$ 18,791
Cost of goods sold	4,073	3,015	6,996	5,114
Gross Profit	\$ 6,428	\$ 6,753	\$ 13,010	\$ 13,677
Gross Margin	61.2	% 69.1	% 65.0	% 72.8

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

Revenue increased \$0.7 million, or 8%, to \$10.5 million during the three months ended June 30, 2018, compared to \$9.8 million for the same period in 2017. Revenue for the six months ended June 30, 2018 increased \$1.2 million, or 6%, to \$20.0 million compared to \$18.8 million for the same period in 2017. The growth in revenue for both comparable periods was attributable to an increase in the number of hospitals ordering our devices, which increased to approximately 935 in the three months ended June 30, 2018 compared to 825 for the same period in 2017. We continue to see increased procedure use of our single use devices driven by growing adoption of our PhotonBlade® in breast and electrophysiology procedures. The number of our direct sales representatives was 50 as of June 30, 2018, compared to 65 as of June 30, 2017. This is consistent with our efforts of consolidating our direct sales representatives in the highest value geographic markets. In less dense geographic markets, we will employ an indirect approach and partner with local distributors.

Cost of goods sold increased \$1.1 million, or 35%, to \$4.1 million during the three months ended June 30, 2018, compared to \$3.0 million for the same period in 2017. Cost of goods sold increased \$1.9 million, or 37% to \$7.0 million during the six months ended June 30, 2018, compared to \$5.1 million for the same period in 2017. The increase in cost of goods sold was primarily due to the increase in the number of devices sold.

Gross margin for the three months ended June 30, 2018 was 61.2% compared to 69.1% for the same period in 2017. Gross margin for the six months ended June 30, 2018 was 65.0%, compared to 72.8% for the same period in 2017. Gross margins in 2018 were impacted by a change in product mix as a result increased in sales of our PhotonBlade®, which have a higher cost per unit and have yet to benefit from manufacturing efficiencies associated with volume production.



Table of Contents

## Operating Expenses

	Three Months Ended June 30,				Six Months Ended June 30,				
	2018		2017		2018		2017		
	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	\$ 2,145	20 %	\$ 2,410	25 %	\$ 4,027	20 %	\$ 4,839	26 %	
Selling general and administrative	12,498	119	14,204	145	27,610	138	29,057	155	
Total operating expenses	\$ 14,643	139 %	\$ 16,614	170 %	\$ 31,637	158 %	\$ 33,896	181 %	

## Research and development expenses:

Expenses decreased by \$0.3 million, or 11%, to \$2.1 million during the quarter ended June 30, 2018, compared to \$2.4 million during the quarter ended June 30, 2017. Research and development expenses decreased \$0.8 million, or 17%, to \$4.0 million during the six months ended June 30, 2018, compared to \$4.8 million during the comparable period ended June 30, 2017. The decrease quarter over quarter is primarily due to a decrease of \$0.2 million in payroll-related expenses in addition to \$0.1 million in reduced research and development expenses. The year over year decrease in expenses was primarily attributable to a decrease of \$1.0 million in payroll, consulting fees, and research and development expenses offset by an increase of \$0.2 million reduction in operational expenses. Overall research and development expenses will vary with the cadence of new product launches.

## Selling, general and administrative expenses:

Expenses decreased by \$1.7 million, or 12%, to \$12.5 million during the quarter ended June 30, 2018, compared to \$14.2 million during the quarter ended June 30, 2017. The decrease in expenses was primarily attributable to a decrease of \$1.2 million in professional services, including litigation expenses, and a decrease of \$1.4 million in sales related expenses, including payroll and payroll related expenses, associated with the consolidation of the direct sales force from 65 direct sales representatives during the quarter ended June 30, 2017, to 50 direct sales representatives during the quarter ended June 30, 2018. These decreases were offset by an increase in consultant expenses of \$0.8 million. Selling, general and administrative expenses decreased \$1.5 million, or 5%, to \$27.6 million during the six months ended June 30, 2018, compared to \$29.1 million during the comparable period ended June 30, 2017. The year over year decrease in expenses was primarily attributable to a decrease of \$1.5 million in payroll and payroll related expenses, \$0.8 million in professional services, and \$0.4 million in sales and marketing expenses offset by an increase in consultant expenses of \$1.1 million.

Table of Contents

Interest expense, interest income, and other expense, net:

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018		2017		2018		2017	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(In thousands)		(In thousands)		(In thousands)		(In thousands)	
Interest expense	\$ (794)	(8)	\$ (527)	(5)	\$ (1,568)	(8)	\$ (1,014)	(5)
Interest income	109	1	53	1	164	1	110	1
Other expense, net	(50)	(0)	(52)	(1)	(116)	(1)	(178)	-
Loss on extinguishment of debt	—	—	—	—	—	—	(2,303)	(12)
Total	\$ (735)	(7)	\$ (526)	(5)	\$ (1,520)	(8)	\$ (3,385)	(16)

The total interest expense, interest income, and other expense increased by \$0.2 million or 40% during the quarter ended June 30, 2018, compared to the quarter ended June 30, 2017. This increase was primarily due to more interest expense on a higher debt balance. For the six months ended June 30, 2018, the total interest expense, interest income, and other expense decreased by \$1.9 million or 55% primarily due to the March 2017 expense of \$2.3 million in association with the extinguishment of our loan with HCRP. This expense included a \$1.8 million prepayment penalty, approximately \$0.4 million in expense relating to the immediate recognition of debt discounts that were being amortized over the term of the original loan, and a \$150,000 fee for ending our access to our Silicon Valley Bank, or SVB, credit facility. This decrease was offset by higher interest expense as a result of our higher debt balance.

#### 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.

Except for the accounting policies for revenue recognition and deferred commissions that were updated as a result of adopting Topic 606, there have been no changes to our significant accounting policies described in the Annual Report on Form 10-K filed with the SEC on March 5, 2018, that have had a material impact on the Company's condensed financial statements and related notes.

#### Liquidity and Capital Resources



Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing or to raise capital. The accompanying financial statements have been prepared on a basis which assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. We have incurred net losses from operations since inception, including \$20.1 million in the six months ended June 30, 2018, and have an accumulated deficit of \$206.3 million as of June 30, 2018. In March 2018, we issued and sold a total of 6,800,000 shares of our common stock at \$3.50 per share, resulting in total net proceeds of approximately

Table of Contents

\$21.7 million. We have \$23.9 million in cash and cash equivalents and short-term investments, and \$34.7 million in net debt outstanding as of June 30, 2018. We expect to incur additional losses and negative cash flows for the foreseeable future as we continue to invest in our sales and marketing efforts and research and development activities to continue to grow our business.

We are required to comply with a financial covenant relating to certain quarterly minimum Net Revenue requirements on a trailing twelve-month basis. As of June 30, 2018, we were not in compliance with this covenant. As disclosed in Note 10, we entered into an Amendment No. 3 to the Credit and Security Agreement with MidCap Financial Trust to revise the financial covenant. After the execution of the amendment, we were in compliance with the revised covenant. The minimum Net Revenue requirement on a trailing twelve month basis as amended, for the remainder of 2018, is \$41.5 million for the period ending September 30, 2018, \$42.5 million for the period ending December 31, 2018, \$45.7 million for the period ending March 31, 2019, and \$47.7 million for the period ending June 30, 2019.

The amendment also added a minimum cash covenant of \$5.0 million that is triggered if Net Revenue is not in excess of \$45.0 million on a trailing twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter.

We believe that our cash, cash equivalents and short-term investments as of June 30, 2018, and expected sales from our products together with additional funding available under our revolving credit facility will not provide sufficient funds to enable us to meet our projected operating requirements for the next twelve months from the issuance of the financial statements included in this Quarterly Report on Form 10-Q.

We intend to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to support our operating and capital needs. If we are not able to perform according to our 2018 operating plan, our available capital resources may be consumed more rapidly than currently expected, and therefore we may be required to raise additional funds sooner than anticipated. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Without additional funds, we will be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations.

The uncertainty around the achievement of our plans to mitigate the risk of going concern raises substantial doubt about our ability to continue as a going concern for a one year period from the issuance of the financial statements included in this Quarterly Report on Form 10-Q. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## Cash Flows

The following table summarizes our cash flows (in thousands) for the periods indicated:

	Six Months Ended June 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$ (18,075)	\$ (19,350)
Investing activities	(5,949)	472
Financing activities	21,388	7,373

Edgar Filing: Invuity, Inc. - Form 10-Q

Net decrease in cash and cash equivalents and restricted cash	\$ (2,636)	\$ (11,505)
---	------------	-------------

During the six months ended June 30, 2018, net cash used in operating activities was \$18.1 million, which consisted of a net loss of \$20.1 million, adjusted by non-cash charges of \$2.4 million. The non-cash charges were primarily comprised of stock-based compensation of \$1.6 million and depreciation and amortization of \$0.7 million. The overall change to net operating assets and liabilities changes was negligible. Accrued and other current liabilities increased \$0.4 million and accounts receivables decreased \$0.8 million. These changes were offset by an increase of \$1.1 million in inventories and \$0.3 million in prepaid expenses and other current assets.

During the six months ended June 30, 2017, net cash used in operating activities was \$19.4 million, which consisted of a net loss of \$23.6 million, adjusted by non-cash charges of \$3.9 million and a net change of \$0.3 million in

## Table of Contents

our net operating assets and liabilities. The non-cash charges were primarily comprised of stock-based compensation of \$1.4 million, depreciation and amortization of \$1.0 million, and loss on extinguishment of debt of \$2.3 million, offset by \$0.8 million of original debt discount associated with our prior HRCF loan. The increase in our net operating assets and liabilities was primarily due to a \$0.3 million decrease in accounts receivable, a \$0.7 million increase in accounts payable as a result of our increase in operational related activities, and a \$0.4 million decrease in prepaid expenses and other current assets. The increase was offset by a \$0.5 million increase in our inventory due to ramping production in order to meet the increase in customer demands and a \$0.5 million decrease in accrued liabilities.

During the six months ended June 30, 2018, net cash of \$5.9 million used in investing activities was primarily due to the purchase of \$8.6 million in marketable securities and \$0.4 million in capital expenditures offset by the maturity of \$3.1 million in marketable securities.

During the six months ended June 30, 2017, net cash provided by investing activities was primarily due to maturity of \$10.7 million in marketable securities, offset by the purchase of \$9.5 million in marketable securities, \$0.6 million in capital expenditures and the purchases of distribution license for \$0.3 million.

During the six months ended June 30, 2018, net cash provided by financing activities was primarily due to net proceeds of \$21.7 million from our secondary offering in March 2018, offset by a reduction of \$0.5 million in the draw-down under our revolving credit facility.

During the six months ended June 30, 2017, net cash provided by financing activities was from the issuance of \$20.0 million in long term debt under our agreement with MidCap, partially offset by the repayment of the outstanding loan balance with HCRP, along with the associated prepayment penalties. In addition, we drew down \$3.5 million under the revolving credit facility.

### Off-Balance Sheet Arrangements

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

### Contractual Obligations

During the six months ended June 30, 2018, 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 on Form 10 K filed with the SEC on March 5, 2018.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### Interest Rate Risk

Our operations are primarily within the United States. We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate, inflation risks, and changes in the general economic conditions in the countries where we conduct business. We had cash, cash equivalents, and short-term investments of \$23.9 million and \$21.0 million as of June 30, 2018 and December 31, 2017, respectively.

Our short-term investments primarily consisted of corporate bonds. The cash and cash equivalents are held for working capital purposes. Our investments are made for capital preservation purposes. We do not enter into

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

As of June 30, 2018 and December 31, 2017, we had total outstanding net debt of \$34.7 million and \$35.0 million, respectively. Our term loans with MidCap that were outstanding as of June 30, 2018 and December 31, 2017, accrue interest at a floating rate equal to 6.50% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. Our accounts receivable facility accrues interest at a floating rate equal to 3.25% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR as amended. See Note 5, "Debt", of the Notes to Condensed Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10 Q for more details.

## Table of Contents

### Foreign Currency Risk

In June 2017, we started selling into Asia. In June 2018, we began selling into Europe and Australia; however, as of June 30, 2018, our business has primarily been conducted in U.S. Dollars. As we begin to conduct transactions in foreign currencies, we may become increasingly subject to foreign currency risks related to our revenue and operating expenses denominated in currencies other than the U.S. dollars. As our international operations grow, our risks associated with fluctuation in currency rates will become greater, and we will continue to reassess our approach to managing this risk.

### Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

### Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13(a)-15(d) and 15d-15(d) under the Exchange Act that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Limitations on Effectiveness of Controls and Procedures

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

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

23

---

Table of Contents

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On February 27, 2017, a purported stockholder class action titled *Paciga v. Invuity, Inc., et al.*, Case No. 3:17 cv 01005, was filed in the United States District Court for the Northern District of California against us, our Chief Executive Officer, and our Chief Financial Officer. The complaint alleges that the defendants made false or misleading statements to investors regarding our business prospects. The complaint purports to assert claims for violation of Sections 10(b) and 20(a) of the Exchange Act of 1934, and SEC Rule 10b-5 on behalf of a purported class consisting of all purchasers of our common stock between July 19, 2016 and November 3, 2016, and seeks unspecified compensatory damages, attorney fees and costs, and other relief. On May 30, 2017, the Court appointed Mike Paciga as lead plaintiff. The lead plaintiff filed an amended complaint on July 31, 2017. Defendants filed a motion to dismiss on September 14, 2017, and the lead plaintiff filed his opposition to the motion on October 30, 2017. Defendants filed a reply brief on December 4, 2017. We intend to defend the litigation vigorously. Based on information currently available, we have determined that the amount of any possible loss or range of possible loss is not reasonably estimable.

In addition, we are, and 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 may be required to obtain additional funds to continue as a going concern. If we are unable to obtain sufficient funds, we may be unable to invest in our sales and marketing efforts and research and development activities in order to grow our business. Additionally, we may not be able to secure these funds on commercially reasonable terms, or at all.

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 \$20.1 million for the six months ended June 30, 2018 and \$39.9 million and \$40.6 million for the years ended December 31, 2017 and 2016, respectively. As of June 30, 2018, our accumulated deficit was \$206.3 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. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of issuance of the financial statements, included in this Quarterly Report on Form 10-Q. 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 we fail to continue to grow our revenue, 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.

## Table of Contents

Substantially all of our revenue to date has been 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 photonics technology platform for the illumination of certain open and minimal access surgeries. For the six months ended June 30, 2018 and for the years ended December 31, 2017 and 2016, our revenues of \$10.5 million, \$39.6 million, and \$32.5 million, respectively, were derived entirely from sales of devices incorporating our Intelligent Photonics® technology. Because we expect our revenue to be derived substantially 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 introduced our PhotonBlade® device in 2017 and there can be no assurance on the level of market acceptance or revenue generated by this product.

In the third quarter of 2016, we announced that we had 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 initiated a limited launch of the PhotonBlade® device in the first quarter of 2017 to obtain feedback from initial users with a goal of launching the product more broadly in the middle of 2017. Shortly after the limited launch, we received a small number of customer complaints which related to possible unintended energy discharge from the device with the potential to cause tissue damage to patients. In June 2017, we initiated a voluntary recall of the device. We redesigned the device to correct the performance issues that prompted the recall and relaunched the product in September of 2017. We cannot be assured that we have successfully redesigned the PhotonBlade® so as to eliminate the performance issues that prompted the recall. We have devoted and will continue to devote significant resources to market the PhotonBlade® and cannot be assured that these activities will generate revenue as anticipated. If our redesign of the device fails to successfully eliminate the performance issue or if our revenue grows more slowly than we expect, our business and financials will be adversely affected.

Failure to achieve revenue or cash targets under our credit facility with MidCap would constitute an event of default, which may require us to repay the amounts outstanding under the facility earlier than expected.

As of June 30, 2018, we had borrowed \$30.0 million in term loans and drawn down \$5.4 million under our revolving credit facility. Our credit facility with MidCap requires us to comply with a financial covenant relating to certain quarterly minimum Net Revenue requirements on a trailing twelve month basis. The minimum Net Revenue requirements on a trailing twelve month basis for the remainder of 2018 is \$41.5 million for the period ending September 30, 2018, \$42.5 million for the period ending December 31, 2018, \$45.7 million for the period ending March 31, 2019, and \$47.7 million for the period ending June 30, 2019. In March 2018, we were not in compliance with this financial covenant and we entered into an amendment with MidCap to revise it. In June 2018, we were not in compliance with the revised financial covenant. As disclosed in Item 5, we entered into an Amendment No. 3 to the Credit and Security Agreement with MidCap to further revise the financial covenant. After the execution of the amendment, we were in compliance with the further revised covenant. Amendment No. 3 to the Credit and Security Agreement also added a minimum cash covenant of \$5.0 million that is triggered if Net Revenue is not in excess of \$45.0 million on a trailing twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter.

If we do not comply with the financial covenant again in the future, it would constitute a breach of the credit agreements and may cause all of the outstanding indebtedness under our credit agreements, as amended, to become immediately due and payable. If the Company was unable to obtain a waiver for this default, the lenders may terminate all commitments to extend further credit and the agent, on behalf of the lenders, may proceed against the collateral in which we granted the agent and the lenders a security interest. Further, renegotiating our credit facility can be costly and time consuming and divert the resources of our management. The amendments to our credit facility have resulted in increased fees, the acceleration of repayment schedules and additional covenants and restrictions, which could negatively impact our results of operations and operational flexibility.

Table of Contents

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 "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 our devices as compared to alternatives, 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.

Failure to retain existing accounts or attract new accounts could cause our revenue growth rates to decline.

In addition to adding new accounts, we must sell additional products and accessories to existing accounts and encourage them to maintain or increase their usage levels to increase our revenue. If our existing and prospective users do not perceive our products and accessories to be of sufficiently high value and quality, we may not be able to retain our current accounts or attract new ones.

Our accounts' usage levels may decline or fluctuate as a result of a number of factors, including:

- their surgeons level of satisfaction with our products;
- our ability to provide features and functionality demanded by the hospitals and their surgeons;
- the prices of our products compared to our competitors;
- mergers and acquisitions affecting our hospital account base; and
- reduction in hospital accounts' spending levels or economic decline in our hospital accounts' markets.

If we do not add new accounts, our reusable retractor revenue may decline, as reusable retractors are typically sold when we open new accounts. In addition, our existing accounts could significantly curtail their usage and our revenue would be lower than expected and our operating results could suffer.

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 in the United States. Our direct sales force works with independent sales agents or agencies, which assist us in educating targeted surgeons. Our operating results

Table of Contents

are dependent upon the sales and marketing efforts of our direct sales representatives. If our direct sales force fails to adequately promote, market and sell our devices, our sales may suffer.

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

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

The medical device industry is highly competitive. 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, and advanced energy market segments 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 these market segments, and we expect the intensity of competition will increase over time. 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.



## Table of Contents

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

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. 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;
- the impact of recent key employee departures and our sales team realignment;
- the impact and timing of taxes or changes in tax law; 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,





## Table of Contents

we expect sales to these customers to decrease as a percent of revenue. However, the loss of any of our key customers for any reason, or a change in our relationship with any of our key customers may cause a significant decrease in our total revenue.

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

We rely on a number of suppliers who manufacture certain components of our devices, including specialty machining for our retractors, molding for PhotonGuides® and handheld components, and stamping and molding of PhotonBlades®. 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 new premarket submissions 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;
- additional political, business, logistical and regulatory risks affecting our relationships with international suppliers in China and South Korea, including increased costs due to Chinese tariffs on U.S. goods, which the Chinese government has recently implemented in retaliation to the U.S. government's substantial changes to foreign trade policy with China;
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements; and
- we may encounter undesirable issues, such as the inability to exercise the same degree of quality control as we can our own facilities, with our overseas suppliers that may force us to find another supplier, which would create a delay in service.

In addition, we rely on single- and limited-source suppliers for several of our components and sub-assemblies. For example, the optical molding for Photonguides® 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.

## Table of Contents

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 breadth of our offering. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory could become obsolete, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. For example, we introduced our Eikon LT retractor series at the beginning of 2016 which quickly displaced its predecessor the Eikon Classic retractor series. As a result, we recorded a 100% reserve against finished good inventory on hand and trunk stock inventory held by our sales representatives for the Eikon Classic retractor series for the year ended December 31, 2017. In the six months ended June 30, 2018, the ending inventory reserve balance included \$0.5 million related to obsolete and slow moving inventories.

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, do not require clinical data or completion of clinical studies to obtain clearance for marketing. As a result, the FDA has not required, and we have not developed, clinical data supporting the cost effectiveness of our devices. Therefore, we currently lack clinical data supporting the benefits and cost effectiveness of our devices compared to other surgical 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 cost advantages over our competitors' surgical 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;

30

---

Table of Contents

- avoid infringing upon the intellectual property rights of third-parties by developing our own intellectual property to protect our inventions;
- 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;
- comply with FDA regulations regarding the advertising and promotion of new devices or modified devices;
- provide adequate training to potential users of our devices; and
  - receive adequate coverage and reimbursement for procedures performed with our devices.

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

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

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

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

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

Adverse litigation or settlements resulting from legal proceedings in which we may be involved in the normal course of our business could negatively impact our business, financial condition and results of operations.

From time to time, we are subject to allegations, claims and legal actions arising in the ordinary course of our business, which may include claims by third parties, including customers, competitors, employees or regulators. In this regard, we are currently subject to a securities litigation. In February 2017, a purported stockholder class action was filed

## Table of Contents

against us, alleging that we made false or misleading statements about our business to investors who purchased our common stock between July 19, 2016 and November 3, 2016 in violation of Sections 10(b) and 20(a) of the Exchange Act, and the SEC Rule 10b-5. This securities litigation is discussed in greater detail under Part II, Item 1, “Legal Proceedings” and Note 8, “Commitments and Contingencies” to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Additionally, one of our former employees has received a letter from Medtronic PLC, or Medtronic, 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.

We intend to defend any proceedings vigorously. If any proceedings were to be determined adversely against us or resulted in legal actions, claims, regulatory proceedings, enforcement actions, or judgments, fines, or settlements involving a payment of material sums of money, or if injunctive relief were issued against us, our business, financial condition and results of operations could be materially adversely affected. Even the successful defense of legal proceedings may cause us to incur substantial legal costs and may divert management’s attention and resources.

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 productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively.

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

In addition, 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.

On February 27, 2018, Philip Sawyer informed the board of directors that he would resign from his role as President, Chief Executive Officer, and a member of our board of directors, effective as of February 28, 2018. Scott Flora, currently serving as a member of our board of directors, assumed the additional role of Interim President and Chief Executive Officer, and as such became the Company’s principal executive officer effective on March 1, 2018. At the appropriate time, the board of directors will commence a search to recruit a permanent successor with the assistance of a leading executive search firm.

In addition, in May 2018, we implemented a corporate restructuring program to streamline the business and increase productivity in our commercial operations and product development process. In connection with this restructuring, several of our executive officers were also impacted. These changes in the Company’s management team, may be disruptive to, or cause uncertainty in, the Company’s business, and any additional changes to the management team or the board of directors could have a negative impact on the Company’s ability to manage and grow its business.

effectively. In addition, if the Company is not effective in its succession planning, it may have a negative impact on the Company's ability to successfully recruit for its management team. Any such disruption or uncertainty or difficulty in efficiently and effectively filling key management roles could have a material adverse impact on the Company's business, results of operations and/or the price of the Company's common stock.

Table of Contents

The realignment of our sales organization could adversely affect client relationships and affect our future growth.

We periodically make adjustments to our sales organization in response to market opportunities, management changes, product introductions, and other internal and external considerations. In May 2018, in connection with our corporate restructuring, we realigned our sales force to help increase productivity. These changes could result in a temporary lack of focus and reduced productivity. In addition, these adjustments could result in our customers experiencing a change in our employees with whom they interact. Any of these changes could adversely impact individual client relationships, client retention, and sales of products to existing clients. It is also possible that these changes could adversely affect our ability to sell our products to new clients. Any such events could materially and adversely impact our business, financial condition and operating results.

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

We have been growing our revenue in recent periods and have a relatively short history of operating as a commercial company. 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 revenue growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

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

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

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



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

We do all of our internal manufacturing, development and management activities in a 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

33

---

Table of Contents

disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We have limited 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 and began selling in Asia in June 2017 and in Europe and Australia in June 2018. We had \$20,000 and \$141,000 in total international sales for the three months ended March 31, 2018 and June 30, 2018, and \$0.2 million in total international sales for the six months ended June 30, 2018.

We also expect to continue to expand sales in these 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, such as from suppliers in China and South Korea, subject us to United States 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. Additionally, the U.S. government has called for substantial changes to foreign trade policy with China and has recently raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on U.S. goods, which we anticipate will increase our cost of doing business in China. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the FCPA 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, called Photoguides®, for use with reusable retractors, single-use handheld illuminated aspiration devices, PhotonBlade®, 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 United States-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 obtaining, 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 United States and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;



Table of Contents

- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
  - changes in diplomatic and trade relationships, including the imposition of new trade restrictions, trade protections measures, import or export requirements, trade embargoes and other trade barriers;
  - tariffs imposed by the U.S. on goods from other countries and tariffs imposed by other countries on U.S. goods, including the tariffs implemented in July 2018 by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remains uncertain;
  - scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
  - laws and business practices favoring local companies;
  - longer payment cycles;
  - foreign currency exchange rate fluctuations;
  - difficulties in maintaining consistency with our internal guidelines;
    - difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
    - the imposition of costly and lengthy new export licensing requirements; and
  - 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.
- 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 cannot predict what impact the new administration will have on the political and regulatory environment in the United States, the timing of any such changes, or the impact of any such changes 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

## Table of Contents

potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets, be successful in entering into an agreement with any particular target, or obtain the expected benefits of any acquisition or investment.

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

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

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

### Risks Related to Our Intellectual Property

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

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

Furthermore, we do not have any patent rights in certain foreign countries in which a market may exist in the future, and the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws

of the U.S. 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

## Table of Contents

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 to defend or settle, 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, and, if adversely adjudicated, could harm our business.

Our success depends, in part, on not infringing the patents or violating the proprietary rights of others. Significant litigation regarding patent rights occurs in the medical device industry. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our devices. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, sell, or offer to 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 former employees received a letter from Medtronic 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, offering to sell, making, or using devices that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, offering to sell, 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, treble 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.



## Table of Contents

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

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

### Risks Related to Our Capital Structure

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

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we seek to continue to grow our business. We believe that our growth will depend, in part, on our ability to fund our commercialization efforts and our efforts to develop new technologies, 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 additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the six months ended June 30, 2018 and for the years ended December 31, 2017 and 2016, our net cash used in operating activities was \$18.1 million, \$36.9 million, and \$36.6 million, respectively. As of June 30, 2018, we had working capital of \$22.2 million, which included \$23.9 million in cash and cash equivalents and short-term investments. 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 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. We have sold, and plan in the future to sell, shares of our common stock in underwritten offerings. In March 2018, the Company issued and sold a total of 6,800,000 shares of its common stock at \$3.50 per share, resulting in total net proceeds of approximately \$21.7 million. Additionally, we

have established, and

38

---

Table of Contents

may in the future establish, “at-the-market” offering programs pursuant to which we may offer and sell shares of our common stock. If we raise additional funds by issuing equity securities, our stockholders may experience dilution.

In March 2017, we also entered into a debt agreement with MidCap (as defined below), as amended in September 2017, April 2018 and July 2018, for up to \$30.0 million in term loans and up to \$20.0 million under a revolving credit facility. As of June 30, 2018, we had borrowed \$30.0 million in term loans and drawn down \$5.4 million under our revolving credit facility. This debt arrangement imposes upon us, and 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. See below for more information. 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.

We cannot be certain that additional funding will be available on acceptable terms, if at all. Additionally, we cannot be certain that we will have access to the full amount available under our revolving credit agreement with MidCap if we fail to achieve certain revenue thresholds or meet other conditions, or that we will be able to renegotiate the terms of our credit facility to access further funding. We may not be able to issue equity securities under our shelf registration statement or ATM program due to unacceptable terms and conditions to us in the capital markets. If we do not have, or are not able to obtain, sufficient funds, we may have to reduce our cash burn rate, delay hiring of new staff, delay research and development projects, 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, and reduce discretionary operating expenses. If we are unable to generate sufficient cash flows or to raise adequate funds to finance our forecasted expenditures, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. We also may have to reduce sales, marketing, engineering, customer support or other resources devoted to our existing products, or cease operations. Any of these actions could impede our ability to achieve our business objectives and harm our operating results.

The uncertainty around the achievement of our plans to mitigate the risk of going concern, including future compliance with the financial covenant described above, raises substantial doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm, included in our Annual Report on Form 10-K for the year ended December 31, 2017, included a going concern explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise doubt about our ability to continue as a going concern.

We may not be able to generate sufficient cash to service our indebtedness, which currently consists of our credit agreements with MidCap.

On March 10, 2017, we entered into a credit and security agreement with MidCap Financial Trust and their affiliates, or MidCap, that provides for up to \$30.0 million in term loans. We amended this credit and security agreement in September 2017, April 2018 and July 31, 2018. Under the terms of the agreement, we borrowed the first term loan of \$20.0 million on March 10, 2017 and an additional term loan of \$10.0 million on September 26, 2017. The term loans accrue interest at a floating rate equal to 6.50% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. Principal is payable in 39 equal monthly installments beginning January 1, 2019 until paid in full on March 1, 2022.

In connection with entry into the credit and security agreement with MidCap, we terminated the HCRP loan agreement and used a portion of the term loan proceeds to repay all amounts outstanding under such agreement.

On March 10, 2017, we also entered into a separate credit and security agreement with MidCap that provides for a revolving credit facility of up to \$10.0 million based on the eligible accounts receivable and inventory balances. We amended this credit and security agreement in September 2017, April 2018 and July 31, 2018. In July 2018, the total commitments under the revolving credit facility were increased from \$10.0 million to \$15.0 million. As of June 30, 2018, we have outstanding borrowings of \$5.4 million under this revolving credit facility. We may increase the total commitments under the revolving credit facility by up to an additional \$10.0 million, subject to certain conditions. Loans under the revolving credit facility accrue interest at a floating rate equal to 3.25% per annum, plus the greater of (i) 1.5% or (ii) one month LIBOR. The facility terminates in full on March 1, 2022 unless terminated earlier. This new revolving

## Table of Contents

credit facility replaces our \$7.5 million accounts receivable credit facility that existed with SVB, under which no principal or interest was outstanding.

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 the credit agreements with MidCap, we may not be allowed to draw additional amounts and we may be required to repay any outstanding amounts earlier than anticipated. In the event of a liquidation, MidCap 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 MidCap, were first repaid in full.

The credit agreements, as amended, with MidCap contain restrictive covenants that may limit our operating flexibility.

Borrowings under the credit agreements, as amended, with MidCap are secured by substantially all of our assets, including our intellectual property. The credit agreements, as amended, with MidCap contain customary restrictive covenants that, among other things, limit our ability to dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of our lenders. We must also comply with a financial covenant relating to certain quarterly minimum Net Revenue requirements on a trailing twelve month basis. The minimum Net Revenue requirements on a trailing twelve month basis for the remainder of 2018 is \$41.5 million for the period ending September 30, 2018, \$42.5 million for the period ending December 31, 2018, \$45.7 million for the period ending March 31, 2019, and \$47.7 million for the period ending June 30, 2019. In addition, we must comply with a minimum cash covenant of \$5.0 million that is triggered if Net Revenue is not in excess of \$45.0 million on a trailing twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter.

The operating and financial restrictions and covenants in the credit agreements, as amended, as well as any future financing agreements that we may enter into, could restrict our ability to finance our operations and to engage in, expand or otherwise pursue business activities and strategies that we or our stockholders may consider beneficial. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the credit agreements, as amended. Future defaults, if not waived, could cause all of the outstanding indebtedness under our credit agreements, as amended, to become immediately due and payable and would permit the lenders to terminate all commitments to extend further credit and permit the agent, on behalf of the lenders, to proceed against the collateral in which we granted the agent and the lenders a security interest.

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, 2017, we had net operating loss, or NOLs, carryforwards for federal and state income tax purposes of approximately \$171.0 million and \$124.8 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in the future, our ability to utilize NOLs could be further limited by Section 382. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Section 382. Furthermore, we may be unable to use a substantial part of our NOLs if we do not attain profitability in an amount sufficient to offset such losses. Any limitation on using NOLs could result in our retaining less cash after payment of U.S. federal and state income taxes

## Table of Contents

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.

The Tax Cuts and Jobs Act (the “Tax Reform Act”) was enacted on December 22, 2017 and provides for significant changes to U.S. tax law. Among other provisions, the Tax Reform Act reduces the U.S. corporate income tax rate to 21%, effective in 2018. As a result, the Company has remeasured its U.S. deferred tax assets and liabilities as of December 31, 2017 to reflect the lower rate expected to apply when these temporary differences reverse. The Company estimates that the remeasurement resulted in a decrease in deferred tax assets of \$22.5 million, which was fully offset by a corresponding change to the Company’s valuation allowance. The impact will likely be subject to ongoing technical guidance and accounting interpretation, which the Company will continue to monitor and assess.

### 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 510(k) exempt, or Class II medical devices in the United States and, with respect to our Class I and Class II 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 over time and can involve lengthy and detailed laboratory and clinical testing procedures and an extensive agency review process, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements depending on the complexity and novelty of the device. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

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

Our devices remain subject to strict regulatory controls on manufacturing, advertising and promotion. 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.

## Edgar Filing: Invuity, Inc. - Form 10-Q

Our devices are medical devices that are subject to extensive regulation by the 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;

41

---



## Table of Contents

- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for, an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval, or PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA will 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 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. 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. In June 2017, we submitted a Correction and Removal report to the FDA in connection with the voluntary recall of our PhotonBlade® product, and had not received additional information from the FDA that would increase our exposure to additional risks.

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;

Edgar Filing: Invuity, Inc. - Form 10-Q

- 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;

42

---

Table of Contents

- 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 lawsuits, 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 field action notice or correction to inform surgeons of changes to instructions for use or of a deficiency, or of a suspected deficiency, found in a device. 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. For example, shortly after the limited launch of PhotonBlade® we received a small number of customer complaints which related to possible unintended energy discharge from the device with the potential to cause tissue damage to patients. In June 2017, we initiated a voluntary recall of the device. We devoted significant resources to relaunch and market the PhotonBlade® and could not be assured that these activities will generate revenue as anticipated. If our redesign of the device fails to successfully eliminate the performance issue or if our revenue grows more slowly than we expect, our business and financials will be adversely affected.

Depending on the corrective action we take to address 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.

43

---

Table of Contents

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. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties.

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 Public Health, or CDPH. 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 CDPH 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 CDPH in February 2015, and the inspection revealed no minor or major issues. We were also subjected to an FDA inspection in April 2016 resulting in two observations. The FDA will evaluate and validate whether our corrective actions have been effective during its next routine inspection, which has not been scheduled. 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.

44

---

Table of Contents

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 \$165,786 per year (and up to an aggregate of \$1.105 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 United Kingdom Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors;





Table of Contents

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

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

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our 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.

In June 2017, we expanded sales to Asia. In June 2018, we expanded sales to Europe and Australia. Prior to such date, we did not have any direct sales outside of the United States. In addition, our corporate partners 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.

## Table of Contents

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

Our operations are impacted by the PPACA. Compliance with the ACA has imposed significant administrative and financial burdens on us. For example, the PPACA imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The current administration has expressed an intention to repeal the ACA and replace it with alternative reforms. For example, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. The details and timing of any further such actions are unknown at this time. However, it is possible that these changes could adversely affect our business.

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, the American Taxpayer Relief Act of 2012, or the ATRA, came into effect, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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.

We face uncertainties that might result from modification or repeal of any of the provisions of the PPACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But, any changes to the PPACA are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

### Risks Related to our Common Stock

We expect that the price of our common stock will fluctuate substantially.

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:

- 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 analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- announcements of significant new devices or device enhancements by us or our competitors;
- actual or anticipated quarterly variations in our or our competitors' results of operations;

- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- changes in our pricing policies or the pricing policies of our competitors;

Table of Contents

- 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 to our organizational structure and the realignment of our sales team;
- any stockholder activism, including public criticism of our company or our management team, based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business;
- 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. As a result, stockholders have filed securities class action litigation following periods of market volatility. Any securities litigation, 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. See Part II, Item 1, “Legal Proceedings” and Note 8, “Commitments and Contingencies” to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information. These factors may materially and adversely affect the market price of our common stock.

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

Sales of a substantial amount of common stock in the public market, or the perception that these sales may occur, could adversely affect the market price of our common stock. As of June 30, 2018, we have 24,073,537 shares of common stock outstanding. 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, and we filed a prospectus supplement for our ATM program of up to \$25.0 million. In August 2016 and March 2018, we sold 3,220,000 shares and 6,800,000 shares, respectively, in secondary offerings pursuant to this shelf registration and a prospectus supplement for each offering.

Certain 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

## Table of Contents

for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired. These registration rights terminate in June 2022.

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

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

As of June 30, 2018, our stockholders holding more than 5% of our capital stock, and their affiliates, own a significant portion 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 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 the 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 is 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 our technology in minimal access surgery 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 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

Table of Contents

costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We will incur substantial compensation costs as we pay our executive officers cash compensation commensurate with that of executive officers of other similarly sized public medical device companies, which increases 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 increases the cost of director and officer liability insurance, and, to the extent our risk profile changes, 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 disclosure of information in filings required increases in a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, brand, reputation and operating results.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take, and intend to take, advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (1) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (2) we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (3) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (4) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

We may remain an "emerging growth company" until as late as December 31, 2020, the fiscal year-end following the fifth anniversary of the completion of our IPO, though we may cease to be an "emerging growth company" earlier under certain circumstances, including if (1) we have more than \$1.07 billion in annual revenue in any fiscal year, (2) the market value of our common stock that is held by non-affiliates exceeds \$700 million as the last business day of our most recently completed second fiscal quarter or (3) we issue more than \$1.0 billion of non-convertible debt over a three-year period.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.



In the event that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the trading price of our common stock could decline.

We are subject to the periodic reporting requirements of the Exchange Act. As a result, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. As a public

Table of Contents

company, we are required, under Section 404(a) of the Sarbanes-Oxley Act of 2002, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. 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 in the future and not be detected.

In addition, once we cease to be an emerging growth company under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls under Section 404(b) of the Sarbanes-Oxley Act. While we may remain an “emerging growth company” until as late as December 31, 2020, the fiscal year-end following the fifth anniversary of the completion of our IPO, we may cease to be an “emerging growth company” earlier under certain circumstances and that could accelerate our timeline for complying with Section 404(b).

If we are unable to confirm that our internal control over financial reporting is effective, or if our auditors, when required, are unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, or be delayed in producing these financial reports, both of which could cause the price of our common stock to decline. We could also be subject to, among other things, regulatory or enforcement actions by the SEC and the Nasdaq Global Market and could be subject to securities litigation.

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;

Table of Contents

- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

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

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

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

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

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

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Amendment to Credit Agreements

On July 31, 2018, the Company entered into an Amendment No. 3 to Credit and Security Agreement (Term Loan) (the “Term Loan Amendment”) to its Credit and Security Agreement (Term Loan), dated as of March 10, 2017 (as

52

---

Table of Contents

amended, the “Term Loan Credit Agreement”), with MidCap Financial Trust, as agent, the lenders party thereto and the Company. Pursuant to the Term Loan Amendment, the Company revised the financial covenant relating to certain quarterly minimum Net Revenue (as defined in the Term Loan Credit Agreement) requirements on a trailing twelve month basis and added a minimum cash covenant of \$5.0 million that is triggered if Net Revenue (as defined in the Term Loan Credit Agreement) is not in excess of \$45.0 million on a trailing twelve month basis as of December 31, 2018, which ends if and when Net Revenue is in excess of \$50.0 million for any twelve month period thereafter. The Term Loan Amendment also revised the repayment schedule such that principal on each term loan advance is now payable in 39 equal monthly installments beginning January 1, 2019 until paid in full on March 1, 2022. The Exit Fee (as defined in the Term Loan Credit Agreement) was also increased from 6.5% of the total amount of all term loans advanced under the Term Loan Credit Agreement, to 7.0% of the total amount of all term loans advanced under the Term Loan Credit Agreement. The other terms of the Term Loan Credit Agreement remain as previously disclosed.

In connection with the Term Loan Amendment, the Company also entered into an Amendment No. 3 to Credit and Security Agreement (Revolving Loan) (the “Revolving Loan Amendment”) to its Credit and Security Agreement (Revolving Loan), dated as of March 10, 2017 (as amended, the “Revolving Loan Credit Agreement”), with MidCap Financial Trust, as agent, the lenders party thereto and the Company. Pursuant to the Revolving Loan Amendment, the Company revised the financial covenant relating to certain quarterly minimum Net Revenue (as defined in the Revolving Loan Credit Agreement) requirements on a trailing twelve month basis, which financial covenant revision is identical to the amendment to the financial covenant in the Term Loan Credit Agreement described above. The Revolving Loan Amendment added a minimum cash covenant relating to minimum cash requirements, which is identical to the minimum cash covenant in the Term Loan Credit Agreement described above. Additionally, the total commitments under the Revolving Loan Credit Agreement were increased from \$10.0 million to \$15.0 million. The Company may increase the total commitments under the Revolving Loan Credit Agreement by an additional \$10.0 million, subject to certain conditions. The other terms of the Revolving Loan Credit Agreement remain as previously disclosed.

The foregoing description of the Term Loan Amendment and the Revolving Loan Amendment do not purport to be complete and are qualified in their entirety by reference to the Term Loan Amendment and the Revolving Loan Amendment, copies of which are attached hereto as Exhibits 10.1 and 10.2, respectively, and incorporated herein by reference.

Table of Contents

## Item 6. Exhibits

Exhibit Number	Description
10.1	<u>Amendment No. 3 to Credit and Security Agreement (Term Loan), dated as of July 31, 2018, by and among the Company, MidCap Financial Trust, as Agent, and the lenders party thereto.</u>
10.2	<u>Amendment No. 3 to Credit and Security Agreement (Revolving Loan), dated as of July 31, 2018, by and among the Company, MidCap Financial Trust, as Agent, and the lenders party thereto.</u>
31.1	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1*	<u>Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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 certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are being furnished and not filed with the U.S. Securities and Exchange Commission, or the SEC, and are 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.

Table of Contents

SIGNATURES

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

Invuity, Inc.

Date: August 3, 2018 By: /s/ Scott Flora  
Scott Flora  
Interim President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 3, 2018 By: /s/ James Mackaness  
James Mackaness  
Chief Financial Officer  
(Principal Financial Officer and Chief Accounting Officer)